



MRI

The IAC Standards and Guidelines for MRI Accreditation

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Introduction

The Intersocietal Accreditation Commission (IAC) accredits facilities specific to magnetic resonance imaging (MRI). IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

An MRI facility (i.e., imaging center, physician office and hospital) is a unit under the overall direction of a Medical Director with a Technical Director who is appointed and responsible for direct supervision of the technical staff members and the daily operations of the facility.

The intent of the accreditation process is two-fold. It is designed to recognize facilities that provide quality MRI services. It is also designed to be used as an educational tool to improve the overall quality of the facility.

The following are the specific areas of MRI for which accreditation may be obtained:

- cardiovascular MRI
- breast MRI
- body MRI [chest (non-cardiac), abdomen, pelvis, extremity]
- musculoskeletal MRI
- neurological MRI
- MRA

These accreditation Standards and Guidelines are the minimum standards for accreditation of MRI facilities. Standards are the minimum requirements to which an accredited facility is held accountable. *Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.*

Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface in narrative form.*

Standards that are highlighted are content changes that were made as part of the May 15, 2020 revision. These Standards will become effective on November 15, 2020. Facilities applying for accreditation after November 15, 2020 must comply with these new highlighted Standards.

In addition to all Standards listed below, 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: Personnel and Supervision

STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician and certified by an American Board of Medical Specialties (ABMS) recognized board in a relevant specialty 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 Medecins du Quebec.

1.1.1A Medical Director Required Training and Experience

The Medical Director must demonstrate an appropriate level of training and experience by meeting one or more of the following:

1.1.1.1A Established Practice – A physician who has worked in an MRI facility for at least five years, has acquired 150 hours of Category I CME relevant to MRI to include courses specifically designed to provide knowledge of the techniques, safety, limitations, accuracy and methods of interpretation and clinical applications specific to the anatomic area and has interpreted a minimum of 1,000 MRI examinations.

OR

1.1.1.2A Formal Training Program – Completion of a residency or fellowship that includes appropriate didactic and clinical MRI facility experience as an integral part of the program and a minimum number of cases interpreted specific to the anatomic area as indicated:

- i. body – 300 cases
- ii. cardiovascular – 300 cases
- iii. musculoskeletal – 300 cases
- iv. neurological – 300 cases
- v. MRA – 150 cases
- vi. breast – 150 cases

Comment: The formal training experience is to be documented by a letter from the director of the training program verifying the areas of MRI expertise and the extent of the training experience.

OR

1.1.1.3A Informal Training

- i. Didactic: Appropriate background for proper qualifications to interpret MRI facility studies can be achieved through accredited postgraduate continuing medical education (CME). A minimum of 150 hours of AMA Category I CME credits must be acquired within a three-year period. These hours must be met with courses specifically designed to provide knowledge of the techniques, safety, limitations, accuracy and methods of interpretation of MRI examinations and clinical applications specific to the anatomic area.

Documentation of the CME courses, with a listing of the content, must be submitted.

- ii. Practical Experience: In addition to the formal didactic education outlined above, the individual must acquire a minimum of six months of supervised practical experience observing or participating in MRI procedures, preferably in an accredited facility. The practical experience must include all areas of MRI for which the facility is applying. This experience is to be documented with a letter from the Medical Director of the facility where the practical experience was obtained.

For those examinations the Medical Director will interpret, experience in interpreting the following minimum number of MRI or MRA studies, while under supervision, must be documented:

- body – 300 cases
- cardiovascular – 300 cases
- musculoskeletal – 300 cases
- neurological – 300 cases
- MRA – 150 cases
- breast – 150 cases

1.1.1.4A Neuroimaging Subspecialty

- i. Current Neuroimaging subspecialty certification by the United Council for Neurologic Subspecialties (UCNS).

OR

- ii. Current certification in MRI by the American Society of Neuroimaging (ASN).

1.1.2A Medical Director Responsibilities

The Medical Director responsibilities include but are not limited to:

- 1.1.2.1A all clinical MRI services provided and for the determination of the quality of imaging provided related to the MRI services;
- 1.1.2.2A supervising the entire operation of the facility or delegating specific operations to facility staff members;
- 1.1.2.3A selecting and approving medical staff members and supervising their work; and
- 1.1.2.4A assuring compliance of the medical and technical staff to the Standards outlined within this document.

1.1.3A Continuing Medical Education (CME) Requirements

- 1.1.3.1A The Medical Director must show evidence of maintaining current knowledge by participation in CME courses that are relevant to MRI. A minimum of 15 hours of AMA Category I CME is required every three years. It is recommended that a minimum of 1 CME hour include MRI safety instruction.

Comment: To be relevant to MRI, the course content must address the principles, instrumentation, techniques and/or interpretation of MRI specific to the anatomic area.

- 1.1.3.2A Yearly accumulated CME must be kept on file and available to IAC when requested.

Comment: If the Medical Director has completed formal training as specified under 1.1.1.2A in the last three years, the CME requirement will be considered fulfilled. Correlation conferences or other internal meetings are not to be counted as part of this requirement.

STANDARD – Technical Director

- 1.2A A qualified Technical Director (i.e., supervisor, chief technologist, manager, etc.) is designated for the facility.

1.2.1A Technical Director Required Training and Experience

The Technical Director must have appropriate training, technical certification and documented experience in the field of MRI. The Technical Director must meet one of the following criteria:

- 1.2.1.1A American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) certification in MRI (RT (MR)).

OR

- 1.2.1.2A An appropriate credential from a nationally recognized credentialing organization in another medical imaging specialty (i.e., NMTCB, ARDMS, ARRT or ARMRT).

AND

One year (12 months) of full-time (35 hours/week) equivalent experience as an MRI technologist performing a minimum of 100 examinations.

OR

- 1.2.1.3A For personnel operating scanners capable of performing only peripheral joint imaging, all of the following criteria must be met:
- i. medical practitioner state license or state certification acceptable to IAC MRI (i.e., basic operator, LMRT, RE);
 - ii. three months clinical experience performing examinations;
 - iii. performance of at least 125 MRI examinations; and
 - iv. certificate from MRI vendor documenting a minimum of 56 hours of uninterrupted (but not necessarily contiguous) training. No more than 16 of the 56 hours may be acquired through self-study that includes successful completion of structured education that is Recognized Continuing Education Evaluation Mechanism (RCEEM) approved. The vendor's training on the device must include:
 - MRI safety;
 - basic anatomy;
 - basic MRI physics;
 - slice orientation; and
 - sequence and protocol development.

1.2.2A Technical Director Responsibilities

- 1.2.2.1A The Technical Director reports directly to either the facility administrator or the Medical Director. Responsibilities include, but are not limited to, and may be delegated to other staff:
- i. all facility duties delegated by the facility administrator and/or Medical Director;
 - ii. supervision of the technical and ancillary staff;
Comment: The Technical Director must provide oversight of the technical staff.
 - iii. the delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff;
 - iv. daily technical operation of the MRI facility (i.e., staff scheduling, patient scheduling, record-keeping, etc.);
 - v. operation and maintenance of MRI imaging equipment;
 - vi. the compliance of the technical and ancillary staff to the *Standards* outlined within this document;
 - vii. working with the Medical Director, medical staff and technical staff to ensure quality patient care; and
 - viii. technical training.

1.2.3A Continuing Education (CE) Requirements

- 1.2.3.1A The Technical Director must document at least 15 hours of Category I AMA or RCEEM approved MRI-related CE over a period of three years. It is recommended that a minimum of 1 CE hour include MRI safety instruction.
- Comment: To be relevant to MRI, the course content must address the principles, instrumentation, techniques and/or interpretation of MRI specific to the anatomic area.
- 1.2.3.2A Yearly accumulated CE must be kept on file and available to IAC when requested.
- Comment: If the Technical Director has successfully acquired an appropriate MRI credential within the past three years, the CE requirement will be considered fulfilled.

STANDARD – Medical Staff

- 1.3A All members of the medical staff must be licensed physicians and American Board of Medical Specialties (ABMS) board certified in a relevant specialty 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 Medecins du Quebec.

1.3.1A Medical Staff Required Training and Experience

The medical staff must demonstrate an appropriate level of training and experience by meeting one or more of the following:

- 1.3.1.1A Established Practice – A physician who has worked in a MRI facility for at least three years, has acquired 150 hours of Category I CME relevant to MRI to include courses specifically designed to provide knowledge of the techniques, safety, limitations, accuracy and methods of interpretation and clinical applications specific to the anatomic area and has interpreted a minimum of 500 MRI facility examinations.

OR

1.3.1.2A Formal Training Program – Completion of a residency or fellowship that includes appropriate didactic and clinical MRI facility experience as an integral part of the program and interpreted a minimum of 150 cases specific to the anatomic area:

- i. body – 150 cases
- ii. cardiovascular – 150 cases
- iii. musculoskeletal – 150 cases
- iv. neurological – 150 cases
- v. breast – 150 cases
- vi. MRA – 150 cases

Comment: The formal training experience is to be documented by a letter from the director of the training program verifying the areas of MRI expertise and the extent of the training experience.

OR

1.3.1.3A Informal Training

- i. Didactic – Appropriate background for proper qualifications to interpret MRI facility studies can be achieved through accredited postgraduate continuing medical education (CME). A minimum of 150 hours of AMA Category I CME credits must be acquired within a three-year period. These hours must be met with courses specifically designed to provide knowledge of the techniques, safety, limitations, accuracy and methods of interpretation of MRI examinations and clinical applications specific to the anatomic area. Documentation of the CME courses, with a listing of the content, must be submitted.
- ii. Practical Experience – In addition to the formal didactic education outlined above, the individual must acquire a minimum of six months of supervised practical experience observing or participating in MRI procedures, preferably in an accredited facility. The practical experience must include all areas of MRI for which the facility is applying. This experience is to be documented with a letter from the Medical Director of the facility where the practical experience was obtained.

For those examinations the medical staff member will interpret, experience in interpreting the following minimum number of MRI or MRA studies, while under supervision, must be documented:

- body – 150 cases
- cardiovascular – 150 cases
- musculoskeletal – 150 cases
- neurological – 150 cases
- breast – 150 cases
- MRA – 150 cases

1.3.1.4A Neuroimaging Subspecialty

- i. Current Neuroimaging subspecialty certification by the United Council for Neurologic Subspecialties (UCNS).

OR

- ii. Current certification in MRI by the American Society of Neuroimaging (ASN).

Comment: ASN and UCNS certification is accepted for physicians who only interpret brain and spine examinations.

1.3.2A Medical Staff Responsibilities

Medical staff responsibilities include but are not limited to:

- 1.3.2.1A the medical staff reports to the Medical Director; and
- 1.3.2.2A the medical staff interprets and/or performs clinical MRI studies in accordance with privileges approved by the Medical Director.

1.3.3A Continuing Medical Education (CME) Requirements

- 1.3.3.1A The medical staff members must obtain a minimum of 15 hours of AMA Category I CME every three years. The medical staff must show evidence of maintaining current knowledge by participation in CME courses that are relevant to MRI. It is recommended that a minimum of 1 CME hour include MRI safety instruction.

Comment: To be relevant to MRI, the course content must address the principles, instrumentation, techniques and/or interpretation of MRI specific to the anatomic area.

- 1.3.3.2A Yearly accumulated CME must be kept on file and available to IAC when requested.

Comment: If the medical staff member has completed formal training as specified under 1.3.1.2A in the past three years, the CME requirement will be considered fulfilled. Correlation conferences or other internal meetings are not to be counted as part of this requirement.

STANDARD – Technical Staff

- 1.4A The technical staff must have appropriate training, technical certification and/or documented experience in the field of MRI.

1.4.1A Technical Staff Required Training and Experience

All members of the technical staff must meet one or more of the following criteria:

- 1.4.1.1A American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) certification in MRI (RT (MR)).

OR

- 1.4.1.2A Successful completion of a MRI training program, which includes verified didactic and supervised clinical experience in MRI. These programs must be accredited by the Joint Review Committee on Education in Radiologic Technology (JRCERT) or accredited by the Canadian Medical Association Committee on Conjoint Accreditation (CMA-CCA).

OR

- 1.4.1.3A Completion of **six months** full-time **supervised** (35 hours/week) postgraduate clinical MRI experience plus one of the following:
- i. an appropriate credential from a nationally recognized credentialing organization in another medical imaging specialty (i.e., NMTCB, ARDMS, ARRT or ARMRIT);
 - ii. completion of a formal two-year program or equivalent in another medical imaging profession (*see 1.4.1.2A*); or
 - iii. completion of a bachelor's degree in another medical imaging specialty.

OR

- 1.4.1.4A For personnel operating scanners capable of performing only peripheral joint imaging, all of the following criteria must be met:
- i. medical practitioner state license or state or national certification acceptable to IAC MRI (i.e., CMA, basic operator, LMRT, RE);
 - ii. certificate from MR **vendor** documenting a minimum of 56 hours of uninterrupted (but not necessarily contiguous) training;

Comment: No more than 16 of the 56 hours may be acquired through self-study that includes successful completion of **structured education that is RCEEM approved**. The **vendor's** training on the device should include:
 - MRI safety;
 - basic anatomy;
 - basic MRI physics;
 - slice orientation; and
 - sequence and protocol development.
 - iii. three months clinical experience performing examinations; and
 - iv. performance of at least **125** MRI examinations.

OR

- 1.4.1.5A For personnel operating a MRI scanner **full time prior to and consistently since 2013**, without meeting any of the above required training and experience criteria (1.4.1.1A, 1.4.1.2A, 1.4.1.3A, 1.4.1.4A), the following must be provided:
- i. a letter from the current Medical Director or Technical Director verifying the training, experience and competency **prior to and consistently since 2013**, specific to the testing area for which they are applying;
 - ii. if less than five years at the current position, a letter from the previous Medical or Technical Directors **prior to and consistently since 2013**, verifying training, experience and competency specific to the testing area for which they are applying.

1.4.2A Technical Staff Responsibilities

Technical staff responsibilities include but are not limited to:

- 1.4.2.1A reports to the Technical Director; and
- 1.4.2.2A assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical examinations and other tasks assigned.

1.4.3A Continuing Education (CE) Requirements

1.4.3.1A The technical staff must document at least 15 hours of Category I AMA or RCEEM approved MRI-related continuing education over a period of three years. It is recommended that a minimum of one CE hour include MRI safety instruction.

Comment: To be relevant to MRI, the course content must address the principles, instrumentation, techniques and/or interpretation of MRI specific to the anatomic area.

1.4.3.2A Yearly accumulated CE must be kept on file and available to IAC when requested.

Comment: If the technical staff member has successfully acquired an appropriate MRI credential within the past three years, the CE requirement will be considered fulfilled.

STANDARD – Support Services

1.5A Ancillary personnel (i.e., clerical, nursing, transport, etc.), if necessary for safe and efficient patient care, must be provided.

1.5.1A Clerical and administrative support is sufficient to ensure efficient operation and record keeping.

1.5.2A Supervision: The Medical Director must ensure that support services are appropriate and in the best interest of patient care.

STANDARD – Medical Physicist

1.6A The medical physicist must be certified by the American Board of Radiology in Diagnostic Medical (or Diagnostic Radiologic) Physics, by the American Board of Medical Physics in Diagnostic Medical Physics or MRI Physics, or by the Canadian College of Physicists in Medicine in MRI Physics. In states where medical physicists are licensed, a full license to practice Diagnostic or MRI Medical Physics is acceptable.

1.6.1A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, are permitted to assist the medical physicist in data collection. The medical physicist must approve all work performed by assistants and must sign the final report.

1.6.2A The medical physicist must document at least 15 hours of Category I AMA Continuing Medical Education (CME) or Commission on Accreditation of Medical Physicists Educational Programs (CAMPEP) continuing education related to medical physics and/or medical imaging over a period of three years.

1.6.2.1A A minimum of three hours of the documented 15 hours of CE must be related to MRI safety.

1.6.2.2A Yearly accumulated CE must be kept on file and available to IAC MRI, when requested.

Section 2A: Facility

STANDARD – Examination Areas

- 2.1A Examinations must be performed in a setting providing reasonable patient comfort and privacy.
 - 2.1.1A The space required by an MRI system varies depending on the magnetic field strength and size of the system.
 - 2.1.2A The patient screening area and any other public passageways or areas must be placed beyond the magnetic fringe field (5.0 Gauss).
 - 2.1.3A Warning signs must be posted, as appropriate, to ensure that unauthorized personnel are not entering the magnet area.

STANDARD – Interpretation Areas

- 2.2A Adequate space, apart from patient care areas, must be provided for the interpretation of examination results and preparation of reports.

STANDARD – Storage Space

- 2.3A Adequate designated space must be provided for the convenient storage of supplies, records and reports.

Section 3A: Examination Reports and Records

STANDARD – Records

- 3.1A Provisions exist for the generation and retention of examination records of all studies performed which will permit evaluation of annual procedure volumes.
- 3.1.1A Essential portions of all examinations must be documented and retained on appropriate media. This may include hard copy (printed, photographic and/or digital media) cine images and graphics, and, if applicable, printed documentation of measurements.
- 3.1.2A All examination recordings including images and a signed, dated final report, as outlined in Standards 3.1A and 3.2A, must be maintained in an accessible fashion for a minimum of the applicable legal requirements for medical record-keeping.

STANDARD – Examination Interpretation and Reports

- 3.2A MRI examinations are interpreted and reported by the Medical Director or by a member of the medical staff of the MRI facility.

Comment: The report represents the final interpretation of the MRI examination and is part of the patient's legal medical record. As such, the report must be in the form of a document that is retrievable and/or reproducible for review by health care personnel. In general, the report must contain sufficient information so that any health care professional has access to adequate information regarding the indications for the examination, the type of examination performed and the results of the diagnostic study.

(See Guidelines on Page 15 for further recommendations.)

- 3.2.1A All of the MRI examination images must be reviewed by the interpreting member of the medical staff or the Medical Director.
- 3.2.2A Final interpretations must be verified and, either manually or electronically, signed by the Medical Director or a member of the medical staff of the facility.
- 3.2.3A A permanent record of the interpretation must be made and retained in accordance with applicable standards for medical records.
- 3.2.4A The report must accurately reflect the content and results of the study. The contents of the report must include, but are not limited to:
- 3.2.4.1A date of the examination;
- 3.2.4.2A clinical indications leading to the performance of the examination;
- 3.2.4.3A an adequate description of the test performed including the:
- i. patient ID or name;
 - ii. date of birth;
 - iii. name of the examination.
- (See Guidelines on Page 15 for further recommendations.)*
- 3.2.4.4A an overview of the results of the examination including pertinent positive and negative findings;

Comment: This must include localization and quantification of abnormal findings (where appropriate).

- 3.2.4.5A the reasons for limited examinations;
- 3.2.4.6A a summary of the test findings;
- 3.2.4.7A comparison with previous related studies (where available);
- 3.2.4.8A The final report must be reviewed, signed and dated manually or reviewed, signed and dated **digitally** by the interpreting physician.
 - i. Stamped signatures or signatures by non-physician staff are not acceptable.
 - ii. If the report is manually signed by the interpreting physician, the date of the signature must also be manually recorded on the report with the signature.
 - iii. If the report is signed **digitally**, the signatures must be password protected with sign off only by an interpreting physician. The signature must have a valid digital date/time stamp.
 - The report must be in a form that cannot be modified or altered after it has been digitally signed.
- 3.2.4.9A the **brand** and **volume** of IV contrast used in the examination.
- 3.2.5A If preliminary reports are issued, their preliminary nature must be clearly indicated. Verified final reports must be provided within a reasonable interval after posting of preliminary results. A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs substantially from the preliminary report.
- 3.2.6A A mechanism must be defined whereby the results of examinations which demonstrate urgent or life-threatening findings are communicated to the appropriate health care professionals immediately.
- 3.2.7A The physician's final interpretation (in the form of paper, digital storage or voice system) must be available within two working days of the examination date and the final, verified, signed report sent to the referring physician within four working days, unless awaiting additional clinical information.

Section 3A: Examination Reports and Records

Guidelines

3.2A *Experienced technologist should be able to reproduce the exam based on the description provided.*

Identification of the technologist performing the MRI examination should be documented.

3.2.4.3A *an adequate description of the test performed should include:*

- pulse sequences (imaging contrast);*
- imaging planes used in the performance of the examination.*

Section 4A: Facility Safety

STANDARD – Patient and Facility Safety

- 4.1A 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.
- 4.1.1A Patient Identification Policy – For all clinical procedures there must be a **current** process that assures accurate patient identification immediately prior to initiating the procedure.
- (See Guidelines on Page 18 for further recommendations.)*
- 4.1.2A Environmental Safety Policy – A policy must be established to educate, train and screen all MRI facility staff members and personnel that may be required to enter the MRI environment. It is mandatory that all individuals who may potentially enter the MRI environment be aware of the **potential hazards and** appropriate safeguards necessary with regard to the force of the magnet on ferromagnetic objects (i.e., oxygen tanks, tools, etc.).
- 4.1.2.1A A mechanism must be in place to identify those patients/staff members/visitors at high risk for untoward effects or complications from entering the MRI environment (i.e., individuals or patients with cardiac pacemakers, implantable cardioverter defibrillators and certain ferromagnetic implants).
- 4.1.2.2A A method for continuous visual, verbal and/or physiologic monitoring of the patient during the examination must be present.
- 4.1.2.3A A procedure must exist for identification of a patient or individual (i.e., visitor, staff member) who suffers an incident or complication from the MRI examination or exposure to the MRI environment. **Any incident or complication must be immediately documented. This documentation must be stored and retrievable upon request.**
- 4.1.2.4A **Protective** ear devices must be available and offered to every patient and all other individuals present in the scan room during the procedure.
- 4.1.2.5A To avoid radio frequency burns caused by the combination of electrical and magnetic fields, proper patient setup is necessary when utilizing electrical conductors such as RF coils, ECG leads, monitoring equipment, etc.
- 4.1.2.6A MRI 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.
- 4.1.2.7A MRI 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.
- 4.1.2.8A The facility must meet the standards set forth by the Occupational Safety and Health Administration and other applicable agencies.

- 4.1.3A 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.
- 4.1.4A Contrast Administration and Supervision Policy – MRI safety procedures must address possible contraindications and/or risk factors including (but not limited to): Nephrogenic Systemic Fibrosis (NSF), diabetes, liver/kidney disease, hypertension, contrast material sensitivity, history of reactions to contrast media, age and allergies to medications. Patient management must address these possible contraindications prior to the MRI procedure and must be listed on the screening questionnaire.
- 4.1.4.1A The administration of contrast agents, medication and/or sedation must be performed by licensed or qualified trained personnel, under the direct supervision of a licensed physician and in compliance with applicable federal, state and local laws.
- (See Guidelines on Page 18 for further recommendations.)*
- 4.1.5A Acute Medical Emergency Policy – In the event of an MRI procedure-related emergency (i.e., respiratory arrest, cardiac arrest, severe agent reaction, quench, 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 the magnet room and administration of emergency medical care.
- 4.1.5.1A For medical emergencies, proper MR safe and MR conditional equipment and supplies (i.e., defibrillator, oxygen tank, suction, monitoring device, etc.) must be accessible and used, as needed.
- 4.1.5.2A Appropriate (i.e., MR safe and MR conditional) equipment, supplies and 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.
- 4.1.5.3A In the event of a superconducting magnet quench, the patient must be removed from the scan room as quickly as possible to avoid risks such as potential life-threatening injuries and/or death.
- 4.1.6A Incident Report/Adverse Events Policy – A policy for documentation of adverse events (i.e., contrast reactions, patient incidents, patient falls, etc.) must be in place.
- 4.1.7A Patient Pregnancy Screening Policy – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and contain the signature/initials of the patient and/or technologist verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant.
- 4.1.8A Cardiac Procedures – MRI safety policies in a cardiovascular facility must include a detailed description of graded protocols and/or infusion protocols used; timing of assessing symptoms, heart rate, blood pressure and electrocardiographic tracings; exercise testing end points; pharmaceutical injection criteria; post stress monitoring.

Section 4A: Facility Safety *Guidelines*

- 4.1.1A *Two independent patient-specific identifiers must be used. Examples of patient-specific identifiers include the patient's identification bracelet, hospital identification card, driver's license, or asking the patient to state his or her full name or birth date avoiding procedures in which the patient can answer "yes" or "no."*
- 4.1.4A *Documentation of contrast should include contrast type, amount, lot number and should be communicated to the manufacturer when necessary.*

Section 5A: Administrative

STANDARD – Patient Confidentiality

- 5.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

(See Guidelines below for further recommendations.)

STANDARD – Patient or Other Customer Complaints

- 5.2A 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 or adjudicates complaints/grievances (e.g., patient advocate on site).

STANDARD – Primary Source Verification

- 5.3A 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 certification and training of all technical staff members and any other direct patient care providers.

(See Guidelines below for further recommendations.)

Section 5A: Administrative Guidelines

- 5.1A All staff in contact with patients should have documentation of confidentiality training on file (i.e., an online Health Insurance Portability and Accountability Act course).
- 5.3A Signed and dated verification of credentials, certifications and licenses of all staff should be retained at the facility.

Sample documents are available for each of the required policies listed in Section 5A on the IAC website at www.intersocietal.org/helpful-resources/sample-documents-repository.

Section 6A: Multiple Sites (Fixed and/or Mobile)

STANDARD – Multiple Sites

- 6.1A When testing is performed at more than one physical facility, the facility may be eligible to apply for a single accreditation as a multiple site facility if the following criteria are met:
- 6.1.1A all technologists performing any MRI procedures at any of the sites must be included in the application for accreditation;
 - 6.1.2A all physicians interpreting any MRI procedures at any of the sites must be included in the application for accreditation in the Organization section;
 - 6.1.3A all sites must have the same Medical Director and Technical Director;
 - 6.1.4A all physicians and technologists must participate together in Quality Improvement and education programs, including in-house conferences;
 - 6.1.5A all sites utilize similar protocols;
 - 6.1.6A technical and interpretive quality assessment, as outlined in Section 2C: QI Measures, must be evaluated for all MRI testing sites.

Section 6A: Multiple Sites (Fixed and/or Mobile) *Guidelines*

Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at www.intersocietal.org/legal/policies-procedures.

Part B:

Examinations and Procedures

Section 1B: Instrumentation and Equipment

STANDARD – Instrumentation

- 1.1B FDA approved MRI device(s) must be available.
- 1.1.1B The MRI unit must be capable of performing multiplanar images using T1, T2 and STIR sequences with a field of view large enough to consistently image all relevant anatomy in the region of interest.
 - 1.1.2B Equipment specifications and performance must meet all state, federal and local requirements.
(See Guidelines on Page 24 for further recommendations.)

STANDARD – Equipment Quality Control

- 1.2B The Equipment Quality Control (QC) documentation must consist of MRI system installation acceptance testing and acceptance testing following a major upgrade.
(See Guidelines on Page 24 for further recommendations.)
- 1.2.1B The manufacturer’s representative, service engineer or Qualified Medical Physicist or qualified expert must perform the acceptance testing.
 - 1.2.2B 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. Acceptance testing must include (where applicable to the scanner):
 - 1.2.2.1B magnetic field homogeneity;
 - 1.2.2.2B geometric accuracy / gradient and RF calibration;
 - 1.2.2.3B slice thickness accuracy;
 - 1.2.2.4B slice position accuracy;
 - 1.2.2.5B system image quality performance:
 - i. high contrast spatial resolution;
 - ii. artifact assessment; and
 - iii. low contrast detectability / contrast-to-noise ratio.
 - 1.2.2.6B performance testing of each coil used clinically:
 - i. physical / visual inspection;
 - ii. RF transmitter gain / attenuator verification;
 - iii. signal-to-noise ratio (SNR) evaluation;
 - iv. image intensity uniformity (volume coils); and

v. artifact assessment.

1.2.2.7B image acquisition monitor performance;

1.2.2.8B inspection of physical and mechanical integrity of system;

1.2.2.9B establishment and documentation of baselines and action limits for all parameters measured at acceptance testing (for future QC and preventative maintenance use).

1.3B Routine (daily and periodic) quality control (QC) tests are to be conducted according to performance measurements as outlined by the manufacturer's system specifications or industry standards.

(See Guidelines on Page 24 for further recommendations.)

1.3.1B Daily QC assessments must include:

1.3.1.1B proper function of audible and visual patient safety equipment;

1.3.1.2B center frequency (CF) tests;

1.3.1.3B signal-to-noise ratio (SNR);

1.3.1.4B image uniformity; and

1.3.1.5B artifact assessment.

1.3.2B Periodic QC assessments must include (where appropriate to the scanner):

1.3.2.1B setup and positioning accuracy (mechanical check);

1.3.2.2B transmitter gain or attenuation (reference [head or other] coil RF calibration);

1.3.2.3B geometric accuracy along each of the three major axes (gradient calibration);

1.3.2.4B high-contrast spatial resolution;

1.3.2.5B low-contrast detectability / contrast-to-noise ratio (CNR); and

1.3.2.6B acquisition workstation monitor quality control.

(See Guidelines on Page 24 for further recommendations.)

1.3.3B Deviations from established thresholds must be documented and corrective action taken where appropriate.

1.3.4B Preventive maintenance (PM) service is required per the manufacturers' recommendations but not less than annually for each MRI scanner at the facility.

1.3.5B A manufacturer's service engineer and/or the MRI site's representative, who has been properly trained to maintain the equipment, must perform the preventive maintenance.

1.3.6B The PM/quality control assessment must include (but need not be limited to) the following (on an annual basis):

1.3.6.1B Performance testing of each coil used clinically:

i. physical / visual inspection;

ii. RF transmitter gain/attenuator verification;

- iii. signal-to-noise ratio (SNR) evaluation;
 - iv. image intensity uniformity (volume coils); and
 - v. artifact assessment.
- 1.3.6.2B magnetic field homogeneity;
- 1.3.6.3B slice thickness accuracy;
- 1.3.6.4B slice position accuracy;
- 1.3.6.5B system image quality performance:
- i. high contrast spatial resolution;
 - ii. artifact assessment; and
 - iii. low contrast detectability / contrast-to-noise ratio.
- 1.3.6.6B General equipment inspection (e.g., RF coil cables and connectors, RF shielding, scan table manipulation, etc.).
- 1.3.6.7B At least annually, the appropriate staff (as specified in 1.2.2B) must review and approve the results of the daily, periodic, and annual QC assessments. A report and summary of findings and recommendations for corrective action must be provided to the Medical Director and Technical Director.

(See Guidelines on Page 24 for further recommendations.)

STANDARD – Quality Control Documentation

- 1.4B All QC results must be documented and reviewed.
- 1.4.1B A written report of the acceptance tests must be maintained at the MRI facility. The report must include the QC tests performed, the results as compared to manufacturer’s 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.
- 1.4.2B A complete report of PM, quality control tests and service records must be maintained at the MRI facility. The reports must be signed and dated by the person(s) performing the tests.
- 1.4.3B A complete service record for all ancillary MRI equipment must be maintained at the MRI facility. The reports must be signed and dated by the person(s) performing the tests.

(See Guidelines on Page 24 for further recommendations.)

Section 1B: Instrumentation and Equipment

Guidelines

- 1.1.2B *Comment: The requirements may include maximum rate of change of magnetic field strength (dB/dt), specifications of maximum static magnetic field strength, maximum auditory noise levels and maximum radiofrequency power deposition (specific absorption rate).*
- 1.2B *Quality control tests, standards, thresholds, timelines and results should be reviewed and discussed on a regular basis by appropriate staff.*
- Quality control tests should be performed according to the manufacturer's performance standards by the MRI technologist, service engineer, medical physicist, or qualified expert on a timely basis.*
- 1.3B *A major upgrade is a hardware upgrade that replaces one or more of the following: main magnet, gradient coil, body coil, gradient amplifiers, RF transmitter, and/or RF receiver subsystem. This means hardware with new/different specifications and capabilities. A system upgrade that results in the system being assigned a new serial number by the manufacturer is considered a major upgrade. In addition, a limited-scope acceptance test should be performed for routine replacement of individual coils and for upgrade replacements of individual coils. Acceptance testing should be considered after repairs to a system resulting from major damage including, but not limited to, magnet quench, fire, flooding, and so forth.*
- 1.3.2.2B *The reference coil is the coil designated by the facility for use in periodic QC assessments. This is usually the head coil for MRI systems equipped with one. If the manufacturer directs the use of a specific coil for daily or other routine QC procedures, this would be a reasonable choice for the reference coil. The reference coil should be able to fit the phantom(s) used for the periodic QC assessments and facilitate reproducible positioning of the phantom and coil. The reference coil used for daily and periodic QC shall be documented for the facility's QA program.*
- 1.3.6B *Annual QC assessments may be performed by the service engineer as part of PM service or may be performed by the Qualified Medical Physicist.*
- 1.4B *Periodic evaluations should be established at weekly, monthly, or quarterly intervals in the facility's quality assurance policies and procedures.*

Section 2B: Protocols

STANDARD – Procedure Volumes

- 2.1B The annual procedure volume must be sufficient to maintain proficiency in examination performance and interpretation.

(See Guidelines on Page 26 for further recommendations.)

STANDARD – Indications

- 2.2B MRI testing is performed for appropriate indications.

Comment: Accepted indications will vary depending on clinical considerations that are provided by the referring health care provider and can only be assessed at the time of the examination. Appropriate indications include evaluation of patients with suspected pathology.

- 2.2.1B Indications for performance of a comprehensive or limited examination must be included *(See Appendix A on Page 32 for examination types)*.

- 2.2.2B Verification of the Indication – A process must be in place in the facility for obtaining and recording the indication. Before a study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.

STANDARD – Techniques

- 2.3B Examination performance must include proper technique (e.g., pulse sequences, coil selection and positioning).

- 2.3.1B Elements of study performance include, but are not limited to:

2.3.1.1B proper coil selection and patient positioning;

2.3.1.2B appropriate protocol selection based on the clinical indication and patient history;

2.3.1.3B optimization of pulse sequence(s) and equipment settings that are necessary to achieve a diagnostic study and answer the clinical indication; and

2.3.1.4B utilization of appropriate software, workstations, techniques and measurements to aid in the diagnosis.

- 2.3.2B A protocol that defines the components of the standard examination must be in place and modified to answer the clinical indication.

- 2.3.3B The facility must have a complete, written description of each protocol that is being utilized for each MRI examination and the protocol must include (as appropriate).

2.3.3.1B description of the IV contrast (to include: type of contrast, amount, injection rate and scan delay protocol);

2.3.3.2B other medications administered including dose and route of administration.

(See Guidelines on Page 26 for further recommendations.)

Section 2B: Protocols Guidelines

2.1B *In general, a facility should perform a minimum of 300 MRI examinations annually. In some settings, facilities may perform quality examinations with lower volumes.*

2.3.3B *Protocol(s) should include:*

- *The indication for the study*
- *Anatomical region(s) to be imaged*
- *Utilization of the correct scanner for the given indication*
- *Clear criteria for deviating from protocols*
- *Adherence to established practice guidelines*
- *All orientations/views that will be displayed*
- *Scanner settings or acquisition parameters to include:*
 - *Pulse sequence parameters:*
 - *Name of pulse sequence*
 - *TR/TE*
 - *FA*
 - *Matrix*
 - *FOV*
 - *Slice thickness*
 - *Interval or slice gap*
- *Filming instructions to include window level and contrast settings, views, format and magnification.*
- *Instruction on data archiving and transmission of images including what files are to be stored/transmitted.*

Part C:

Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

- 1.1C The facility must have a written Quality Improvement (QI) program for all imaging procedures. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:
 - 1.1.1C test appropriateness;
 - 1.1.2C technical quality and safety of the imaging;
 - 1.1.3C interpretive quality review;
 - 1.1.4C report completeness and timeliness.
- 1.2C The Medical Director, staff and/or an appointed QI Committee must provide oversight to the QI program including but is not limited to, the review of the reports of the QI evaluations and any corrective actions taken to address any deficiencies.

Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.4C.

(See Guidelines on Page 29 for further recommendations.)

2.1.1C **Test Appropriateness:** The facility must evaluate the appropriateness of the test performed based on criteria published and / or endorsed by professional medical organizations (if available) and categorize as:

2.1.1.1C appropriate/usually appropriate;

2.1.1.2C may be appropriate; or

2.1.1.3C rarely appropriate/usually not appropriate.

(See Guidelines on Page 29 for further recommendations.)

2.1.2C **Technical Quality Review:** The facility must evaluate the technical quality of the images and the safety of the procedure. The review must include but is not limited to the evaluation of:

2.1.2.1C review of the clinical images for clarity of images and/or evaluation for suboptimal images or artifact to include but not limited to: field of view, contrast enhancement, coil and ROI positioning;

2.1.2.2C completeness of the study;

2.1.2.3C adherence to the facility imaging acquisition protocols; and

2.1.2.4C patient and facility safety (see Section 4A – Facility Safety).

(See Guidelines on Page 29 for further recommendations.)

2.1.3C **Interpretive Quality Review:** The facility must evaluate the quality and accuracy of the interpretation based on the acquired images.

(See Guidelines on Page 29 for further recommendations.)

2.1.4C **Final Report Completeness and Timeliness:** The facility must evaluate the final report for completeness and timeliness as required in the *Standards*.

Section 2C: Quality Improvement Measures

Guidelines

2.1C Administrative Quality Review – Under the supervision of the Technical Director and the Medical Director, the facility should have a defined QI Program that evaluates the ongoing administrative quality (e.g., backlog for scheduled examination, late reporting and long patient wait times) of the imaging procedures performed in the facility.

2.1.1C Test Appropriateness:

- A mechanism should be in place for education of referring physicians to improve the appropriateness of testing.
- A program for education and reporting should be developed and may include but is not limited to:
 - patterns of adherence to test appropriateness;
 - baseline rates of adherence;
 - goals of improvement of adherence to test appropriateness;
 - measurement of improvement rate; and
 - confidential comparison reports on patterns of adherence in aggregate by ordering physician, ordering practice and interpreting practice.

2.1.2C Technical Quality Review:

- Peer review may also be used to compare reproducibility.
- Physicians and technologists should be involved in the peer review process in order to achieve standardized protocols.
- Results of the peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve, physician, technologist and patient confidentiality.
- Thresholds should be determined for each indicator (e.g., a threshold for the percentage of scans that should be free from motion artifact=90%).

2.1.3C Interpretive Quality Review:

- Peer review may be used to compare reproducibility of interpretation with previous interpretation, or with interpretation of the same study by other interpreting physicians.
- Physicians should be involved in the peer review process in order to achieve standardized reporting.
- Results of peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve physician, technologist, and patient confidentiality.
- Clinical correlation and confirmation of results: For patient who have undergone MRI examinations and surgical intervention or treatment, the results of the MRI examination and other procedures may be compared. A process for reviewing variations between MRI examination results and results of other procedures may be in place.

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

- 3.1C The facility must have a minimum of two QI meetings per year.
 - 3.1.1C The content of at least one meeting per year must include the reviews of the results of the QI analyses and any additional QI related topics.
 - 3.1.2C All staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation

4.1C QI Documentation and Record Retention

4.1.1C The facility QI documentation must include, but is not be limited to:

4.1.1.1C the data for the QI measures above;

4.1.1.2C a description of how the QI information is used to improve MRI quality;

4.1.1.3C minutes from the QI meetings.

i. Participant list (may include remote participation and/or review of minutes).

4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

Appendix A

Body Imaging: MRI body imaging includes examinations of the chest, neck, abdomen, pelvis, breast and vascular structures and is a technological challenge due to physiological motion artifacts. However, since the emergence of fast scan and motion compensation techniques, MRI examinations of the body have become more practical. The ability to acquire scan data during a breath hold has greatly improved spatial resolution of structures in areas previously degraded by motion artifacts. In addition, the ability of MRI to demonstrate anatomy and pathology in multiple planes, and the improved conspicuity provided by chemical shift imaging, has made MRI an important tool for imaging of body structures. In many instances, MRI has become the imaging method of choice for demonstrating organ function and morphology, and the detection, differentiation and staging of benign and malignant lesions.

Cardiovascular Imaging: Cardiovascular MRI involves imaging of the heart and central vascular system using single-planar and multi-planar acquisitions. Included in disorders of the heart are disorders of the myocardium, heart chambers, valves, coronary blood vessels, blood pathways and the pericardium. Included in disorders of the central vascular system are abnormalities of the aorta (ascending, arch, thoracic descending, abdominal descending and the iliac bifurcation), the pulmonary vasculature and the thoracic venous system.

Musculoskeletal Imaging: MRI is a valuable tool in the visualization, detection and staging of a wide range of musculoskeletal disorders. These include degenerative, infectious, neoplastic and traumatic evaluation of articular structures, non-articular soft tissues, bones and bone marrow.

Neurological Imaging: Neurological MRI involves imaging of the brain and spine using both 2-D and 3-D acquisitions and neuro physiological techniques. Included in disorders of the brain are conditions of the skull base, intra and extra cranial vasculature, the cranial nerves as well as other structures. Included in disorders of the spine are conditions involving the cervical, thoracic lumbar and sacral regions.

Breast Imaging: MRI is a valuable diagnostic tool in assessing breast health when used in conjunction with a clinical examination, mammography and ultrasound. MRI scans are used to produce high quality images that show increased or abnormal blood flow in the breast (often a sign of early cancers); aid in the detection of abnormalities in dense and fatty breast tissues; and use subtraction and 3-D imaging to delineate suspicious lesions.

MRA Imaging: MR angiography is used to evaluate abnormalities and disease processes of blood vessels in all parts of the body. Common indications for the use of MRA include, but are not limited to, the diagnosis and evaluation of: atherosclerosis, aneurysms, arterial venous malformations, patency of vessels following stent placement, aortic dissections and the evaluation of tumors, blood supply.

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