Special Communication

Interrelating Sentinel Event Alert #38 With the ACR Guidance Document on MR Safe Practices: 2013. An MRI Accreditation Safety Review Tool

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When, in 2008, the Joint Commission released its Sentinel Event Alert #38 regarding MRI safety, it joined the ACR's Guidance Document on MR Safe Practices as one of two radiology best-practice documents establishing MR safety protections. However, particularly for MR providers who held both modality-level accreditation from the ACR, and enterprise-level accreditation from the Joint Commission, there has been confusion about which institution's standard takes precedence, or whether there are inherent conflicts between the two. With the release of the 2013 update to the ACR Guidance Document on MR Safe Practices, the authors have cross-referenced the performance criteria of both MR safety standards, and correlated the ACR Guidance Document performance criteria with the Joint Commission's Environment of Care standards.

Key Words: MRI safety; regulation; accreditation; standard of care; standard of practice; accident; injury; adverse event; Joint Commission; Sentinel Event Alert; American College of Radiology; Guidance Document on MR Safe Practices

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THIS STUDY COORDINATES the performance criteria from the Joint Commission's Sentinel Event Alert #38 (Preventing Accidents and Injuries in the MRI Suite) with the ACR Guidance Document on MR Safe Practices: 2013 to facilitate provider compliance with industry standard of care practices in MR safety.

In the absence of explicit federal requirements (and with the implicit expectations for radiology safety standards from patients, States, and accrediting bodies), it is incumbent upon MR providers to identify and adhere to established best practice standards for MRI safety. Presently, there are currently two industry-recognized MRI safety practice standard documents, which, though different wording may be used, share objectives which are fully compatible.

This document reciprocally coordinates—for the first time—the performance criteria of the Joint Commission's Sentinel Event Alert #38 on MRI Accidents and Injuries with the new 2013 update to the ACR Guidance Document on MR Safe Practices. Beyond cross-referencing the shared performance criteria, this document also references those performance criteria of the 2013 ACR Guidance Document on MR Safe Practices which are also directly applicable to the Joint Commission's Environment of Care (EC) standards for both hospital and ambulatory accredited service providers.

By dovetailing the two industry recognized MR safety best practice documents, it is the authors' intent that MR providers, as well as those with regulatory, accreditation, or license responsibility for quality and safety of healthcare providers, will be equally empowered to implement the agreed upon industry best practice standards which will provide appropriate protections to all in the MR environment.

THE JOINT COMMISSION'S SENTINEL EVENT ALERT #38 (10 + 3) PRACTICE STANDARDS

Joint Commission accredited facilities are likely well familiar with the ten explicit objectives put forth in the Joint Commission Sentinel Event (SEA) #38 on MRI Accidents and Injuries released in February of 2008, restated below:

1. Restrict access to all MRI sites by implementing the four zone concept as defined in the ACR Guidance Document for Safe MR Practices: 2007. The four zone concept provides for progressive restrictions in access to the MRI scanner:
   - Zone I: General public
   - Zone II: First access/contact points between MR patients/family members and MR staff
   - Zone III: Regions from which potentially hazardous energies (related to the MR imaging process) may be accessed
   - Zone IV: The room housing the MR scanner itself

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2. Use trained personnel to screen all nonemergent patients twice, providing two separate opportunities for them to answer questions about any metal objects they may have on them, any implanted devices, drug delivery patches, tattoos, and any electrically, magnetically, or mechanically activated devices they may have on or in them. If the patient is unconscious or unable to answer questions, question the patient's family members or surrogate decision maker and use other means to determine if the patient has implants or other devices that could be negatively affected by the MRI scan (e.g., look for scars or deformities, scrutinize the patient's history, use plain-film radiography, use ferromagnetic detectors to assist in the screening process, etc.).
3. Ensure that the MRI staff has the patient's complete and accurate medical history to determine whether or not the patient can be safely scanned. All implants should be checked against product labeling or manufacturer literature specific to that implant or peer-reviewed published data regarding the device or implant in question. Technologists should be provided with ready access to this information.
4. Have a specially trained MR staff person ("MR personnel") who is knowledgeable about the MRI environment safety issues accompany all patients, visitors and other staff who are not familiar with the MRI environment at all times that they are within Zones III or IV.
5. At least annually, provide all MR personnel with safety education about the MRI environment and provide all non-MR staff, patients and their families with appropriate materials (e.g., guidelines, brochure, poster) that explain the potential for accidents and adverse events in the MRI environment.
6. Take precautions to prevent patient burns during scanning, including:
   - Ensure that no electrically conductive loops are formed in the MR scanner bore during the MR imaging process.
   - Use nonconducting foam pads to insulate the patient's skin and tissues and prevent the patient from contacting the inner bore of the MR scanner.
   - Prospectively place a cold compress or ice pack on EKG leads, surgical staples, and tattoos (or other electrically conductive material in contact with the patient's tissues/skin) that will be exposed to radiofrequency irradiation during the MR imaging process to prevent thermal injury to tissue adjacent to these electrically conductive items.
7. Only use equipment and devices (e.g., fire extinguishers, oxygen tanks, physiologic monitors, and aneurysm clips) that have been tested and approved for use in MRI environments.
8. Proactively plan for managing critically ill patients who require physiologic monitoring and continuous infusion of life sustaining drugs and gases while in the MRI suite.
9. Provide all MRI patients with hearing protection (e.g., ear plugs).
10. Never attempt to run a cardio-pulmonary arrest code or resuscitation within the MR magnet room (Zone IV) itself.

Joint Commission accredited MR providers may also recognize three more objectives from co-author of this paper, Dr. Emanuel Kanal, then chairperson of the MR Safety Committee for the American College of Radiology, published in SEA #38 alongside the 10 numbered goals:

+1* Appoint a safety officer who is responsible for implementing and enforcing safety procedures in the MRI suite.

+2* Implement systems to support safe MRI practices such as written MR safety policies and guidelines and periodically review and assess compliance with your organization's MRI policies, procedures and protocols.

+3* In general, do not bring any device or equipment into the MRI environment unless it is proven to be MR Safe or MR Conditional. MR Safe items pose no known hazard in all MRI environments, and MR Conditional items have been demonstrated to pose no known hazards in a specified MRI environment within specified conditions of use. The Safety of "MR conditional" items must be defined for a specific scanner field strength and MR imaging environment and conditions in which it was found to be safe. For MR Unsafe devices extra caution and watchfulness must be exerted at all times that they might need to be brought into Zones III and IV to ensure that they are handled in such a way that they will not pose a threat to patients, family members, and/or staff in Zones III and/or IV.

By and large, these goals as stated in SEA #38 are formatted as objectives. Without making SEA #38 unduly long, the breadth of these recommendations means that the bulk of the supporting best practice information could not be directly quoted within the Sentinel Event Alert. The responsibility of finding specific supporting details and implementation strategies for these objectives were, as a result, left largely to the individual provider.

The most comprehensive and authoritative document on MR safety practices currently published is the American College of Radiology's ACR Guidance Document on MR Safe Practices: 2013. While the Guidance Document does not provide prescriptive solutions to every MR safety issue, it does provide detail far beyond the 10 + 3 objectives outlined in SEA #38. Providers will find information in this MR Safety Guidance Document to be very helpful both in clarifying the underlying reasons for the specific SEA #38 objectives and for providing greater information on methodologies available to mitigate the identified risks.

To more directly correlate the 10 + 3 objectives of the Joint Commission Sentinel Event Alert #38 with the specific section of this latest edition of the ACR MR Safety Guidance Document, we have developed a correlating index between these two documents. The table below will provide only a citation to the appropriate section of the ACR Guidance Document, and not the full text.

#	SEA Performance Objective	Guidance Document Citation
1	Restrict access to all MR sites by implementing the four zone concept as defined in the ACR Guidance Document	Section B. 1.
2	Use trained personnel to screen all non-emergent Patients twice	Section B. 3. e.
3	Ensure that the MR technologist has the patient's complete and accurate medical history to ensure that the patient can be safely scanned	Section B. 3.
4	Have a specially trained staff person who is knowledgeable about the MR environment accompany any patient, visitors and other staff... at all times.	Section B. 3. d.
5	Annually, provide all medical and ancillary staff... with safety education about the MR environment and provide all staff and Patients and their families with appropriate materials that explain the potential for accidents and adverse events in the MRI environment.	Section B. 2. Section B. 3. a.
6	Take precautions to prevent patient burns during scanning	Section H.
7	Use only equipment that has been tested and approved for use during MR scans	Section B. 5.
8	Proactively plan for managing critically ill Patients	Section B. 1. d. Section C.
9	Provide all Patients with hearing protection	Section G.
10	Never attempt to run a cardio-pulmonary arrest code or resuscitation within the MR magnet room itself	Section B. 1. d.
+1*	Appoint an MR Safety Officer	Section A. 3.
+2*	Develop MR safety policies & procedures	Section A.
+3*	Keep untested and unlabeled equipment out of the MR suite.	Section B. 5. c.

While the Joint Commission Sentinel Event #38 is significant in its approach to MR safety, providers should be aware that there are many other critical issues pertaining to MR safety identified in the SEA-referenced ACR Guidance Document. Certainly the above 10 + 3 objectives should be met, but those objectives alone should not be mistaken for a comprehensive or sufficient approach to MR safety.

To facilitate a broader review of MR safety standards and best practices, each MR provider should compare their practices against the full list of objectives and policies outlined in the contemporary edition of the ACR MR Safety Guidance Document.

To assist MR providers in this review, we have distilled the ACR Guidance Document on MR Safe Practices: 2013 to a table identifying specific objectives in the Guidance Document, the risks that they are intended to mitigate, and the citation to the point in the body of the Guidance Document where the reader can find the full text.

Joint Commission accredited providers, as well as those accredited by other organizations as proxies for CMS participation, must also maintain an appropriate "environment of care", both physical provisions and operational procedures necessary to provide safe and effective care. Managing the risks within an environment of care necessarily requires responding to the type of care being delivered. The environment of care (EC) standards from the Joint Commission's hospital accreditation relevant to MRI safety are cited below.

EC 01.01.01 The [organization] plans activities to minimize risks in the environment of care.

EC 02.01.01 The [organization] manages safety and security risks.

EC 02.02.01 The [organization] manages risks related to hazardous materials and waste.

EC 02.03.01 The [organization] manages fire risks.

EC 02.03.05 The [organization] maintains fire safety equipment and fire safety building features.

EC 02.04.01 The [organization] manages medical equipment risks.

EC 02.04.03 The [organization] inspects, tests, and maintains medical equipment.

EC 02.05.07 The [organization] inspects, tests, and maintains emergency power systems.

EC 02.05.09 The [organization] inspects, tests, and maintains medical gas and vacuum systems.

EC 02.06.01 The [organization] establishes and maintains a safe, functional environment.

EC 03.01.01 Staff and licensed independent practitioners are familiar with their roles and responsibilities relative to the environment of care.

EC 04.01.01 The [organization] collects information to monitor conditions in the environment.

EC 04.01.03 The [organization] analyzes identified environment of care issues.

EC 04.01.05 The [organization] improves its environment of care.

In the table below, the authors have included a column labeled "EC" which indicates whether a performance criterion from the 2013 edition of the ACR MR Safety Guidance Document should be interpreted as being directly applicable to the establishment of a safe and effective environment of care for MR services under one of the above EC standards.

SECTION A. Safety Policies & Procedures

Performance Criteria	Risk(**s**)	Citation	EC
Establish MR Safety Policies & Procedures	Multiple	(A. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Regularly Update MR Safety Policies & Procedures	Multiple	(A. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Name MR Medical Director / Safety Officer	Multiple	(A. 3.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Report all MR Accidents & Near Misses to Vendor / FDA	Multiple	(A. 4.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 04.01.01 EC 04.01.03 EC 04.01.05

SECTION B. Static Magnetic Field Issues: Site Access

Performance Criteria	Risk(**s**)	Citation	EC
MR Suite Zoning Establish 4-Zone Access / Screening	Multiple	(B. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Zone I is Comprised of all Non-MR Areas in which there are No MR-Related Hazards	Multiple	(B. 1. a.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Provide Zone II Area Outside All MR-Related Hazards for MR Patient / Visitor Receiving, Waiting and Screening.	Multiple	(B. 1. b.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Provide Secured Zone III Area, Restricted to Only Persons Successfully Screened, for any Areas with Magnetic Field Hazards or Direct Access to Magnet Room (Zone IV)	Multiple	(B. 1. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
All Non-MR Personnel in Zone III to be Under the Direct Supervision of Trained MR Staff.	Multiple	(B. 1. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Secure All Areas with Magnetic Field Hazard as Zone III, Including Occupiable Areas Outside the MR Suite (i.e. above and below)	Multiple	(B. 1. C.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Provide Clear Hazard Marking at the Entrance(s) to the Magnet Room (Zone IV), Including Backup Powered, Illuminated "The Magnet Is On" Signage	Multiple	(B. 1. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Provide Direct 'Line-of-Sight' Observation from Console to Magnet Room Entrance	Multiple	(B. 1. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Prospectively Designate a Code Area Outside the Magnet Room (Zone IV). In Case of Emergency, Stabilize and Remove Persons from Zone 4 Prior to full Resuscitative Efforts	Multiple	(B. 1. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01

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SECTION B. (Continued)

Performance Criteria	Risk(**s**)	Citation	EC
Quenching a Superconducting MR is Not to be Performed for Emergent Situations where Persons can be Expediently Evacuated	Multiple	(B. 1. d.)	√ EC 02.01.01 EC 02.02.01 EC 02.04.01 EC 02.06.01
MR Personnel And Non-MR Personnel			
Require Training, at Least Annually, for any Staff Working Within Zone III of the MR Suite	Multiple	(B. 2. a.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Provide Minimal Training (Level 1) for any Staff Working Within Zone III of the MR Suite to Help Ensure Their Safety	Multiple	(B. 2. b.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Provide Advanced Training (Level 2) for MR Staff Charged with a Broad Range of Safety Responsibilities (i.e. burns, peripheral nerve stimulation, device screening)	Multiple	(B. 2. b.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
All Persons Who have Not Successfully Completed MR Safety Training Within Prior 12 Months to be Designated "Non-MR Personnel"	Multiple	(B. 2. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Patient And Non-MR Personnel Screening			
All Non-MR Personnel to be Successfully Screened for MR Risks Prior to Being Permitted Entrance to Zone III	Multiple	(B. 3. a.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Provide Comprehensive Clinical Screening for All Persons Entering Zone III, Including Non-Patients	Multiple	(B. 3. b.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Physical Screenings are Not to be Conducted with Conventional 'Airport Style' Metal Detectors	Projectile	(B. 3. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Ferromagnetic Detection Screening for All Persons Entering Zone III to be Completed as an Adjunct to Established Screening Protocols	Projectile	(B. 3. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
All Non-MR Personnel to be Under Direct MR Personnel Supervision Within Zones III and IV	Multiple	(B. 3. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Non-Emergent Patients to be Clinically Screened Twice by Separate MR Personnel	Multiple	(B. 3. e.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Patients to Remove All Removable Metallic Materials Prior to Entering Zone III	Projectile & Heating	(B. 3. f.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
All Persons w/ Intraoccular / Intraorbital foreign bodies to be Restricted From Magnet Room (Zone IV) Unless Prospectively Cleared by Level 2 Staff, Radiologist, MR Safety Officer as Proscribed by MR Medical Director	Movement & Torque	(B. 3. g.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01

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SECTION B. (Continued)

Performance Criteria	Risk(**s**)	Citation	EC
Patients with History of Metallic Object Penetration Must Receive Specific Screening for Hazard	Movement & Torque	(B. 3. g.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Conscious / Alert Patients Must Complete & Sign Screening Form. MR Personnel to Review Completed Form w/ Patient and Co-sign	Multiple	(B. 3. h.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Patients with (Potential) Intracranial Aneurism Clips Must Receive Specific Screening for Hazard	Movement & Torque	(B. 3. i.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Unresponsive Patients Requiring MR Exams Must Receive Thorough Physical Screening by Level 2 MR Staff for Indications of Contraindications	Multiple	(B. 3. j. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Unresponsive Patients Requiring MR Exams Must be Carefully Monitored During MR Examination for Indications of Hazards	Multiple	(B. 3. j. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Final Determination to Scan Patients w/ (Potential) Contraindications to be Made by Level 2 Staff, Radiologist, MR Safety Officer as Proscribed by MR Medical Director	Multiple	(B. 3. k.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
MR Safety Officer / Medical Director to be Consulted if Implant is Discovered During MR Imaging to Determine Appropriate Action to Protect Patient.	Multiple	(B. 3. k.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
All Persons w/ Implanted Devices to be Restricted From 5-gauss Exclusion Zone and Magnet Room (Zone IV) Unless Prospectively Cleared by Level 2 Staff, Radiologist, MR Safety Officer as Proscribed by MR Medical Director	Multiple	(B. 3. l.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Metallic Restraints and RFID Tracking Devices to be Removed From Persons Prior to Entering Magnet Room (Zone IV) and may be Replaced Following Egress From Magnet Room (Zone IV)	Multiple	(B. 3. m.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Emergency Responders to MR Suite to be Met Onsite by Trained MR Personnel Prior to Entering Controlled Access Areas Within MR Suite	Multiple	(B. 3. n.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Prospectively Meet and Coordinate with First Responders Regarding MR Environment Hazards	Projectile	(B. 3. n.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Conventional Firefighting Equipment and Portable Extinguishers Not Demonstrated as Safe in MR Environment to be Restricted from Zone III	Projectile	(B. 3. n.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
If Emergency Evacuation of the Magnet Room (Zone IV) Requires Manual Quench of a Superconducting Magnet, Trained MR Personnel Must Verify Magnetic Diminution Prior to Admitting Unscreened Responders Into the Room	Multiple	(B. 3. n.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
For MR Magnets for which Magnetic Field Can Not Be (Fully) Diminished, MR Personnel Should be Present to Advise First Responders of Risk	Multiple	(B. 3. n.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01

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SECTION B. (Continued)

Performance Criteria	Risk(**s**)	Citation	EC
MR Personnel Screening			
All MR Personnel to Successfully Complete MR Clinical Screening Prior to Beginning Job Duties	Multiple	(B. 4.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
All MR Personnel to Report Trauma, Procedure and Surgery That May Have Introduced Ferromagnetic Materials	Movement & Torque	(B. 4.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Device And Object Screening			
Restrict Ferromagnetic Materials From Entering Zone III	Projectile	(B. 5.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Use Powerful Hand-Held Magnet (1,000 Gauss or Greater) or Ferromagnetic Detector to Test Magnetic Properties of Objects and Devices Introduced to Zone III	Projectile	(B. 5.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Safety Conditions for All Portable (Partially) Metallic Objects to be Ascertained and Documented Prior to Entering Zone III	Projectile & Heating	(B. 5. a.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
MR Unsafe Objects May be Brought Into Zone III Only Under Carefully Controlled Circumstances	Projectile	(B. 5. b.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Objects With Unknown or Untested Safety Properties are Not to be Assumed Safe or Brought Into Zone III	Projectile	(B. 5. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Labeling / Documentation of Site Tested Objects to Include Tester, Methodology and Date of Test	Projectile	(B. 5. c.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
All Portable (Partially) Metallic Objects to be Brought Into Zone IV (Magnet Room) to be Labeled in Accordance With FDA Standards	Multiple	(B. 5. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Disregard Labeling That Does Not Conform to Current FDA Standards, Including "Safe" on any Metallic Object or Undefined Terms Such as "Non-Magnetic"	Multiple	(B. 5. d.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Recognize That Safety Claims are Typically Limited to Specific MR Scanner / Scan Parameters. Do Not Assume an Object to be Safe Outside the Stated Conditionally Safe Parameters.	Multiple	(B. 5. e.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Any Alteration or Modification to a Manufacturer-Tested and Labeled Object May Modify the Object's Safety Characteristics.	Multiple	(B. 5. f.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Lenz Forces May Produce Effects of Magnetic Resistance on Non-Ferromagnetic Materials That may be Inappropriately Acted Upon if Thought to be a Ferromagnetic-Attractive Effect	Multiple	(B. 5. f.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01

SECTION C. MR Technologists

Performance Criteria	Risk(**s**)	Citation	EC
MR Technologists to Maintain Qualifications Meeting Accreditation Program Requirements	Multiple	(C. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
For Non-Emergent Coverage, MR Suite to be Staffed with At Least Two Trained MR Personnel	Multiple	(C. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
For Emergent Coverage, MR Suite to be Staffed with Minimum of One MR Technologist with Ready Emergent Support Coverage From Radiologist or Radiology Staff	Multiple	(C. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION D. Pregnancy-Related Issues

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Performance Criteria	Risk(**s**)	Citation	EC
Pregnant Health Care Practitioners are Not Precluded from MR Duties with Exception of Remaining In or Immediately Adjacent to the Scanning Volume of the MR Device During Scanning	Precautionary	(D. 1.)	
Female Patients of Childbearing Age to be Screened for Potential Pregnancy	Precautionary	(D. 2.)	√ EC 02.01.01
If Pregnant, Patients May Undergo MR Examination if Risk – Benefit Analysis by MR Attending Radiologist Indicates	Precautionary	(D. 2. a.)	√ EC 02.01.01 EC 03.01.01
The Use of Gadolinium-Based Contrast Agents for Pregnant Patients Requires Risk – Benefit Analysis by MR Attending Radiologist	Precautionary	(D. 2. b.)	√ EC 02.01.01 EC 03.01.01
Obtain Written Informed Consent for MR Examinations of Pregnant Patients	Precautionary	(D. 2. c.)	√ EC 02.01.01 EC 03.01.01

SECTION E. Pediatric MR Safety Concerns

Performance Criteria	Risk(**s**)	Citation	EC
Follow Joint Commission, ASA and State Provisions for Pediatric Sedation and Monitoring	Multiple	(E. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Monitor Body Temperature of Neonate / Young Pediatric MR Patients During Examination	Multiple	(E. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Clinical Screening of Pediatric Patients to be Completed Both Privately and in the Presence of Parent / Guardian	Multiple	(E. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
It is Recommended that Pediatric Patients be Changed out of Street Clothes for MR Examination	Multiple	(E. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01
Comfort Items (i.e. Stuffed Animals) to be Carefully Screened if Permitted to Accompany Patient During MR Exam	Projectile	(E. 2.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01

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SECTION E. (Continued)

Performance Criteria	Risk(**s**)	Citation	EC
Persons Accompanying the MR Patient in Zone IV During MR Examination to be Successfully Screened	Multiple	(E. 3.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Persons Accompanying the MR Patient in Zone IV During MR Examination to be Provided Hearing Protection	Auditory	(E. 3.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION F. Time-Varying Gradient Magnetic Field Issues: Induced Voltages

Performance Criteria	Risk(**s**)	Citation	EC
Patients with Implanted or Retained Wires (Leads) in Sensitive Areas to Have MR Examination Protocols Reviewed Prior to Exam	Multiple	(F. 1.)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION G. Time-Varying Gradient Magnetic Field Issues: Auditory Considerations

Performance Criteria	Risk(**s**)	Citation	EC
All Persons in the Magnet Room (Zone IV) During MR Examination to be Provided and Encouraged to Use Hearing Protection	Auditory	(G. 1)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
Patients Examined by MR Systems Capable of Producing Sound Pressure Levels Greater Than 99 Decibels (Db) Must be Provided Hearing Protection	Auditory	(G. 1)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01
All Persons in the Magnet Room (Zone IV) During non-FDA Approved Research MR Examinations Must Use Hearing Protection	Auditory	(G. 2)	√ EC 02.01.01 EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION H. Time-Varying Radiofrequency Magnetic Field-Related Issues: Thermal

Performance Criteria	Risk(**s**)	Citation	EC
Unnecessary and Unused Electrically Conductive Components to be Removed from Patient / MR Device During MR Examination	Burn	(H. 1.)	√ EC 02.04.01 EC 02.06.01
All Electrically Conductive Components to be Visually Inspected by MR Personnel Prior to Each Use for Continuity of Thermal and Electrical Insulation	Burn	(H. 1.)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01 EC 04.01.01
Electrically Conductive Components to Remain Near / On the Patient During MR Exam to be Arranged with No Large Caliber Loops or Coils	Burn	(H. 2.)	√ EC 02.04.01 EC 02.06.01
MR Conditional Criteria for Thermal Safety are Unique to Stated Test Conditions. No Safety Relationship Should be Inferred For Differing Field Strengths or Scan Parameters	Burn	(H. 2.)	√ EC 02.04.01 EC 02.06.01

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SECTION H. (Continued)

Performance Criteria	Risk(**s**)	Citation	EC
Electrically Conductive Components to Remain Near / On the Patient During MR Exam to be Positioned With Thermal Insulation Between Conductor and Patient	Burn	(H. 3.)	√ EC 02.04.01 EC 02.06.01
Electrically Conductive Components to Remain Near / On the Patient During MR Exam to be Positioned as Far as Possible From Inner Walls of the MR Device	Burn	(H. 3.)	√ EC 02.04.01 EC 02.06.01
Due to Burn Risks Associated with Electrically Conductive Elements in Clothing, it is Recommended to Change Patients Into Known Safe Garments	Burn	(H. 4.)	√ EC 02.04.01 EC 02.06.01
For Many MR Devices, Patients to be Positioned so as Not to Contact Inner Walls. Insulating Padding may be used	Burn	(H. 5.)	√ EC 02.04.01 EC 02.06.01
Patients to be Positioned so as to Not Form Large Caliber Skin-to-Skin Loops (i.e. Crossed Arms / Legs or Inner-Thigh Contact)	Burn	(H. 6.)	√ EC 02.04.01 EC 02.06.01
If Located Outside Regions of RF Deposition, Non-Ferromagnetic Metallic Staples / Sutures may be Permitted	Burn	(H. 7.)	√ EC 02.04.01 EC 02.06.01
If Non-Ferromagnetic Metallic Staples / Sutures are Located Within Regions of RF Deposition, Instruct Patient to Notify MR Personnel Immediately of Any Warmth or Burning Sensation	Burn	(H. 7. a.)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01
If Non-Ferromagnetic Metallic Staples / Sutures are Located Within Regions of RF Deposition, Place Ice Pack or Cold Compress Along Staples During Imaging	Burn	(H. 7. b.)	√ EC 02.04.01 EC 02.06.01
Ice Pack or Cold Compress is Recommended for Large or Dark Tattoos, and for Tattoos on Sensitive Areas	Burn	(H. 8.)	√ EC 02.04.01 EC 02.06.01
Paramagnetic Ink Tattoos Placed Within 48 Hours Prior to MR Imaging May be Subject to Peripheral 'Blurring'	Precaution	(H. 8.)	
Electrically Conductive Leads (Partially) Within the Imaging Volume on a Non-Responsive Patient to be Covered with Ice Pack or Cold Compress	Burn	(H. 9.)	√ EC 02.04.01 EC 02.06.01
Electrically Conductive Leads Internal to the MR Patient May Experience Significant MR-Related Heating. All Implants and Catheters to be Positively Identified and Cleared Prior to MR Exam	Burn	(H. 10.)	√ EC 02.04.01 EC 02.06.01
Multiple Factors Influence Heating Potential of Electrically Conductive Materials. Inferences are Not to be Made for Thermal Safety of a Material Outside of its Tested Safety Parameters	Burn	(H. 11.)	√ EC 02.04.01 EC 02.06.01
Unlike Projectile Safety, Thermal Safety of a Given Lead at 3.0 Tesla Does Not Assure Thermal Safety at Lower Field Strengths or Other Scanning Conditions	Burn	(H. 11.)	√ EC 02.04.01 EC 02.06.01

SECTION I. Drug Delivery Patches and Pads

Performance Criteria	Risk(**s**)	Citation	EC
RF Heating of Metallic Foil Patches May Result in Burn. Consult Proscribing Physician Regarding Drug Delivery Patches that may Remain in the Volume of RF Excitation	Burn	(I)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01
Removal and Replacement of Drug Delivery Patches May Adversely Affect Dose. Follow Proscribing Physician's Instructions Regarding Patches	Altered Dose	(I)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01
Foil Containing Patches Remaining on the Patient Within the Imaging Volume May Experience Significant Heating. Heating or Prophylactic Cooling May Alter Dose Delivery. Consult Supervising Physician Prior to Scan	Altered Dose & Burn	(I)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION J. Cryogen-Related Issues

Performance Criteria	Risk(**s**)	Citation	EC
Evacuate all Persons from the Magnet Room as Quickly and Safely as Feasible in the Event of a MR System Quench	Hypothermia & Asphyxia	(J. 1.)	√ EC 02.02.01 EC 02.04.01 EC 02.06.01
Restrict Access to the Magnet Room if Evidence of Cryogenic Gas Clouds or Fog	Hypothermia & Asphyxia	(J. 1.)	√ EC 02.02.01 EC 02.04.01 EC 02.06.01
MR System Quench May Not Result in Immediate Diminution of Magnetic Field. Trained MR Staff to Verify Magnetic Field Status Prior to Admitting Others	Projectile & Device Interference	(J. 1.)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01
Oxygen Sensors / Alarms May Not Accurately Report Hypoxic Conditions in Certain Failure Modes, Providing False-Negative Feedback	Hypothermia & Asphyxia	(J. 2.)	√ EC 02.02.01 EC 02.04.01 EC 02.06.01

SECTION K. Claustrophobia, Anxiety, Sedation, Analgesia, and Anesthesia

Performance Criteria	Risk(**s**)	Citation	EC
Administration of Anxiolysis, Sedation, Analgesia, and Anesthesia for MR Patients to Follow ACR, Joint Commission and ASA Standards	Multiple	(K.)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01

SECTION L. Contrast Agent Safety

Performance Criteria	Risk(**s**)	Citation	EC
Prescription MR Contrast Agents to be Administered Only on Orders of Duly Licensed Physician	Multiple	(L. 1.)	
Qualified Technologist may Start and Attend IV After Site-Approved Training and Corresponding Demonstration and Proficiency Documentation	Multiple	(L. 1.)	
Qualified Technologist may Administer Gadolinium-Based Contrast as Directed by Physician	Multiple	(L. 1.)	
Administration of Contrast is to be Performed According to ACR Policy, Including Immediate Personal Availability of Radiologist or Physician Designee	Multiple	(L. 1.)	
Physician Designees, Nurses and Radiological Technologists Must Receive Written Authorization From the Facility Medical Director to Administer Contrast Agents, in Accordance with Applicable State Law	Multiple	(L. 1.)	
Physician Designees, Nurses and Radiological Technologists Must Receive Continuing Medical Education on Injected Materials and Related Procedures	Multiple	(L. 1.)	
The Administration of Contrast must be Fully Documented	Multiple	(L. 1.)	
Contrast Reactions are More Likely in Patients With History of Prior Contrast Reaction, Allergies and/or Asthma	Adverse Reaction	(L. 2. a.)	
Patients who Have Previously Reacted to one MR Contrast Agent can be Injected with Another Agent if they are Restudied	Adverse Reaction	(L. 2. b.)	
At-risk Patients can be Premedicated with Corticosteroids and, Occasionally, Antihistamines	Adverse Reaction	(L. 2. b.)	
Patients with Asthma, History of Allergic Respiratory Disorders, Prior Iodinated or Gadolinium-Based Contrast Reactions, etc., Should be Followed More Closely	Adverse Reaction	(L. 2. c.)	
Use of Gadolinium-Based Contrast Should Follow Guidance in "Nephrogenic Systemic Fibrosis" in ACR Manual on Contrast Media, 2010	Adverse Reaction	(L. 3.)	

SECTION M. Patients in Whom There Are or May Be Intracranial Aneurysm Clips

Performance Criteria	Risk(**s**)	Citation	EC
For Patients for Whom it is Unclear Whether or Not Intracranial Aneurysm Clips are Present, Radiograph or CT Examination Should be Reviewed Prior to MR Examination	Movement & Torque	(M. 1.)	√ EC 02.04.01 EC 02.06.01
In Patients in Whom There are Intracranial Aneurysm Clip(s) Present, MR Examination should Not be Authorized Until Clip(s) are Documented as MR Safe or MR Conditional	Movement & Torque	(M. 2.)	√ EC 02.04.01 EC 02.06.01
All Documentation of Types of Implanted Clips, Dates, etc., Must be in Writing and Signed by a Licensed Physician	Movement & Torque	(M. 2.)	√ EC 02.04.01 EC 02.06.01
Clips Manufactured in 1995 or Later may be Accepted for MR Scanning Without Further Testing if Supported by a Current Manufacturer Claim of Safety	Movement & Torque	(M. 3.)	√ EC 02.04.01 EC 02.06.01
Clips Manufactured Prior to 1995 Require Documentation / Pre-Testing for Safety Prior to MR Examination	Movement & Torque	(M. 4.)	√ EC 02.04.01 EC 02.06.01
A Review of Prior MR Images may be Used by Supervising Radiologist to Assess Ferromagnetic Risks Based on Prior Study's Artifact	Movement & Torque	(M. 4.)	√ EC 02.04.01 EC 02.06.01
Prior MR Examination, Alone, is Not Acceptable as Documentation of the Safety of Non-Positively-Identified Clip	Movement & Torque	(M. 5.)	√ EC 02.04.01 EC 02.06.01
Without Positive Identification of Clip(s) Conditional Safety, a Risk-Benefit Assessment Must be Performed, and Informed Consent Obtained, Prior to MR Examination	Movement & Torque	(M. 6.)	√ EC 02.04.01 EC 02.06.01

SECTION N. Patients in Whom There Are or May Be Cardiac Pacemakers or Implantable Cardioverter Defibrillators

Performance Criteria	Risk(**s**)	Citation	EC
Refer to Implant ID Cards, Prior Imaging Studies, Industry References and Operative Notes to Determine MR Conditionality of Cardiac Implantable Electronic Device (CIED)	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Patient Statements of MR Conditionality are Not Sufficient to Establish MR Safety	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Develop Institutional Policies and Protocols for Safety of Patients with CIEDs	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Determinations Regarding Appropriateness of Scanning Patients with MR-Untested CIEDs to be Made on a Case-By-Case Basis Only If Site Staffed with Appropriate Expertise	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Unless Specifically Tested and Labeled for MR Safety, No Distinction Between the Safety of 'Older' and 'Modern' Devices Should be Inferred	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Informed Consent Should be Obtained from all Non-Emergent Cardiac Device Patients Prior to MR Examination	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Radiology and Cardiology Personnel and Equipment Should be Readily Available for Emergent Response for CIED Patient During MR Exam	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Cardiac Device Patients are to be Actively Monitored During MR Examination, Including ECG and Pulse-Oximetry	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
Following the MR Exam, the Device is to be Examined / Interrogated to Verify Proper Function	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01
In the Event of Inadvertent Exposure of a Cardiac Device Patient to MRI Magnetic Fields, the Patient's Cardiologist is to be Consulted Prior the Person's Discharge from the MRI Suite	Device Interference	(N.)	√ EC 02.04.01 EC 02.06.01 EC 03.01.01

Since this paper is intended to assist Joint Commission Accredited MR providers address the physical hazards present in the MR environment, we strongly recommend that readers also refer to Appendix 3 of the ACR Guidance Document on MR Safe Practices: 2013, "MR Facility Safety Design Guidelines," which specifically addresses a number of physical risk factors that would similarly be immediately applicable to a number of the Joint Commission's Environment of Care standards.

Through the careful use of the newest ACR MR Safety Guidance Document's information, coupled with Joint Commission Sentinel Event Alert #38 and other advisory publications, MR providers now have a significant resource at their disposal to eliminate any potential ambiguity or perceived conflict with and between the two dominant industry standard of care documents.

MR Safety Web Resources:

ACR Guidance Document on MR Safe Practices: 2013

http://onlinelibrary.wiley.com/doi/10.1002/jmri.24011/pdf

ACR MR Safety Website

http://acr.org/Quality-Safety/Radiology-Safety/MR-Safety

Joint Commission Sentinel Event Alert #38

http://www.jointcommission.org/sentinel_event_alert_issue_38_preventing_accidents_and_injuries_in_the_mri_suite/