American College of Radiology™

ACR® Manual on MR Safety

2024

ACR Committee on MR Safety

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ACR Manual on MR Safety

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PREFACE

This 2024 edition of the ACR Manual on MR Safety replaces all earlier versions. This document is published in a web-based format so that it can be revised and updated in a timelier manner as needed.

In 2001, the American College of Radiology (ACR) formed a Blue-Ribbon Panel on Magnetic Resonance (MR) Safety in response to various reports in the medical literature and print media detailing MR imaging (MRI) adverse events and incidents involving patients, equipment, and personnel. Initially published in 2002, the ACR MR Safe Practices Guidelines are often looked to as authoritative guidance for establishing safe and responsible practices in clinical and research MR environments. Subsequently, these guidelines have been reviewed and updated throughout the years to address feedback from the MR community as well as changes in the MRI industry since the original publication. The ACR Manual on MR Safety represents the consensus of those representing the Committee on MR Safety of the ACR. It should be noted that these recommendations are not only appropriate from a scientific point of view but also generally reasonable for real-world application, with consideration given to patient care, throughput, financial pressures, and other considerations.

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. The ACR Manual on MR Safety recommendations are not to be considered inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth herein, the ACR cautions against the use of this document in litigation in which the clinical decisions of a practitioner or imaging practice are called into question. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner/practice considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care.

The views expressed in this document are solely those of the authors and in no way imply a policy or position of any of the organizations represented by the authors.

The ACR sincerely thanks all who have contributed their knowledge and valuable time to this and all previous versions of this publication including the ACR MR Safe Practice Guidelines, ACR Guidance Documents on MR Safe Practices, and the ACR Manual on MR Safety. The ACR Safety Committee thanks those in the MR Safety community who provided valuable comments on the draft version of the ACR Manual on MR Safety. Those comments were instrumental in improving this 2024 version of the manual.

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REVISION HISTORY

The ACR Manual on MR Safety was published in 2020 as a web-based product. Content changes may take place as a result of changes in technology, clinical treatment, or other evidence-based decisions from the MR Safety Committee.

Date	Section	Change
4/15/2020	All	Creation of the ACR Manual on MR Safety based on the reorganization and updates to previously published "ACR Guidance Document on MR Safe Practices: 2013."
	Magnetic Resonance (MR) Personnel	Expanded staffing guidance to align with the Veterans Health Administration Directive on MR safety, 2018.
		Explanation of formal safety roles.
	MR Screening	Deference to the Heart Rhythm Society on guidance regarding the performance of MR examinations in patients with non–MR Conditional cardiac devices.
	Full Stop/Final Check	New
	Special Patient Population Considerations	Updated pregnancy, prisoner/detainee, and parolee sections.
	MR Imaging (MRI) Contrast Agents	Updated language.
	MR Environment	Atypical environments to include complex intraoperative and 7-T environments.
	Screening Form	Formerly Appendix 2: This section has been removed and will be available as a separate document available for download on the acr.org MR Safety webpage.
5/15/2020	All	Grammatical corrections and general editorial changes.
	Screening	Clarification for emergent patients.
1/1/2024	All	Created a chapter-based format.
	Introduction	Basic introduction of MR risks and safety concerns related to the MR fields.
	Management of MR Safety Policies and Standard Operating Procedures	Formerly, establishing, implementing, and maintaining MR safety policies and procedures. Provides new points to consider when developing MR policies and procedures.
	MR Safety Zones	Key definitions of MR safety zones including MR controlled access, MR environment, and MR projectile area.
	MR Environment	IEC update of fringe field to 9 gauss.
	MR Personnel	Updated language for MR safety training levels and responsibilities.
		New training checklist.
		Updated staffing guidance.
		New remote scanning guidance.
	MR Screening	Reorganization of information involving staff/personnel screening, patient screening, screening for ferromagnetic material, risk identification, MR Safe attire, and ferromagnetic detection.
	Final Stop/Final Check	Updated routine and augmented guidance and new language about removal of hearing aids before Zone IV entry.

	Zone IV Exam Preparation and Completion	New
	MRI Fields and Safety Concerns	Reorganization of Time-Varying Radiofrequency (RF) Magnetic Field to include whole-body heating, focal heating, and resonant heating.
		Reorganization of Time-Varying Magnetic Field Gradient (dB/dt) to include auditory considerations, induced voltages, and peripheral nerve stimulation.
	Classification of Objects and Medical Devices in the MR Environment	Formerly implants, devices, and objects section. Includes MR safety labeling classifications.
	Introducing Portable Metallic Objects and Equipment in the MR Environment	New (formerly included in implants, devices, and objects). Contains labeling and testing, MR Unsafe transport equipment temporary provisions, and portable objects in Zone IV.
	Managing Patients/Subjects with Medical Devices in the MR Environment	New (formerly included in implants, devices, and objects). Contains active implanted/on-planted devices, passive implanted devices, and implants, devices, or objects discovered during MR examination.
	Emergency Situations	New (formerly included in MR Environment). Includes emergency table stop, emergency power off, emergency magnet off, quench, fire, code, and entrapment.
	Special Patient and Personnel Considerations	Formerly, special patient population considerations. Includes reorganization of information involving pregnancy, pediatric MR safety concerns, claustrophobia, anxiety, and sedation, /large body habitus (new), prisoners/detainees, and parolees.
	Alternative MR Environments	New (formerly found in MR environment). Includes PET/MR, intraoperative/interventional MR, MR simulator and MR-LINAC (new), point-of-care MR system (new), and mobile MR scanner (new) information.
	Appendix 1	New appendix containing MR safety policies and standard operating procedures guidance.
	Appendix 4	New appendix containing implanted device MR risk/safety assessment.
	Appendix 5	New appendix containing spatial field gradient information.
	Key Points	New Key Points boxes for a quick visual of the important elements in each chapter.
	Key Abbreviations	New Key Abbreviation boxes for a quick visual on important abbreviations used in each chapter.
6-18-2024	Cover	Updated the ACR Manual on MR Safety 2024 cover to align with the updated ACR brand theme

CHAPTER 1: Introduction

It remains the intent of the ACR that this ACR Manual on MR Safety will prove helpful as the field of MRI continues to evolve and mature, providing MR services that are not only safe but also valuable from a clinical or research point of view.

Introduction and Overview of Unique Risks in MRI

While considered a clinically impactful and versatile imaging modality, particularly because of the lack of ionizing radiation, the unique fields encountered in the MR environment do potentially pose serious safety risks* not only for patients, research participants, and health care staff, but also others who may encounter the MR environment, including patient family members, security officers, firefighters, police officers, housekeeping personnel, etc. MR safety accidents have led to serious injuries and deaths. There have been at least 3 deaths, in 2001, 2018, and 2021, from oxygen cylinders that have become lethal projectiles. Additionally, deaths and serious injuries have resulted from improper scanning of patients with implanted devices [2,3]. A death occurred in 2023 when a firearm was brought into the MR environment, and the magnetic field caused a weapon discharge [4]. "On-planted" external devices, those worn or located largely external to the body such as insulin pumps, can be the source of MR safety events if exposed to the MR environment in an unsafe manner. Many other nonlethal projectile-related injuries have also occurred. Every projectile event is preventable. MRI-associated burns constitute the most frequently reported injury in MRI [5-7].

Root cause analyses of MR safety accidents reveal the accident resulted only very rarely from a malfunction of the MR equipment. Instead, accidents are more typically the result of how the equipment was being used, frequently involving a breakdown in adherence to policies and procedures or being impacted by previously unrecognized significant gaps in those policies and procedures. As there will always be potential for human error, it is essential that MR facilities design thoughtful policies and procedures that reliably address predictable as well as unusual situations. Concurrent with this notion is the recognition that contemporary MRI practices encounter ongoing challenges associated with ever-evolving technology, patient throughput, staffing challenges, and increasingly complex patients with increasing numbers of implanted devices.

The following ACR Manual on MR Safety is intended to be used as a template for MR facilities to follow in the development of a safety program. These guidelines were developed to help guide MR practitioners and institutions regarding these issues and to provide a basis for them to develop and implement their own MR policies and practices. These guidelines, along with the policies and procedures that are developed, are intended to be reviewed and updated at defined intervals specific to the policy/standard operating procedure (SOP). These are guidelines and may not be prescriptive or appropriate for all facilities. This version of the manual includes a new appendix (Appendix 1) that could serve as a guide for the development of MR safety policies and SOPs. However, it is impossible to cover all potential configurations of

* Throughout this manual, the term "risk" is used literally to include the occurrence of injury or damage (harm), the potential source of harm (hazard), and the probability of occurrence of harm and the severity of that harm. Definitions for the terms risk, harm, and hazard can be found in ISO/IEC Guide 63:2019, 3.1, 3.2, and 3.10 [1].

an MRI facility in this manual. Indeed, different configurations may be adequate to serve the functional needs of the facility.

The principles found in this safety manual are intended to apply to clinical diagnostic imaging, research, and complex MR settings (e.g., linear accelerator MR, interventional MR, etc.) and encompass information for patients, research participants, and health care personnel. It is worth noting that the use of remote MR imaging does not, in any way, diminish the obligations of the site to provide safe MR patient care. It is also important to emphasize that MR Personnel must be familiar with the specific MR safety guidelines provided by the manufacturer, which in some cases may exceed the recommendations in this manual.

Introduction to MRI Fields and Potential Safety Concerns

The unique safety concerns in MR imaging are primarily caused by the generation and/or presence of 3 independent magnetic fields used for imaging by the MR scanner (Figure 1), and all contribute to specific MR safety challenges:

- static magnetic field (B_0),
- time-varying radiofrequency magnetic field (B_1), and
- time-varying gradient magnetic field (dB/dt).

These topics are elaborated upon in the MRI Fields and Safety Concerns section.

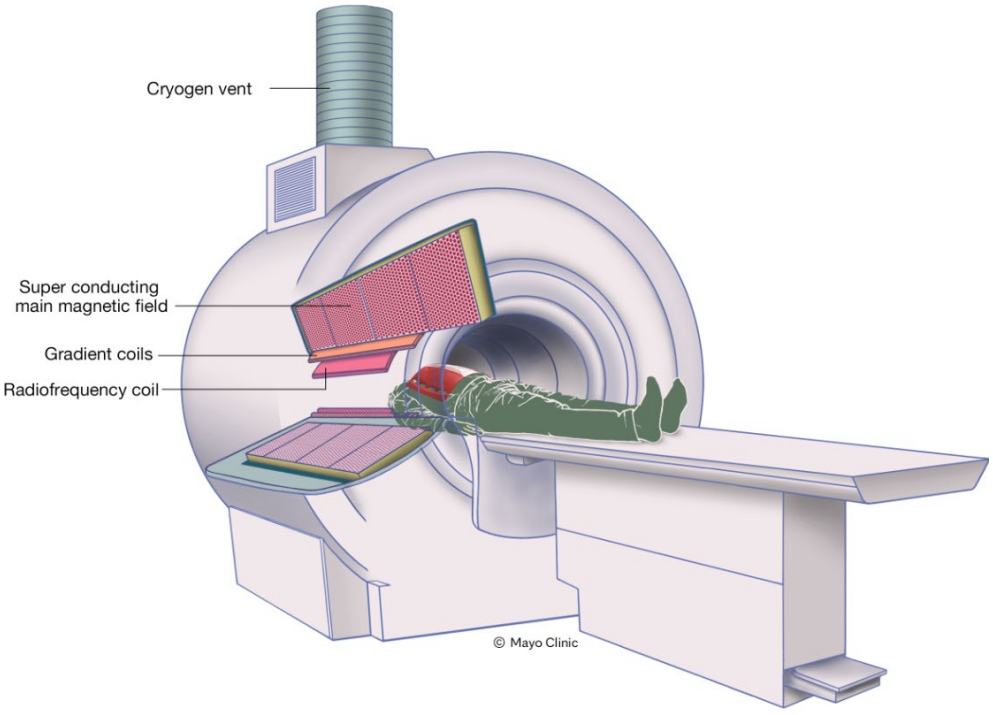

FIGURE 1. Schematic diagram of a typical superconducting magnet MRI system. Closest to the bore wall, adjacent to the patient is the radiofrequency (RF) coil; unsafe physical proximity to this RF coil may cause patient heating and burns. Peripheral to the RF coil are the gradient coils; rapid current changes in these coils produce the characteristic loud noises during MRI. Gradient magnetic fields can also cause peripheral nerve stimulation. The outermost ring is associated with the static magnetic field (B0) that creates the strong magnetic translational and torque on ferromagnetic objects. All 3 electromagnetic fields can interact with implanted or on-planted medical devices or any metallic object in the MR environment.

Static magnetic field (B_0). A very strong magnetic field to polarize the spin of protons in human tissue allows for MR imaging. This is typically measured in units of tesla (T). This field, and its sharp increase approaching the MR system (spatial field gradients, T/m), are the source for potentially large magnetic forces on ferromagnetic objects entering the MR environment. Depending on the scanner room configuration, shielding, and magnitude of the magnetic fields, these fields may extend outside the scanner room confines and potentially affect devices and personnel. For virtually all clinical MRI scanners in use today, this field is usually generated by large currents circulating in cryogen-cooled superconducting coils and so **should be assumed to be always on**, making the safety concerns caused by this field omnipresent and requiring controlled access, supervisory control, and vigilance over personnel and items entering the MR environment [8,9]. Current FDA-cleared MR scanners for human use rely on magnetic fields between 0.064 and 7 T [10]. The main risks of the static magnetic field (B_0) field include translational (projectile effect) and rotational forces. The risks associated with B_0 are always present, even when imaging is not taking place, and may extend several meters away from the MRI scanner in all directions (depending on the properties of the specific MRI scanner).

Time-varying radiofrequency magnetic field (B1). A much smaller magnetic field (mT) oscillating at or near the MR frequency (MHz) of protons is generated orthogonal to the static field by another set of current-carrying coils (i.e., built-in body coil in the bore of the scanner or dedicated anatomical transmit-receive RF coils placed directly around the anatomy of interest) close to the patient during imaging to excite and/or manipulate the polarized spins for signal and

contrast. This field, characterized by its amplitude, frequency, and duty cycle, is responsible for risks caused by the heating of materials, including human tissues, in the bore of the scanner. This field is only present during imaging [8,9]. The risks of the B1 field include general patient heating, localized heating resulting in burns, unintended stimulation, and device malfunction.

Time-varying gradient magnetic field (dB/dt). Three orthogonal linear gradient magnetic fields are generated by another set of coils in the bore and are pulsed during image acquisition for image encoding. These switched gradients have magnitudes (mT/m) in space across the bore, with rise times (ms) that indicate their ramp-up rate defined as the magnetic field slew rate (T/m/s). Gradient fields' continual ramp up and ramp down leads to their standard definition as time-varying magnetic fields, dB/dt (T/s). The rapid switching of large currents through the gradient coils is the source of both the loud acoustic noise generated during MR imaging and peripheral nerve stimulation. The main risks of the gradient (dB/dt) field result from induced voltages/currents and include acoustic injury, unintended arrhythmogenesis, peripheral nerve stimulation, and implant device malfunction. This field is only present during imaging and represents clinical risks of induced electrical currents in tissues or other materials that are within the bore of the MRI during active imaging.

MRI output operating modes. To aid in managing the bioeffects of exposure to these electromagnetic fields in patients, the International Electrotechnical Commission and FDA have recommended output limits for each field, referred to as "Operating Modes."

- **Normal Operating Mode.** Mode of operation of MR equipment in which the biophysical effect induced by a specific electromagnetic field typically presents negligible risk [11]. This is the most commonly used operating mode in clinical practice.
- **First Level Controlled Operating Mode.** Mode of operation of MR equipment in which medical supervision mitigates risks associated with biophysical effects induced by exposure to electromagnetic fields [11]. This mode carries higher risk to the patient than Normal Operating Mode. In some clinical scenarios, the use of first level controlled operating mode may be of benefit to the patient (e.g., patients with limited breath-hold capacity). Risk must be mitigated by employing appropriate medical supervision of the patient for the specific scanning scenario as defined by the facility's policies and procedures.
- **Second Level Controlled Operating Mode.** Mode of operation of the MR equipment for which the responsible organization defines risk acceptability as part of a human studies protocol and in which medical supervision is implemented to mitigate such risks [11]. This higher mode of operation typically is not used in routine clinical practice and is generally reserved for human participant research with appropriate medical supervision.

It is important to note that the operating mode thresholds for each of the fields is independent of the others, and in no way takes into account issues with medical devices or other equipment in the bore of the scanner that may cause a patient injury. MR system operators should be aware and knowledgeable of these operating mode limits and when to employ them. Similarly, newer scanners provide the capability of employing an optimized operating mode with low specific absorption rate (SAR) for specific applications (e.g., patients with MR Conditional devices that have more strict SAR levels for MR imaging) that generally sacrifice image quality for reduced energy deposition. Operating modes are also discussed in the Peripheral Neural Stimulation (PNS) section.

Other unique MR environments and MR-related risks addressed in this ACR Manual on MR Safety include:

- Implanted/on-planted medical devices and associated MR safety risks [12-14].

- Cryogens used for maintaining magnet coil superconduction and risks associated with cryogen exposure loss during magnet quenching.
- MRI safety considerations in unique patient populations, including pregnancy, pediatric, those with claustrophobia and large body habitus, and those with law enforcement considerations (prisoners, monitored parole, etc.).
- Alternative MR environments (PET/MR, radiation oncology, interventional/intraoperative, high/low field, and mobile).
- Gadolinium-based contrast media in MR (with reference to the *ACR Manual on Contrast Media*).

KEY POINTS

- Deaths and serious injuries have occurred in MRI. MR safety events are typically related to unsafe practices, failure to follow MR safety policies and procedures, or gaps in those policies and procedures. Equipment failure or shortcomings rarely underlie serious MR safety events.
- The 3 types of magnetic fields in MR are associated with unique risks.
    1. Main magnetic field B_0
        - Ferromagnetic object translation/torque and projectile incidents
    2. RF field B_1
        - Heating and burns
    3. Time-varying gradient magnetic field
        - Acoustic injury, peripheral nerve stimulation
- The risks associated with the RF field B_1 and gradient fields are managed in part using scanner Operating Modes (Normal and First Level Controlled).
- All 3 types of magnetic fields can interact with implanted and on-planted medical devices in potentially deleterious ways.
- Additional MR risks are addressed in other sections of this manual.

KEY ABBREVIATIONS

ACR: American College of Radiology

B_0: static magnetic field

B_1: time-varying radiofrequency magnetic field

dB/dt: time-varying gradient magnetic field

FDA: Food and Drug Administration

GBCM: gadolinium-based contrast material

IEC: International Electrotechnical Commission

MRI: Magnetic Resonance Imaging

mHz: megahertz

mT/m: millitesla per meter

PET: positron emission tomography

RF: radiofrequency

SAR: specific absorption rate

SOP: standard operating procedure

T: tesla

T/m: tesla per meter

T/m/s: magnetic field slew rate, tesla per meter per second

µs: rise time in microseconds

µT: microtesla

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CHAPTER 2:
Management of MR Safety Policies and Standard Operating Procedures

All clinical and research MR facilities, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or intra- or perioperative applications, should maintain MR safety policies.

Policies and standard operating procedures. These policies and procedures should be reviewed at intervals deemed appropriate by the facility based on their specific content. Also, concurrently with the introduction of any substantial changes in safety parameters of the MR system or site (e.g., related to hardware and/or software upgrades resulting in faster or stronger gradient capabilities or higher radiofrequency duty cycles), these policies and procedures should be updated as needed. A related consideration is the addition of Alternative MR systems (e.g., PET/MR, hybrid procedural interventional suite, etc.) to a facility's MR fleet; due to the unique risks in these specialized environments, appropriate site-specific policies and procedures must be developed to ensure safety. During the review process, national and international standards and recommendations as well as the operator manuals for the MR equipment should be taken into consideration. Points to consider when developing MR safety policies and standard operating procedures can be found in Appendix 1. The MR facility's administrative staff must ensure that the policies and procedures that result from these MR safe-practice guidelines are implemented and adhered to at all times by all of the site's personnel.

MR safety roles. The ACR Committee on MR Safety supports the recommendations of the consensus document calling for formal MR safety roles and responsibilities for facility management of MR safety. These roles include MR Medical Director (MRMD), MR Safety Officer (MRSO), and MR Safety Expert (MRSE) [1].

The following personnel organizational structure recommendations are aimed to ensure the implementation and management of MR safety in and around MRI facilities.

Consistent with the consensus document, the development, implementation, and ongoing management of MR facility responsibility will be shared between a designated physician MRMD, an MRSO, and, in an advisory role, an MRSE. The specific job roles and responsibilities are described below.

MR Medical Director. Each MR facility will name a physician MRMD whose responsibilities will include ensuring that MR safe-practice guidelines are established and maintained as current and appropriate for the facility (e.g., outpatient, inpatient, interventional/intraoperative, radiation oncology, or any site with a human MR system). Specific supervision responsibilities in systems with multiple sites should be designated by the institution policy. Many sites may have a complex organizational structure; the MRMD may serve in one or more roles per institution policy. If the MRMD serves in more than one setting, the institution should ensure it does not compromise their function in this role.

The MRMD responsibility will be assumed by a licensed physician/radiologist with appropriate training in MR safety, which is defined later in this document. The MRMD is responsible for overseeing overall MR facility operational safety. The MRMD responsibility is to ensure policies and procedures are in place for the safe performance of MR procedures. These include:

1. The appointment of an MRSO and advisory MRSE.
2. The development, implementation, and maintenance of specific policies and procedures pertaining to the safe operation of MR services.
3. The implementation and maintenance of appropriate MR safety and quality assurance programs.
4. Appropriate ongoing assessment of risk for the facility.
5. Appropriate system for record keeping and analysis of adverse events (with the MRSO and MRSE as needed).
6. Appropriate investigation and recording of all reported MR safety adverse events.
7. Site-specific MR Safety training requirements for MR Personnel and others accessing the MR environment.

MR Safety Officer. This responsibility will be designated to a suitably trained individual, often an MR Technologist. Multiple MRSOs can be appointed by the MRMD, but a single MRSO should be identified as being responsible and should oversee safety practices within a defined component of the MRI practice at all times. It might be appropriate to name an MRSO for each facility location (i.e., 3 MR systems in the same location) for each shift. The MRSO responsibilities include:

1. Ensuring accessibility at all times, if the MR facility is in use, to the operators of MR scanners.
2. Ensuring that policies and procedures of the MRMD are implemented and enforced at all times.
3. Development, documentation, and execution, in conjunction with and under the authority of the MRMD, of safe working procedures for the MR environment.
4. Ensuring that adequate written safety procedures, emergency procedures, and operating instructions are issued, in consultation with the MRMD and MRSE, as needed.
5. Ensuring the implementation and monitoring of appropriate measures for minimizing risks to staff and patients in cooperation with the MRMD.
6. Managing hazards posed by the MR equipment and monitoring the measures taken to protect against such hazards.
7. Ensuring, in cooperation with the MRMD, that medical, technical, nursing, emergency, and all other relevant staff groups (including ancillary workers) who may be exposed to the MR environment are educated appropriately and updated as necessary as to MR safety requirements.
8. Providing and/or ensuring the provision of MR safety education and training in cooperation with and as per the policies of the MRMD and maintaining records of personnel education.
    a. Ensure safety training to include understanding of the specific Instructions for Use (operator manual) for every MR system.
9. Consulting the MRMD and/or MRSE when further advice is required regarding MR safety.

10. Reporting back to the MRMD in a timely fashion any and all MR safety–related issues.
11. Ensuring that there is a clear policy for purchasing, testing, and clearly marking of all equipment that will be taken into Zones III and IV.
12. Providing safety advice on the modification of MR protocols (in cooperation with the MRMD and/or MRSE) if/as needed.
13. Maintaining regular contact with other relevant groups or committees responsible for the safety and welfare of personnel on-site.
14. Providing expertise in root cause analyses, solutions meetings, etc., related to MR adverse events.

MR Safety Expert. This individual is expected to serve as a resource for the MRMD and MRSO for technical- and physics-related MR safety issues (i.e., issues other than contrast agents, anxiolytics, and other pharmaceuticals). It is assumed the MRMD and MRSO are part of the organization performing the MR examination. However, the MRSE may be external to the organization. It is expected that each organization will have an MRSE prospectively identified. The MRSE is often an MR physicist, but others with suitable expertise could also fill this role. It is expected that the MRSE will serve in an advisory role for one or several MR facilities and thereby does not need to be physically present at the MR facility, although a prospectively and clearly defined means to contact this individual is expected. The MRSE responsibilities include:

1. Providing advice on the engineering, scientific, and administrative aspects of the safe use of MR equipment, which includes quantification assistance for energy, force, and risk exposures.
2. Providing advice on the development and continuing evaluation of a safety framework for the MR environment.
3. Providing advice for the development of local rules and procedures to ensure the safe use of MR equipment.
4. Providing safety advice regarding nonroutine MR procedures, which includes advice regarding safety related to implanted devices and other similar issues.
5. Providing advice on MR Safety and MR quality assurance programs, evaluations, and audits.
6. Providing safety advice regarding equipment acceptance testing.
7. Establishing and maintaining links with appropriate regional and professional bodies and reporting back to the MRMD and MRSO on safety-related issues.
8. Providing expertise in root cause analyses, solutions meetings, etc., related to MRI adverse events.

MR research settings: MR Research Director. Further considerations and valuable information about safety structure related to the scanning of human participants in a research setting, including the role of an MRRD (MR Research Director), have been previously published [2]. The MRRD is the individual who is responsible for the safe operation of research-only/nonclinical facilities in which human scanning is performed. Many parallels exist with the role of the MRMD.

MR Safety Committee. An MR Safety Committee structure centered on MRMD, MRSO, and MRSE organizational structure with the inclusion of pertinent stakeholders (to possibly include other radiologists, physicists, technologists, advanced practice providers, nurses, anesthesia personnel, clinical assistants, MR technical maintenance personnel, desk operations, administrative personnel, facility management personnel, among others) is encouraged,

allowing a timely discussion of MR safety issues and an infrastructure focused on continual improvement.

Reporting of MR-related adverse events and incidents. It is recommended that policies and procedures are in place to ensure that all MR-related adverse events, safety incidents, or "near misses" that occur are reported to the MRMD in a timely manner (e.g., within 24 hours or 1 business day of their occurrence) and used in continuous quality improvement efforts. In general, safety events related to the equipment (e.g., burn, device-related event) should be reported to the manufacturer to ensure no malfunction of the equipment. The FDA has guidelines addressing the reporting of adverse events and incidents via their MedWatch program [3,4]. The ACR Committee on MR Safety supports this recommendation because it is in the best interest of MR practitioners to contribute to the Manufacturer and User Facility Device Experience database of such events to facilitate learning about them and how to better avoid them in the future [5].

KEY POINTS

- Management of MR safety should include the following roles.
  - MRMD: licensed physician/radiologist with appropriate training in MR safety who is responsible for overseeing overall MR facility operational safety policies and procedures.
  - MRSO: responsible for working with the MRMD and MRSE in implementation of day-to-day practice of a comprehensive MR safety program.
  - MRSE: a resource for the MRMD and MRSO for technical- and physics-related issues. Issues related to contrast agents, anxiolytics, and other pharmaceuticals are considered outside the purview of the MRSE.
- ACR MR Safety Committee supports the FDA's request for facilities to report adverse events to MedWatch.
- It is recommended that adverse events and "near misses" are reported to the site's MRMD (and manufacturer when appropriate) in a timely manner per the facility's standard operating procedure.
- Facilities will create and maintain MR safety policies that are reviewed at least annually (Appendix 1).

KEY ABBREVIATIONS

ACR: American College of Radiology

APP: advanced practice provider

FDA: Food and Drug Administration

MAUDE: Manufacturer and User Facility Device Experience

MRMD: Magnetic Resonance Medical Director

MRRD: Magnetic Resonance Research Director

MRSE: Magnetic Resonance Safety Expert

MRSO: Magnetic Resonance Safety Officer

SOP: standard operating procedure

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CHAPTER 3:
MR Safety Zones

Defining areas, zones, and environments located within the MR safety zones helps lend clarity to the rationale for organizing the MR facility into 4 zones. Key definitions pertinent to this, adapted from several sources [1-3], are below.

MR Controlled Access Area: The locally defined area around the MR system that contains the MR Environment (including its associated static magnetic field) to which access is controlled. Frequently, additional areas outside the MR Environment may also have access control.

MR Environment: The 3-D volume surrounding the MR system that contains both the Faraday shielded volume and the 0.90-mT field contour (9 gauss (G) line) (see discussion of 9 gauss line). This volume is the region in which a medical device might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories and for which access control is part of the risk mitigation.

MR Projectile Area: The area around the MR system in which ferromagnetic objects are at risk of becoming projectiles. As individual ferromagnetic objects could become projectiles at different distances from the MR system, there is no intention to define a specific boundary delimiting the margins of the MR Projectile Area. It is implicit that this is located in Zone IV, and strict access control and screening is essential to maintain safety related to projectiles.

The MR facility may be conceptually divided into 4 zones for MR safety purposes (Figure 2).

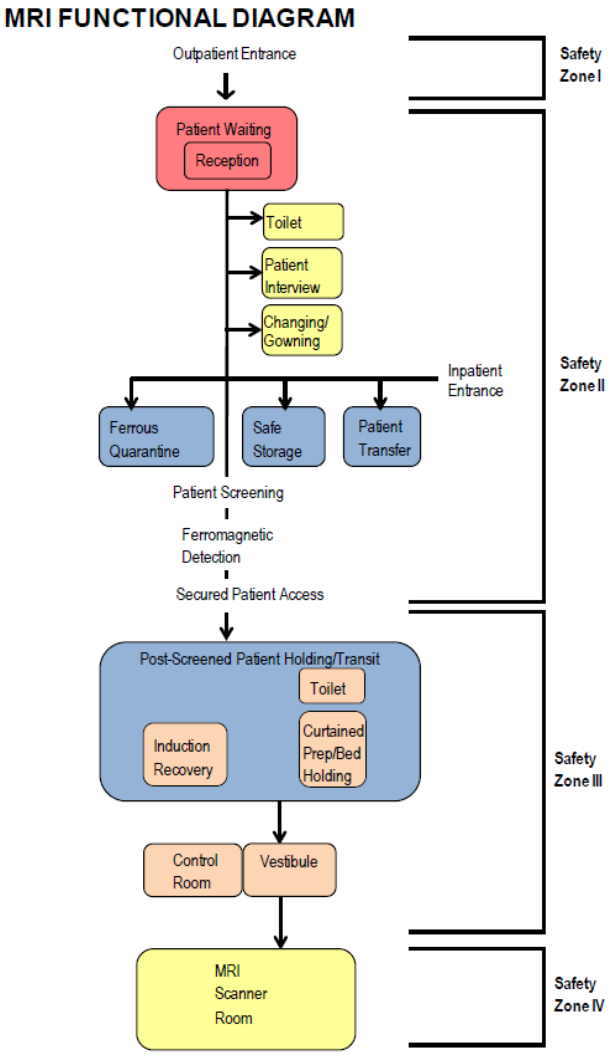

FIGURE 2. Schematic representation of the ACR 4-zone model. This diagram is an example intended for educational illustration purposes only; individual sites should tailor their space to best serve their individual setting and clinical and/or research needs while maintaining MR safety. This MR Functional Diagram was obtained and modified with the permission of the "Department of Veterans Affairs Office of Construction & Facilities Management, Strategic Management Office."

The MR Projectile Area, MR Environment, and MR Controlled Access Area and their relationship to the 4 ACR MR Safety Zones are illustrated in this adaptation of the pertinent figure in the Medicines and Healthcare products Regulatory Agency document [1] (Figure 3).

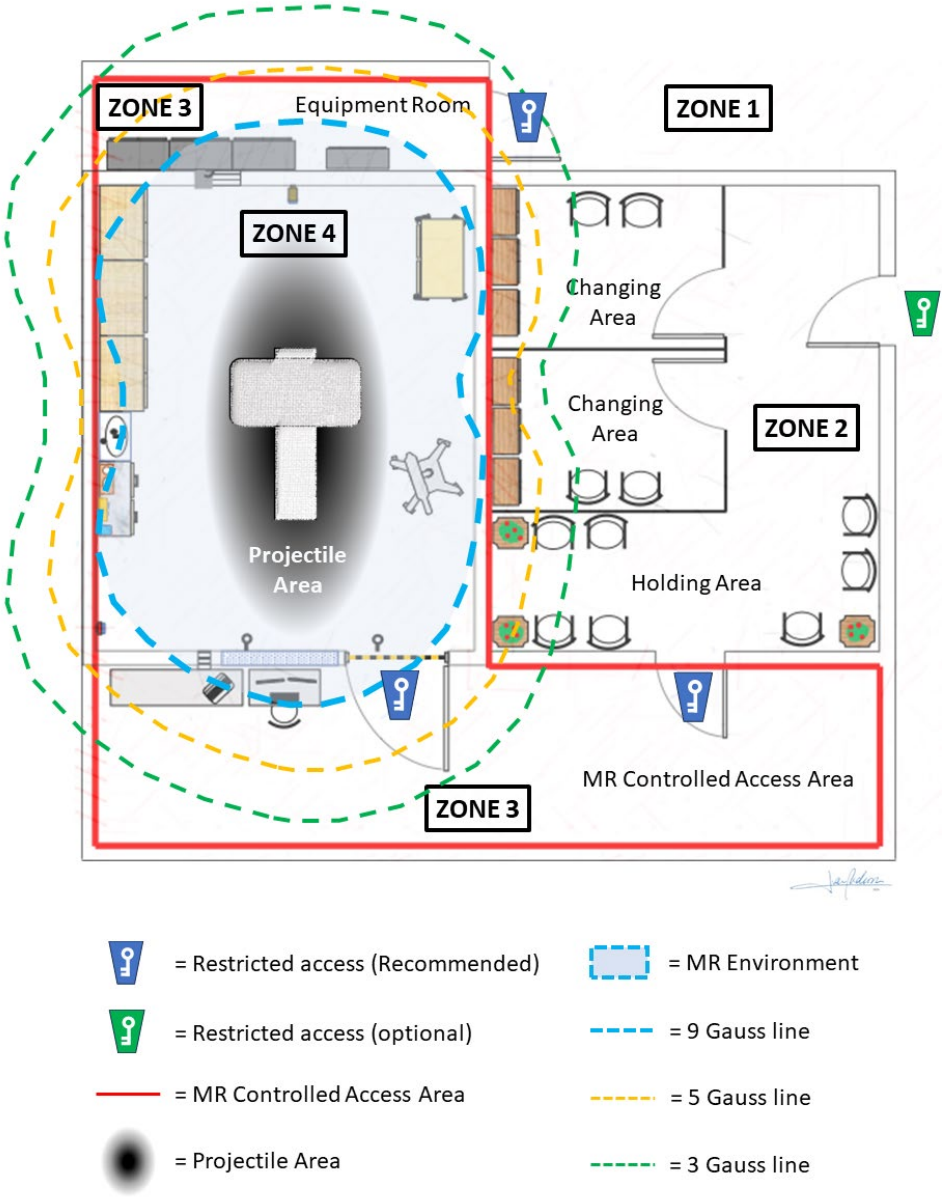

FIGURE 3. Illustrated example layout of an MR facility. This is adapted from Figure 1 in the Medicine and Healthcare products Regulatory Agency Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use [1]. Note depictions of "MR Controlled Access Area," "MR Environment," and "Projectile Area" as they relate to the 4-zone model.

Zone IV. Zone IV is synonymous with the MRI scanner room and is comprised of the physical walled confines where the scanner is located. It includes the **MR Projectile Area** where there is definite, potentially lethal projectile risk. Zone IV, by definition, is generally located within a surrounding **MR Controlled Access Area.** Note that in some special environments, such as

perioperative MR (see Alternative MR Environments), the precise boundaries of Zone IV and Zone III can be in flux depending on the clinical situation and configuration [1].

Zone IV should be clearly labeled as being potentially hazardous because of the presence of the very strong magnetic fields. The entrance to Zone IV with a superconducting magnet should also be clearly marked with a prominently displayed red illuminated warning sign stating, "The Magnet is Always On." Illuminated signs should have a battery backup energy source in case of power failure. In the case of resistive MR systems, the sign may be active only when the magnet is energized.

The entry door to Zone IV (i.e., the MR scanner room) should be closed except when it must remain open for patient care or room/MR system maintenance. During the times that the door to the MR system room must remain open, a "caution" barrier is recommended at the entry to Zone IV to inhibit unintended passage of personnel and/or materials from Zone III to IV. Examples of caution barriers include easily adjusted straps, plastic chains, or other deployable barrier devices secured across the doorway to Zone IV (Figure 4). Strictly controlled entrance to Zone IV is a critical safety consideration for the prevention of ferromagnetic objects entering the room. As such, when the entry door to Zone IV is not being actively monitored by MR Personnel, it is advised that it remains closed and preferably locked. There should be the ability to unlock the Zone IV door from the inside. Periodic inspection and maintenance of the Zone IV door and associated locks, handles, articulating arms, etc., is recommended to minimize the likelihood of failures that may lead to entrapment or inability to reach the patient in a timely manner.

There should be a readily accessible communication system or emergency call button within Zone IV that allows personnel to quickly contact security or request help.

FIGURE 4. Examples of door barriers to Zone IV.

Zone III. Zone III primarily includes **MR Controlled Access Areas** where there is direct doorway access to Zone IV. A common Zone III could serve multiple scanners (Zone IVs). In addition, areas where the magnetic field (i.e., greater than 9 gauss) extends into spaces not connected directly by doorway to Zone IV and considered a B_0 hazard risk area are also considered **MR Controlled Access Areas** and, as such, are included in the Zone III designation.

Entrance to the primary Zone III area should be restricted by reliable key locks, locking systems controlled by access control cards/badges with radiofrequency identification or similar technology, or any method to ensure appropriate access by designated personnel. The use of combination locks is specifically not recommended because combination codes often become more widely distributed than intended, with the possibility of unauthorized access. Doors should be self-closing and self-locking, particularly when in direct contiguity with a Zone IV doorway.

Entrances to Zone III should be identified with signage denoting the Zone III space. Statements on these signs could include "Caution," "Restricted Access," "Screened MRI Patients and Personnel Only," and similar statements and should be pertinent to the particular space (i.e., in contiguity with Zone IV or, alternatively, in a noncontiguous Zone IV space in which there is 9 gauss or greater field intrusion, such as in an adjacent equipment room).

Being 3-D, static magnetic fields may project beyond the confines of the Zone IV room on the same floor as well as into adjacent upper and lower floors, necessitating their designation as a space under the umbrella of an **MR Controlled Access Area**. Magnetic fringe fields of sufficient magnitude can present a hazard to individuals with certain active implants, such as cardiac pacemakers and implantable cardioverter defibrillators.

Historically, the 5-gauss line (0.50 mT field contour) has been a standard threshold for risk. A magnetic fringe field of 5 gauss (0.5 mT) has previously been synonymous with the "pacemaker line" for MR safety. Cardiac implantable electronic device manufacturers are required to demonstrate that these devices are immune to static magnetic fields up to 10 gauss (1.0 mT) (ISO 14117: 2019) [4], which has particular importance for devices that continue to use a reed switch or other sensitive switch for patient therapy control. Thus, prior International Electrotechnical Commission (IEC) standards for the basic safety of MR equipment specified 5 gauss to provide a substantial safety margin (IEC 60601-2-33:2002) [5]. A recent update to the IEC standard has revised the fringe field limit to 9 gauss (0.9 mT) (IEC 60601-2-33:2022) [6]. It is anticipated that MR system manufacturers will include instructions to control access to 9 gauss in the future, which allows for 1 gauss tolerance variability in the cardiac pacemaker test method. The FDA recognizes the new IEC standard of the 9-gauss line defining the B_0 hazard area. The ACR MR Safety Committee endorses the new IEC standard. Herein and throughout the rest of the MR Safety Manual, the ACR MR Safety Committee refers to the B_0 hazard area as the space located within the 9-gauss line. Because the 9-gauss line is located within the 5-gauss line (i.e., it is closer to the magnet), those facilities following previous recommendations to use the 5-gauss line as the B_0 hazard zone should not be expected to make additional adjustments.

In a Zone III region exceeding 9 gauss, an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories [3]. For example, there is the possibility of interaction with implanted electronic medical devices such as cardiac pacemakers if they come within the 9-gauss line that extends beyond Zone IV confines into areas on adjacent floors. For this reason, magnetic field–strength spatial plots for all MRI systems should be analyzed in both horizontal and vertical orientations, identifying areas around, above, and/or below the scanner that may pose potential hazards. These potentially harmful access areas should be clearly identified, and their potential hazard should be clearly marked, even in typically unoccupied areas such as rooftops or storage and equipment rooms. Given its proximity to Zone IV, ferromagnetic objects, including those brought by patients, visitors, contractors, and others, should be restricted from entering Zone III whenever practical. (Note: see the Introducing Portable Metallic Objects and Equipment into Zone III and IV section for additional guidance in Zone III.)

Note that in Zone III regions in which there is direct doorway contiguity with Zone IV (e.g., in typical clinical scanning technologist control rooms), MR Personnel are expected to closely monitor entry of MR Personnel and non-MR Personnel. There is no expectation that MR Personnel closely monitor entry into noncontiguous regions designated as Zone III (e.g., adjacent equipment rooms), although key card access is to be restricted to properly vetted MR Personnel and others as dictated by the site's MR safety policies and standard operating procedures.

Zone II. This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled areas of Zones III and IV. This area typically contains a patient waiting area, patient prep areas, locker rooms, etc. Screening and ferromagnetic detection is often performed in Zone II. Access control to Zone II with personal badges is commonly used so that patients and companions must be allowed to enter into Zone II by MR Personnel.

Zone I. This region includes all areas that are **freely accessible to the general public**. This area is outside the MR facility itself and is the area through which patients, health care personnel, and other employees of the MR facility access the MR environment.

Cryogen Venting Zone. During the quench of a superconducting magnet in which there is a loss of superconductivity, external cryogen vents are associated with potential hazards (e.g., frostbite and/or asphyxiation) given the typical explosive-like rapid venting of cryogen gases. The cryogen vents (typically located on the roof or on an outside wall of the facility) should have access restricted around them to personnel who have been educated about the risks associated with cryogen gas and should be labeled with appropriate signage (Figure 5). See Appendix 2 for further information on cryogen venting.

Although previously designated as Zone III, the area of the facility with the cryogen vents is conceptually different than Zone III in the MR suite (i.e., between Zone II and Zone IV). Some of these differences may include the lack of exposure to the magnetic field, lack of direct access to Zone IV, and the impracticality of having MR Personnel monitoring its access at all times, a requirement for the traditional Zone III in the MR suite. For these reasons, this area is now considered a separate zone, the Cryogen Venting Zone. However, facilities must use signage and ensure controlled access by other means (e.g., restricted access to the facility roof, physical barriers, etc.).

Site planning. Many issues can impact MR safety that should be considered during site planning. This document includes information in separate sections and appendices that address such issues, including cryogen vent locations and pathways, tether anchor point placement, patient access pathways, and other design considerations. It is advantageous during the facility planning process, especially with higher field magnets (i.e., 3 T and 7 T), that efforts are made to limit excessive static field extension outside the physical confines of the Zone IV magnetic fringe field (see 9 gauss fringe field discussion in Zone III paragraphs above). Plans should be carefully reviewed with those experienced with MR site planning and familiar with the patient safety and patient flow considerations prior to committing construction to a specific site design. Enlisting assistance from an architectural firm experienced with MR site design early in the planning process is anticipated to be beneficial. See Appendix 2 for further information on MR Facility Safety Design Guidelines.

FIGURE 5. Example of a cryogen vent with signage.

KEY POINTS

- MR facility is conceptually divided into 4 zones.
- Zone IV
  - Located within the **MR Controlled Access Area** and **MR Environment**. In most cases, it uniquely includes the **MR Projectile Area.**
  - "Magnet is Always On" signage must be visible under all conditions for superconducting systems.
  - Zone IV MR system room door will be closed at all times except for patient transport, etc.
    - A caution barrier is recommended to prevent unauthorized access to Zone IV.
- Zone III
  - Located within the MR Controlled Access Area.
  - The **MR Environment** and an associated 9-gauss line may be found to extend outside the confines of Zone IV into Zone III control room areas, or possibly adjacent noncontiguous areas such as equipment rooms.
  - Entrances to Zone III should be identified with appropriate signage denoting the Zone III space and appropriate access control utilized.
- Zone II
  - Interface between the publicly accessible, uncontrolled Zone I and the MR Controlled Access Area.
  - Typically includes patient waiting, changing, nursing preparation area, patient screening including ferromagnetic detection.
  - Although no part of the **Controlled Access Area**, access to this area is often restricted to MR Personnel.
- Zone I: **Freely accessible** to the general public.
- Cryogen Venting Zone
  - MR-related potentially hazardous environmental areas requiring access control and signage.

KEY ABBREVIATIONS

ACR: American College of Radiology

ASTM: American Society for Testing and Materials

B_0: static magnetic field

CIED: cardiac implantable electronic device

FDA: Food and Drug Administration

G: gauss

IEC: International Electrotechnical Commission

MHRA: Medicines and Health Care products Regulatory Agency

mT: millitesla

RFID: radiofrequency identification

T: tesla

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CHAPTER 4:
MR Personnel

MR Personnel and Non-MR Personnel

MR Personnel. MR Personnel are directly responsible for safety in Zones III and IV and are to be documented as having been successfully educated in MR safety topics (as defined by the facility's MR Medical Director (MRMD)) at least to a level sufficient to ensure that they do not represent a danger to themselves or others in the MR environment. Although basic MRI safety training is often offered at many institutions for personnel who may visit the MRI facility (e.g., physicians, nurses, etc., accompanying a patient), the level of training for MR Personnel is more in depth and formal than that which might be provided to non-MR Personnel.

MR Personnel can either be Level 1 or Level 2, as defined below. Throughout this document, all references to MR Personnel that do not specify Level 1 or Level 2 will apply to both Level 1 and Level 2 MR Personnel.

Non-MR Personnel. Non-MR Personnel are those that within the previous 12 months have not successfully completed the designated formal MR safety education defined by the MRMD of that facility to qualify as MR Personnel. Patients, visitors, facility staff, and health care providers including radiologists and technologists who do not meet the criteria for MR Personnel are non-MR Personnel.

For maintenance, vendor, and engineer personnel considerations, refer to Appendix 3: MR Facility Maintenance and Emergency Preparedness Guidelines for further guidance.

MR Personnel and Training: Level 1 and Level 2

It is essential that MR Personnel are sufficiently trained in MR safety issues that are central to their job responsibilities and roles (Table 1). Level 1 and Level 2 Personnel and associated training provides a basic framework for job/role stratification, recognizing that increasingly complex MR practices are leading to growing needs for specialized training and competencies and stratification beyond those associated with only Level 1 and Level 2. (See Appropriately tailoring MR safety education below.)

It is the responsibility of the MRMD to determine site-specific training that is necessary and appropriate for those individuals who will serve as Level 1 and Level 2 MR Personnel. **We recommend that all Level 1 and Level 2 MR Personnel, including the MRMD, undergo annual MR safety training that will include topics emphasized in this safety manual and are pertinent to the safe care and imaging of MR patients.** Such training could be a condition for permitting site access.

Level 1 MR Personnel. Level 1 MR Personnel are those who have been educated and successfully mastered MR safety topics as defined by the facility's MRMD **to ensure that they would not constitute a danger to themselves or others in the MR environment**.

Level 1 MR Personnel must regularly and routinely work in the MR environment to maintain Level 1 status per institutional policy and MRMD approval. Substantial ongoing engagement and experience in the MR environment in this role is the expectation; undergoing a single

annual lecture and rarely performing a role in the MR environment may be insufficient to maintain Level 1 MR Personnel status. It is important to note that, in some instances, Level 1 MR Personnel must be prepared to respond to emergencies in the MR environment.

Roles in the MR environment often designated as Level 1 MR Personnel include patient aides, technologist assistants, some nursing roles, etc.

Level 2 MR Personnel. Level 2 MR Personnel are **those who have been more extensively trained and educated in MR safety topics** beyond Level 1 MR training. Due to their higher level of MR safety training and associated job responsibilities, Level 2 MR Personnel supervise Level 1 MR Personnel in MR safety–related aspects of a practice.

Included in the table below are training topics anticipated to be valuable for Level 1 and Level 2 MR Personnel. This is not considered to be exhaustive, and the facility's MRMD and MR safety team can identify additional topics that may best serve the facility's needs, particularly as they relate to its staffing model.

TABLE 1. Key Elements of MRI Safety Training

Topic	Level 1 MR Personnel	Level 2 MR Personnel
Ferromagnetic projectile risks	X	X
General magnetic field safety: "Magnet is Always On"	X	X
Importance of maintaining Zone III and IV doorway protection and vigilance	X	X
Emergency procedures and responsibilities in the MRI environment, including when and how to quench	X	X
Importance of MR safety screening prior to entering Zone III and Zone IV	X	X
Understanding the roles of MRMD, MR Safety Officer, MR Safety Expert, and how to contact these personnel	X	X
Understanding the importance of safety events and near-miss reporting and the site-specific mechanisms of doing this	X	X
Procedures to secure potentially unsafe equipment in Zone III (tether, locked storage, etc.)	X	X
Appropriate precautions/procedures for operation in alternative MR environments (e.g., PET/MR, intraoperative/interventional, 7T, etc.)	X	X
Cryogen and quench safety	X	X
Proper use and function of all safety switches	X	X
Understanding of MR Safety labeling: MR Safe; MR Conditional; MR Unsafe	X	X
Elements of MR safety screening prior to entering Zone III and Zone IV, including the proper use of ferromagnetic detection systems, and understanding		X

the factors that impact the safety of implants and devices		
Radiofrequency-related safety		X
Time-varying gradient magnetic field–related acoustic noise and the peripheral neural stimulation		X
Implanted device safety		X
Contrast agent safety		X
Static magnetic field safety: spatial gradients and Lenz forces		X
Thermal burn prevention		X
Procedures to ensure ability to communicate with the patient/research participant when scanning		X
Factors related to scanning of unique patients (pregnant, pediatric, claustrophobic, large body habitus, prisoners/detainees, parolees, etc.)		X

MR Technologists and MR Radiologists are required to be Level 2 MR Personnel with requirements designated by the MRMD in order to perform their specific roles.

Note: MR safety may also be enhanced by appropriate annual job-specific training for non-MR Personnel. Examples include MR scheduling staff, patient transport personnel, nonradiology house staff, and others.

Management of MR safety roles: MRMD, MR Safety Officer, MR Safety Expert. It is understood that those serving in the MRMD, MR Safety Officer (MRSO), or MR Safety Expert (MRSE) role will have the necessary education and experience in MR safety to qualify as Level 2 MR Personnel and should also undergo MR safety–specific education on an annual basis [1].

MR Technologists. MR Technologists are healthcare professionals who have received specific training and satisfy the local requirements to operate MR systems for human scanning. MR Technologists should comply with the technologist qualifications listed in the ACR MRI Accreditation Program Requirements [2]. With their advanced level of MR safety training, Level 2 MR Technologists play the central role in management of the local environment and are the main patient advocate for MR Safety.

Appropriately tailoring MR safety education. MR environments are becoming increasingly complicated (e.g., PET/MR facilities, interventional MRI/hybrid procedural suites, intraoperative MRI facilities, MR-LINAC, etc.), and the personnel working in these environments are becoming increasingly diverse in their backgrounds (e.g., nuclear medicine, ultrasound, anesthesiology, etc.). As a result, it is important that the MRMD and the MR safety education team appropriately tailor necessary and relevant education for these personnel relative to their roles in the MR environment and that there are no unrecognized gaps. Firm expectations for subject matter proficiency must be maintained. **As such, there may be instances when stratification and specialization of Level 1 and Level 2 education and personnel designation may be beneficial to safety and operational efficiency, particularly as it could relate to specific responsibilities in the**

MR environment. For example, there could be stratification such as Level 2a and Level 2b that could be appropriate for specific job roles.

Supervision and Independent Access

Level 1 and Level 2 MR Personnel may be permitted unaccompanied access throughout Zones III and IV following appropriate screening. The presence of untrained non-MR Personnel in the MR environment poses definite safety risks. For this reason, MR facilities must have well-designed policies and procedures to ensure safety when non-MR Personnel are in Zone III and Zone IV.

Specific points related to the presence of non-MR Personnel in the MR environment include the following:

- Level 1 MR Personnel are not permitted to directly admit or be responsible for non-MR Personnel in Zones III or IV.
- Access by non-MR Personnel to Zone III and Zone IV is controlled by and entirely under the supervision of Level 2 MR Personnel.
- Non-MR personnel must be accompanied, monitored, and under the direct supervision of a Level 2 Personnel while in Zone III and Zone IV. Visual contact is to be maintained. An exception to this is when the non-MR Personnel individual is in a changing room and/or bathroom, when verbal communication is sufficient. For non-MR Personnel visitors in the MR environment (nonpatient) who are to be under the direct supervision of a Level 2 MR Personnel, an MR Safe visually distinct identifier, such as a site-specific uniquely colored lanyard (Figure 6), surgical cap/bouffant, or other appropriate means, can serve as a valuable adjunct for MR Personnel monitoring these individuals.
- In the event of the need for handoff of Level 2 responsibility, there must be a formal transfer of responsibility for safety related to the presence of the non-MR Personnel to another Level 2 MR Personnel who fully accepts that responsibility.
- This function of the Level 2 MR Personnel is directly under the authority and responsibility of the MRMD or the Level 2 trained MR Physician of the day for the MR facility. MRSO(s) can lend valuable support to the proper implementation of policies and procedures related to this.

FIGURE 6. Example of an MR Safe lanyard, with no metal components, that could be used to identify non-MR Personnel.

Note: There are special considerations for noncontiguous (i.e., without direct access to Zone IV) areas exceeding 9 gauss, which by definition are Zone III. An exception to the rule related to accompanying MR Personnel requirements occurs for noncontiguous Zone III areas that are defined by extension of the 0.9-mT field outside of Zone IV. These areas include crawl spaces underneath Zone IV, equipment rooms, rooftops, etc.) Access to these areas is permitted by non-MR Personnel that have been safety screened and cleared medically (i.e., see Chapter 5: MR screening).

Staffing

Overriding guiding principles

- **Emergency assistance.** MRI of patients or research participants necessitates that Level 2 MR Personnel who are conducting scans have immediate access to other dedicated MR Personnel (Level 1 or Level 2) at all times to assist in case of an emergency. Level 2 MR Technologists performing human scanning should not be considered the primary emergency responder for other Level 2 MR Technologists conducting MR examinations simultaneously.
- **Minimum staffing plan.** A minimum staffing plan for each MR area in a facility must be established with the aim of ensuring an appropriate number of appropriately trained personnel are staffed to ensure safety.
- **Additional MR Personnel.** During routine hours, there must be a minimum of 1 Level 2 MR Technologist per scanner. There must be a minimum of 1 additional Level 1 or Level 2 MR Personnel in Zone III. *Temporary exception is made when MR Personnel are interviewing the patient/research participant or retrieving the patient/research participant from the waiting/changing areas.* The 2 MR Personnel must be able to directly and immediately communicate and respond at all times. This is in accordance with the Veterans Health Administration Responsibilities Directive 1105.05 for the Medical Facility Director of 2018, which the ACR MR Safety Committee continues to endorse [3].
- **MR Technologist.** In typical clinical situations, it is presumed that the Level 2 MR Personnel operating the MR scanner for human scanning is a trained and certified Level 2 MR Technologist.
- **Research settings.** In nonclinical, typically research settings, other Level 2 MR Personnel who are not technologists may be permitted to operate the MR scanner under the direction of the MR Research Director (MRRD). There must be a minimum of one additional Level 1 or Level 2 MR Personnel in Zone III at these times. Ensuring MR safety in these research settings is the responsibility of the MRRD.
- **Expert consultation.** Depending on the complexity of the examinations, direct or remote consultation to MRMD/MRSO/MRSE or appropriate individuals should be available to give guidance to the Level 2 MR Personnel.

TABLE 1. Example Staffing Scenarios

Routine hours	
One MR magnet per Zone III	For facilities with 1 MR magnet per Zone III performing human scanning, there must be a minimum of 2 MR Personnel. In addition to the Level 2 MR Technologist, there is to be at least 1 additional MR Personnel (Level 1 or Level 2) within the immediate Zone III MR environment whenever patients are in the MR environment. *Temporary exception is made when MR Personnel are interviewing the patient/research participants or retrieving the patient/research participant from the waiting/changing areas.* During this time, the 2 MR Personnel must be able to directly and immediately communicate with each other and respond at all times.
Two MR magnets sharing Zone III	For 2 MR magnets sharing Zone III with both machines in use at the same time, there must be 1 Level 2 MR Technologist per machine and at least 1 additional MR Personnel (Level 1 or Level 2) in the immediate Zone III MR environment (noting the temporary exception when one may need to attend to a patient in Zone II as above) whenever patients are present. During this time, the 2 Level 2 MR Personnel/MR Technologists and the additional MR Personnel must be able to directly and immediately communicate with each other and respond at all times.
Three or more MR magnets sharing a common Zone III	In facilities with multiple scanners in a common Zone III (i.e., 3 or more scanners), in addition to the single Level 2 MR Technologist per scanner, additional MR Personnel should be thoughtfully staffed. This helps ensure appropriate emergency preparedness and safety for patients, research participants, and staff. These minimum staffing decisions should be based on the physical layout of the facility, complexity of the environment, etc. The MRMD and MR safety team should participate fully with the facility's management to establish the appropriate staffing model and plan. Extrapolating the ratio of an additional MR Personnel per magnet pair may be appropriate for a site with multiple magnets sharing a large common Zone III, but final determination of the precise number of necessary personnel at a given facility in such a circumstance may remain locally determined, as above.
Emergent clinical situations	
In emergent, nonroutine clinical situations, a staffing model is recommended to be identical to that employed in routine hours in which an additional MR Personnel is physically located within Zone III to help ensure patient and personnel safety, particularly as these cases can be complex.	

Research environments. The ACR recognizes that, in research facilities where the operation of MRI systems involves the use of phantoms, animals, and human participants, such facilities should develop policies and procedures that ensure safe operation. Site-specific emergency procedures appropriate for these unique environments should be developed.

Remote operation. Remote MR operating technology (a.k.a 'remote scanning') permits the MR Technologist performing the scan to be off-site [4]. Such situations may be beneficial for patients by providing access to an MR Technologist with expertise not available at the facility as well as to increase patient throughput given widespread MR Technologist staffing shortages. *For such an approach to be considered, there must be sufficient on-site trained MR Personnel to ensure the overall safety of the MR facility, including that of patients/research participants and all personnel.* Particular attention must be directed to patient complexity (e.g., routine outpatient versus inpatient requiring life support), anticipating potential safety concerns.

> *The overriding principle in situations in which the MR Technologist is remotely scanning a patient or human research participant is that the safety of those being scanned and the on-site personnel must be maintained at all times to exactly the same level as for standard scanning with the MR Technologist on-site. The MRMD of the facility is to be responsible for the development and implementation of policy regarding staffing and training required for the safety of those being scanned at their facility*.

For all remote operation scenarios, policies and standard operating procedures (SOPs) must be developed and enforced by adequately trained personnel to guarantee the safety of patients and research participants at all times. Essential elements of this include the following:

1. A Level 2 MR Technologist must be in full control of the scanner in either the facility's MR Zone III or at the remote location.
2. The patient/subject must be directly monitored by onsite personnel when being scanned remotely.
3. A dedicated on-site Level 2 MR Personnel with the sole responsibility for monitoring/communicating with both the patient and the Remote MR Technologist must be assigned to each patient in Zone IV.

Presence of an on-site Level 2 MR Technologist. Presently, the ACR MR Safety Committee endorses a remote operation model in which at least 1 MR Technologist with Level 2 training in MR safety is on-site at the location where scanning is being performed by a remotely located MR Technologist. This is to provide on-site expertise related to nonscanning responsibilities with profound MR safety implications, including the following:

- MR safety patient screening (by history and physically)
- Researching implanted devices
- Properly positioning patients in the magnet
- Insulating as necessary to prevent bore contact, internal circuit, or other burns
- Choosing the correct imaging coil and correctly positioning/connecting it
- Providing first response to patient/research participants in Zone III/IV with a change in medical status/emergency

- Providing guidance/instructions to personnel in the MR facility (e.g., nursing, anesthesia, respiratory technologists, etc.)

Although alternative models including on-site "MR tech aides" and a "patient manager" have been recently proposed [5,6], presently, national and state standards for these new job classifications do not exist nor are there training, licensure, or accreditation standards yet for such positions. The ACR MR Safety Committee will continue to evaluate these rapidly evolving remote scanning practices. G*uidance may change as future training standards evolve and will be reflected in future editions of the online ACR Manual on MR Safety.*

Remote scanning staffing considerations. A minimum of 3 MR Personnel is required when remote scanning technology is employed. These include the Remote MR Technologist, an on-site MR Technologist with Level 2 MR safety training, and at least 1 additional on-site Level 1 or Level 2 MR Personnel to assist in maintaining the safety of the patient or research participant and all personnel in the MR facility. The 2 on-site MR Personnel must be able to directly and immediately communicate with each other and respond at all times.

When remote scanning is utilized, the on-site MR Technologist must be within Zones III and IV (with temporary exemption to Zone II as noted above).

A dedicated on-site Level 2 MR Personnel with the sole responsibility for monitoring/communicating with both the patient and the Remote MR Technologist must be assigned to each patient in Zone IV. This monitoring may be done by the on-site MR Technologist or a non-MR Technologist MR Personnel with Level 2–specialized MR safety training. In all scenarios, at least 1 on-site Level 2–trained MR Technologist must be immediately available. Monitoring and/or communicating with more than 1 patient/research participant in Zone IV simultaneously by a single on-site MR Technologist or Level 2 MR Personnel is not recommended. Similarly, the Remote MR Technologist is expected to participate in the scanning of a single patient/research participant at any given time (i.e., remote scanning more than 1 patient simultaneously is not recommended. See Simultaneous remote MR scanning of multiple patients below).

If the Level 2 MR Personnel fulfilling the monitoring role is not a licensed/registered MR Technologist, they must have specialized Level 2 MR safety training as defined by the MRMD that is sufficient to ensure MR safety for patients/research participants in this scenario and to ensure that they do not pose a risk to themselves or others. These non-MR Technologist MR Personnel must be supported by the on-site MR Technologist(s) and be able to immediately contact the on-site MR Technologist if requested by the Remote MR Technologist.

If the on-site MR Technologist is fulfilling the monitoring role, an additional Level 1 or Level 2 MR Personnel is to be present in the immediate Zone III MR environment to assist in maintaining site safety (noting temporary exception when personnel may need to briefly attend a patient/research participant in Zone II) whenever patients/research participants are in the MR environment. (See Table 2 for common responsibilities/duties when remote technology is employed.)

For situations in which multiple scanners share a common Zone III and 1 or more of them are being controlled by a Remote MR Technologist(s), a dedicated on-site MR Technologist or non-technologist Level 2 MR Personnel must be assigned to each patient-occupied MR scanner

room. If 1 or more of such MR scanners are being monitored by Level 2 MR Personnel, the number of on-site MR Technologist(s) assigned to Zones III and IV may be established at a ratio locally determined in consideration of

a) the number of MR scanners served by a common Zone III
b) the suite size/layout
c) local/state/institutional regulations
d) case complexity and scanning personnel requirements
e) maintenance of uncompromised patient safety and care

FIGURE 7 illustrates examples of possible staffing scenarios in remote MR scanning.

TABLE 2. Common Responsibilities/Duties When Remote MR Scanning Technology Is Employed

A	B	C	D
	NOTE: The personnel for column B may be the same person as column A.		
On-site MR Technologist with Level 2 training	**On-site Monitoring Level 2 MR Personnel (MR Technologist or specially trained non-MR Technologist)**	**Additional on-site Level 1 or Level 2 Personnel**	**Remote MR Technologist**
Complete the patient/research participant MR safety screening process. Position the patient/ research participant on the MR scanner, including appropriate elements (as in Chapter 7) to include, but not limited to, the following: Set up of physiological monitoring equipment and other equipment with proper safe placement of wires/cables. Placement of insulating padding, etc. Provide proper hearing protection and ensure	Be in Zone III during the time the patient is in Zone III and IV and be able to communicate with the patient/research participant and the Remote MR Technologist at all times, before, during and after the exam. Continuously monitor each specifically assigned patient/research participant while they are in Zone IV to include, but not limited to, the following: Respond immediately to patient/research participant emergency notification (e.g., squeeze	Assist in maintaining site safety. Assist in event of emergencies (e.g., calling and providing access to Zone III for a code team).	Perform MR scan and effectively coordinate with patient site personnel regarding all aspects of acquiring MR imaging and maintaining patient safety.

that it is used properly by the patient/research participant. Provide emergency squeeze alarm. Be present in Zone III and IV whenever a patient/research participant is in Zone IV or supervise a non-technologist with Level 2 MR safety training. Assist the monitoring Level 2 Personnel in the event of a change in medical status or emergency of the patient/research participant in Zone III and IV.	ball) and other verbal communication in which on-site response is appropriate. Respond to possible contrast agent reactions, contrast agent extravasation, concern for possible excessive heating and/or burns and other related issues. Serve as the point of contact for the remote MR scanning Technologist and assist with conveying any necessary patient/research participant instructions (e.g., issues related to patient motion etc.).		

NOTE: These may vary among facilities based on needs, policies, and procedures as established by the MRMD. On-site MR Personnel must continuously monitor and communicate with the patient before, during and after the scan.

A Level 2 MR Personnel or Level 1 MR Personnel under the direct Level 2 MR Personnel supervision must remove the patient/research participant from Zone IV.

Within the facility's remote MR scanning SOPs, provisions must be in place to ensure patient/research participant safety if the remote connection is interrupted or lost during the scan. Dedicated facilities equipped with high standard internet connection are strongly recommended for personnel scanning remotely (i.e., household internet connections are discouraged).

In some clinical research environments, remote MR scanning of a human research participant may be performed by a remote operator who is not a certified MR Technologist. These situations fall under the purview of the site's MRRD for developing SOPs to ensure research participant and personnel safety.

Simultaneous remote MR scanning of multiple patients. Some remote operators and platforms have the capacity to scan more than 1 patient simultaneously. Several challenges in such scenarios that could compromise patient safety must be considered. For example, the recognition of unanticipated implants or metallic objects requires careful evaluation of the MR images for susceptibility artifact. This task may be compromised if a single operator is concurrently scanning more than 1 patient. The site's MRMD should ensure that there are established policies and provide oversight for the safe scanning of all being scanned at their facility. Therefore, they must be aware of such a possibility and anticipate other potential emerging safety issues and prospectively develop SOPs using the guiding principles above such that safety is not compromised.

MR facilities are discouraged from adopting the aforementioned approach until more widespread information and peer-reviewed literature become available that better define best practices, help ensure patient safety, and illuminate potential unanticipated harms (e.g., worse clinical outcomes due to suboptimal image quality). Given the lack of experience with simultaneous remote scanning of multiple patients, sites are recommended to adopt this approach only if they are confident that they have developed sufficient staffing and SOPs that will in no way compromise patient safety and diagnostic efficacy of the MR examinations. The ACR MR Safety Committee will actively consider new safety information related to this important topic as it emerges.

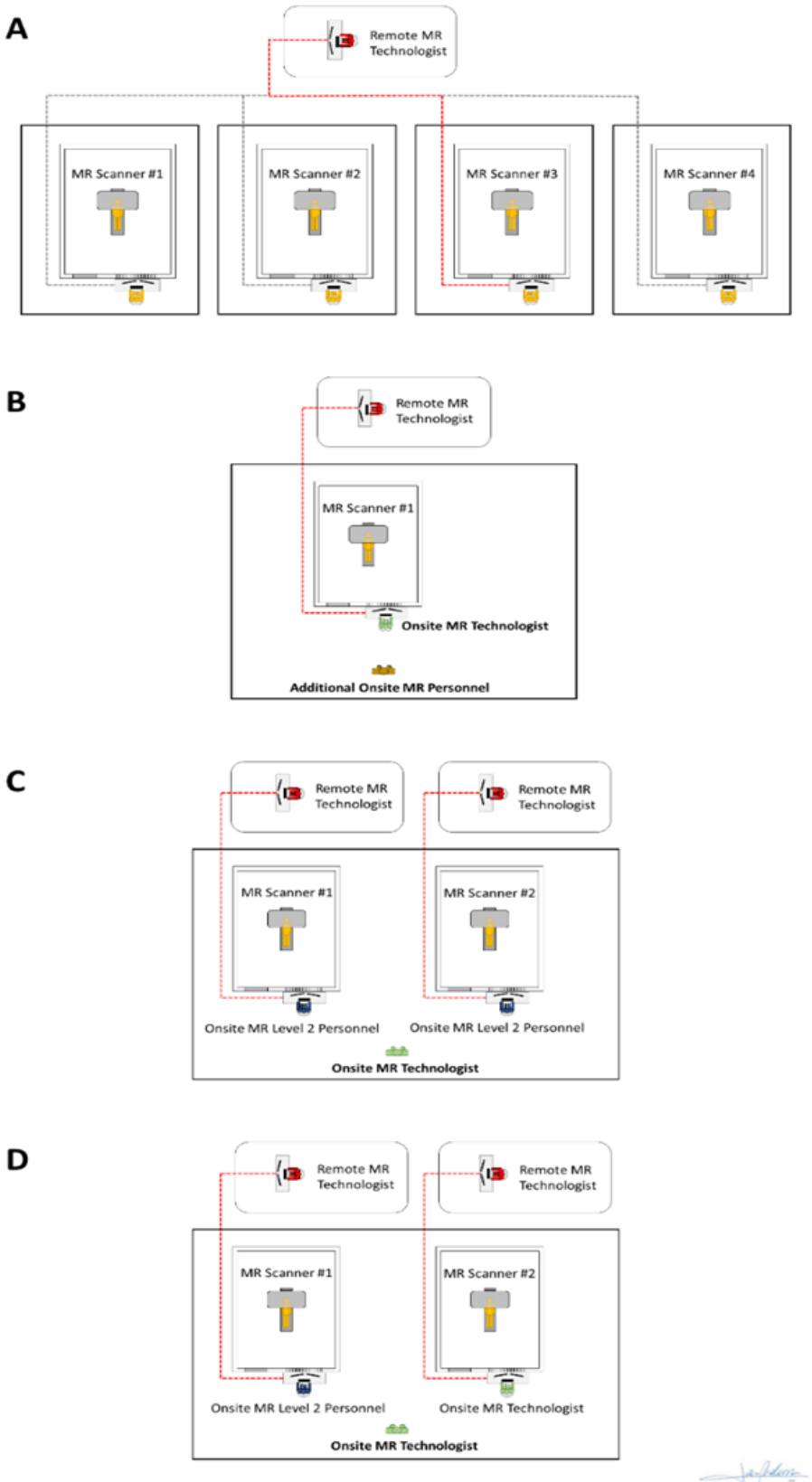

FIGURE 7. Examples of possible staffing scenarios in remote MR scanning. Illustrative examples of different scenarios during remote scanning are presented. Other possible situations may exist and should be addressed by the MRMD at each specific site. (A) A remote console may be connected to a single or multiple MR scanners. However, simultaneous remote monitoring and/or scanning (i.e., active connection) with more than 1 scanner at a given time by a single remote technologist is not recommended. In this example, the remote console is connected to 4 different MR scanners, although the Remote MR Technologist has established an active connection only with scanner #3 (red dashed line). (B) Single scanner per Zone III. An on-site Level 2 MR Technologist monitors the patient while interacting with the remote scanning Level 2 MR Technologist. An additional on-site MR Personnel assists the on-site MR Technologist. (C) Two scanners sharing Zone III with specially MR safety–trained on-site Level 2 Personnel monitoring an individual patient for whom they are responsible while interacting with the remote scanning Level 2 MR Technologist. An MR facility Level 2 MR Technologist is always on-site and immediately available to the monitoring personnel in this situation. (D) Two scanners sharing Zone III with a combination of a specially MR safety–trained on-site Level 2 Personnel and a Level 2 MR Technologist monitoring an individual patient for whom they are responsible while interacting with the remote scanning Level 2 MR Technologist. An MR facility Level 2 MR Technologist is always on-site and immediately available to the monitoring personnel in this situation since the Level 2 MR Technologist monitoring the patient in the MR scanner #2 cannot assist the MR Level 2 Personnel in the MR scanner #1.

KEY POINTS

- **MR Personnel**
- Level 1 MR Personnel: individuals who have passed the facility's MR safety educational requirements (as defined by the facility's MRMD) with the aim that they would not constitute a danger to themselves or others in the MR environment.
- Level 2 MR Personnel: those who have been more extensively trained and educated in the broader aspects of MR safety issues, including but not limited to issues related to the potential for radiofrequency-related thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients.
- **Non-MR Personnel**
- Patients, visitors, or facility staff who do not meet the criteria of Level 1 or Level 2 MR Personnel.
- **Supervision and Independent Access**
- Level 1 and Level 2 MR Personnel may be permitted unaccompanied access throughout Zones III and IV following appropriate screening.
- Level 1 MR Personnel are not permitted to directly admit or be responsible for non-MR Personnel in Zones III or IV.
- Access by non-MR Personnel to Zone III and Zone IV is controlled by and entirely under the supervision of Level 2 MR Personnel.
- Non-MR personnel must be accompanied, monitored, and under the direct supervision of a Level 2 Personnel while in Zone III and Zone IV.
- In the event of the need for handoff of Level 2 responsibility, there must be formal transfer of responsibility for safety related to the presence of the non-MR Personnel to another Level 2 MR Personnel who fully accepts that responsibility.
- **Staffing**
- Appropriate staffing in routine operating hours is essential to maintain patient safety in the MR environment.
- Staffing in emergent situations is recommended at a minimum to be comparable to that employed during routine operating hours. A lone technologist is specifically not recommended in this scenario.
- **Remote MR Scanning**
- Safety should be in no way diminished with the use of a remote MR scanning operator, and adequate staffing is essential.
- In all scenarios, at least 1 on-site level 2 trained MR Technologist must be immediately available.

KEY ABBREVIATIONS

ACR: American College of Radiology

MRMD: Magnetic Resonance Medical Director

MRRD: Magnetic Resonance Research Director

MRSE: Magnetic Resonance Safety Expert

MRSO: Magnetic Resonance Safety Officer

mT: millitesla

PET: positron emission tomography

TJC: The Joint Commission

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CHAPTER 5:
MR Screening

Due to the inherent dangers in the MR environment, well-designed procedures and policies centered on thorough and effective screening of all entering Zones III and IV are essential [1]. Thorough and accurate communication among all involved stakeholders is essential at all levels of the MR screening process. When necessary and appropriate because of language barriers that could negatively impact the accuracy of the screening process, the physical presence of appropriate individuals serving as translators, or reliable communication through electronic means with properly qualified translators, is recommended.

MR Safety Screening Forms

Well-designed written or electronic MR safety screening forms are essential in efforts to prevent unsafe exposures to the Zone IV MR environment for patients, research participants, and other individuals as well as for MR Personnel, non-MR Personnel, and any others. A sample pre-MR screening form is provided on the ACR.org MR Safety webpage, found at https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety. Different MR screening forms, including those with additional information, may be added at the discretion of the facility. No empty responses are accepted, and each question must be answered with a yes or no, or specific further information must be provided as requested. The patient, guardian, or research participant and the screening MR staff member must each physically or electronically sign the completed form to acknowledge the accuracy of the information provided. If the individual is not a patient or a research participant (e.g., guardian), facilities should develop a process to file and store these forms. This form should then become part of the individual's medical record. Additional written or verbal information for inclusion on a screening form must be provided by a physician or an advanced practice provider (such as a licensed nurse practitioner or licensed physician assistant) or other reliable source (e.g., those knowledgeable about specifics related to an implanted device) and documented in writing.

Patients/Research Participants and Accompanying Companions

The MR safety screening form represents one facet of a comprehensive safety screening program. MR safety screening can be enhanced by a multitiered approach that also includes safety questions that are included with the referring physician order sets. Patient screening efforts can be augmented by radiology prescreening scheduling questions and implant device modules/alerts in electronic medical records (EMRs). In this way, scheduling considerations may be enhanced. For example, a patient may be scheduled at the correct magnet in coordination with the cardiology team if there is previsit knowledge of the presence of a cardiac implanted electronic device (CIED).

Screening of conscious nonemergent patients, research participants, and volunteer participants. Conscious nonemergent patients, research participants, and volunteer participants are to complete an MR safety screening questionnaire (written or electronic) prior to their introduction to Zone III. A healthcare proxy may be indicated for a patient in a nonemergent setting if there is concern for lack of response accuracy due to the patient's condition (for example, in the setting of mild or more advanced cognitive impairment).

Conscious nonemergent patients and research or volunteer participants must be MR safety screened at least twice prior to being granted access to Zone IV. At least 1 of these screens must be performed by Level 2 MR Personnel verbally and/or interactively. For example, following completion of the screening form, a Level 2 MR Personnel (typically the technologist) verbally reviews the form's responses and contents in its entirety together with the patient. If safety concerns are identified, entrance into Zone III is not permitted until the concern is rectified. If no disqualifying safety concerns are identified, escorted passage into Zone III can proceed.

Pediatric/minor patients. Children may not be reliable historians. If possible, and allowed by institutional policies, children, especially teenagers, should be screened twice by Level 2 MR Personnel: once in the presence of parents or guardians and once separately to maximize the possibility that all potential dangers are disclosed [2]. As with all patients, pediatric patients are recommended to change into MR Safe pocketless garments to help ensure that no metallic objects, toys, or other unsafe items enter Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent potential risks and should be discouraged from entering Zone IV. These items should be permitted only on a case-by-case basis if thorough screening has ensured their safety in the MR Zone IV. It is common for properly screened parents or guardians to accompany pediatric/minor patients into Zone IV to help ensure the success of the imaging exam. There is no known contraindication for a pregnant parent or guardian to accompany the pediatric/minor patient in Zone IV (see Chapter 15: Pregnancy).

Unconscious, unresponsive, altered-level-of-consciousness, mentally impaired, unable to communicate patients. As these patients cannot provide their own reliable histories regarding possible prior surgery, trauma, or injury by a metallic foreign body, a multifaceted approach to obtaining reliable information is recommended prior to proceeding with the MR examination.

1. Consultation of the EMR (including surgical records and any available implanted devices module) as well as an evaluation of prior imaging can provide additional important safety screening information.
2. Available family members or guardians with appropriate knowledge of such patients should complete a written MR safety screening questionnaire and undergo a verbal interview, if possible, prior to the patient's introduction to Zone III. In certain circumstances, the MR Technologist may enter the responses of the verbal interview in the MR safety screening form (e.g., verbal interview with a translator).
3. If no reliable patient history can be obtained and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that
    a. a thorough visual inspection should be performed for scars, sites of trauma, and/or obvious implants by MR Personnel designated by the MR Medical Director (MRMD).
    b. if recently obtained radiographs, CT studies, or MR studies of core anatomic regions (with the exception of distal extremities) are not available, patients should undergo plain radiography to exclude potentially harmful embedded or implanted metallic foreign bodies, implants, or devices. Plain-film radiography should include the head/neck, chest, abdomen/pelvis, and contiguous upper arms and thighs. If there are obvious post-traumatic changes to the distal extremities, those regions should also undergo imaging

evaluation prior to MR exposure. (See Potential eye foreign body/orbital trauma.)

Emergent patients. Emergent patients and their accompanying non-MR Personnel may be screened only once, provided that the screening individual is Level 2 MR Personnel. Any exceptions to this in extremely extenuating circumstances in which delayed diagnosis could have devastating consequences (such as but not limited to cases in which a screening-induced delay may result in imminent patient paralysis, blindness, and/or death) must be with the mutual agreement of the ordering physician and covering Level 2 MR Physician or MRMD, who specifically acknowledge the potential risks of a decision NOT to screen prior to granting that patient MR access.

Companions in Zones III or IV. Any individual deemed appropriate to accompany or remain with the patient should be screened before entering Zone IV. An abbreviated MR safety screening form that informs of the risks of entering Zone IV and screens for ferromagnetic objects and implanted/on-planted devices may be used, eliminating the need to screen for other medical conditions and personal background (e.g., diabetes, hypertension, gender). It is recommended that the accompanying individual change into facility-provided MR Safe scrubs/gowns, if possible (see Patient Preparation/Gowning).

In general, it is prudent to limit accompanying companions to a single individual. Only a qualified, responsible Level 2 MR Physician should make screening criteria exceptions.

If screening reveals a potential conductive or metallic foreign body or other safety issue and the individual wishes to proceed to Zone IV, a Level 2 MR Personnel or Level 2 MR Physician must discuss with them the requirement for further evaluation and to determine if it is safe for that individual to enter Zone IV.

The use of hearing protection is recommended for accompanying companions within Zone IV.

MR Safe/MR Conditional seating should be made available for accompanying companions within Zone IV.

Service and support animals. Introducing service and support animals in Zone IV is not recommended given the difficulty of screening them to ensure their safety (including hearing protection) and the safety of patients and MR Personnel. The facility must ensure alternative arrangements to facilitate MR imaging of patients in the setting of service and support animals.

Screening with Ferromagnetic Detection Systems

Screening for ferromagnetic materials by direct inspection and use of a ferromagnetic detection system (FMDS) is recommended prior to entering Zone III and Zone IV [3,4]. Implanted and on-planted medical devices, both MR Conditional and MR Unsafe, may include ferromagnetic material (including batteries) that can lead to FMDS activation.

The use of conventional metal detectors that do not specifically differentiate between ferromagnetic and nonferromagnetic materials is not recommended. The use of an FMDS is recommended as an adjunct and not replacement of thorough and conscientious screening of persons and devices prior to being permitted into Zone III and/or IV [5]. FMDS screening may help detect ferromagnetic objects and some medical implants missed during the standard screening [6, 7].

Nonambulatory patients can pose special challenges, as transport equipment can impact the reliability of FMDSs. In such situations, facilities should have standard operating procedures (SOPs), including augmented visual and physical inspection, to investigate for potential metallic devices.

Staff/Personnel Screening

1. **MR Personnel.** All MR Personnel should undergo an initial onboarding MR screening process to identify any potential devices or medical conditions that could impact their or others' safety in the MR environment as part of their employment agreement. This screening record should be reviewed annually. Interval pertinent medical/surgical changes in status (e.g., new implanted/on-planted device) and new injuries/trauma involving ferromagnetic objects could pose safety issues in MRI. These changes must be immediately reported to the MRMD or designated personnel, with appropriate updating of the MR safety screening record, to determine ongoing safety in Zones III and IV, and with appropriate changes in roles, access, and other similar situations implemented as necessary. Similarly, subjective health complaints potentially associated with the B_0 field (e.g., vertigo, dizziness, nausea, metallic taste, and/or illusion of movement) have been reported among MR Personnel, particularly those working in the 3 T environment compared to 1.5 T [8]. MR Personnel should be encouraged to report these known effects to the MRMD [9]. MR Personnel who work in Zone IV during image acquisition should immediately report a pregnancy to the MRMD or designated personnel for appropriate adjustment of job duties. For other pregnant MR Personnel, see Chapter 15: Pregnancy section.
2. **Non-MR Personnel.** Entry into Zone III/IV by non-MR Personnel is granted only following appropriate safety screening by Level 2 MR Personnel. In the special circumstance of a non-MR Personnel with a legitimate need to be in the MR environment with active implanted medical devices (e.g., cardiac pacemaker, implantable cardioverter defibrillator, medication pump, cochlear implant) as well as certain passive implants (including aneurysm clips), they should be prevented from entering Zone III and IV and prevented from passing the 9-gauss line unless specifically cleared in writing by a Level 2 MR Physician or the MRMD of the MR facility.

KEY POINTS

- All non-MR Personnel needing to enter Zone III must first pass an MR safety screening process that includes a written form and verbal interview.
- Level 2 MR Personnel have the final authorization to admit non-MR Personnel into Zone III.
- A sample pre–MR screening form is provided on the ACR.org MR Safety webpage.
- Staff/Personnel screening
  - All MR Personnel must undergo initial onboarding MR screening and a yearly review of this screening.
  - Significant changes in screening status must be reported to the MRMD or designee immediately before returning to the MR environment.
- Conscious nonemergent patients
  - Conscious nonemergent patients and research and volunteer participants are to complete written or electronic MR safety screening questionnaires prior to their introduction to Zone III and must be screened twice, including at least once by a Level 2 MR Personnel.
- Pediatric/minor patients
  - Should be screened twice by Level 2 Personnel, once separately from their parents or guardians.
  - It is recommended that they be changed into MR Safe pocketless garments before entering Zone IV, like all patients and research participants.
- Unconscious, unresponsive, altered-level-of-consciousness patients
  - Family members or guardians of such patients should complete a written MR safety screening questionnaire and undergo a verbal interview prior to the patient's introduction to Zone III.
  - If no reliable patient history can be obtained and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that such patients be physically examined and undergo plain-film radiography as necessary to exclude potentially harmful embedded or implanted metallic foreign bodies, implants, or devices.
- Emergent patients and their accompanying non-MR Personnel may be screened only once, provided that the individual is Level 2 MR Personnel.
  - In cases of extenuating circumstances, there must be agreement between the ordering physician and covering Level 2 MR Physician or MRMD acknowledging the risks of a decision NOT to screen prior to proceeding.
- Companions in Zones III or IV
  - Those deemed appropriate to accompany or remain with the patient should be screened prior to entering Zone IV.

Risk Identification, Assessment, and Mitigation

Level 2 MR Physician/MRMD final determination. Final determination of whether or not to scan a patient is to be made by the MRMD or the designated Level 2 MR Physician responsible for the patient. Frequently, the MRMD delegates this authority to MR Technologists through existing policies and SOPs such that the designated on-duty physician is only consulted for selected patients in whom the decision to proceed is not straightforward. Consideration of both the benefit of the imaging (including diagnosis, care plan, etc.) against the risks of proceeding with the MR examination as well as the risks that may occur if the study is not performed should be made. Potential risks of proceeding with the requested MRI examination may include mechanical, thermal, and functional risks associated with MRI of implants as well as reactions to contrast agents. These complex decisions often involve patients with implanted devices and may require input from multiple healthcare professionals (e.g., physicians, MRSO, MRSE, device manufacturer representative, etc.). See Appendix 4: Implanted Device MR Risk/Safety Assessment.

Implanted devices. If an implanted device is indicated on a screening form, medical record, referring physician order, etc., it is imperative to accurately identify and/or verify the type of implant and its location. For some devices, it is essential to identify its exact make/model and material due to potential injury or other consequences of improper scanning in the presence of the device [10]. Such devices include active electronic implants (CIEDS, neurostimulators) and some passive devices (e.g., aneurysm clips). In contrast, some sites may opt to designate through their SOPs other classes of implants for which there are fewer MR safety concerns, such as coronary stents and orthopedic hardware, as relatively low risk for scanning, obviating the need for precise identification of the make/model of each specific implant.

Verification and positive identification should be in writing or electronically documented. Sources of information may come from operative notes, device identification cards, and electronic medical record implanted device modules. Other sources may include archived MR safety screening forms. Clearance for MRI based on prior screening requires written documentation by a Level 2 MR Personnel of the specific device and conditions for MR imaging.

Once positive identification is complete, the implant must be assessed as being MR Safe, MR Conditional, or MR Unsafe. For MR Conditional devices, the most recently available conditions for safe scanning based on the product information (i.e., the instructions for use) must be assessed. Note that the MR conditions for the same device may be different in different countries. Other sources could include written records of the results of formal testing of the implant prior to implantation and peer-reviewed publications regarding the conditions of MR safety of the specific make, model, and type of implant as long as the device/system is identical to the device that was tested. A key role of MR Safety Officers (MRSOs) and MR Safety Experts (MRSEs) includes helping ensure safe scanning of patients with implanted devices. For devices in which the assurance of MR safety is not provided by the device manufacturer (e.g., unidentified device, device manufacturer does not provide MR safety labeling, MR Conditional device in which at least 1 of the MR conditions is not met), the responsible MR Personnel must perform a risk assessment and subsequently a risk/benefit decision on how to proceed. This 2-step process often involves individuals with different expertise, such as MRMDs, MRSOs, MRSEs, and radiologists. Appendix 4 Implanted Device MR Risk/Safety Assessment may provide some guidance.

Foreign body. All patients and non-MR Personnel with a history of penetrating injury or implantation associated with an unspecified metallic foreign body including bullets and shrapnel must undergo further investigation prior to being permitted entry to Zone III [11]. Examples of acceptable methods of screening/risk assessment include patient history, plain radiographs, prior CT (with adequate thin sections) or recent MR studies of the anatomic area in question, the use of a FMDS, consideration of the anatomic location, procurement of the same metallic object, or access to written documentation as to the type of implant or foreign object that is present. For field strengths up to 3 T, if the metallic object is less than 2 cm in size and more than 3 cm from other conductors, significant heating is not considered to be an issue if the radiofrequency output is limited to Normal Operating Mode [12]. If the object is ferromagnetic or potentially ferromagnetic, the object's anatomic location relative to tissues and organs should be considered. Also, anticipated fibrous scarring or encapsulation of the object relative to the time since the injury should be considered. Fibrous scarring could effectively limit any translation, even if ferromagnetic, limiting the possibility of potential injury. Proximity to sensitive tissues, such as the spinal cord, clearly could be a contraindication versus the location of the object in subcutaneous fat or skeletal muscle where a significant injury would not be anticipated.

Potential eye foreign body/orbital trauma. All patients with a history of orbital trauma by a potential ferromagnetic foreign body for which they sought medical attention or for which there is otherwise high clinical suspicion for globe penetration by a ferromagnetic body are to have their orbits evaluated either by a single orbit radiograph [13,14] with additional views as necessary or by a radiologist's review and assessment of prior thin-section CT (obtained since the suspected traumatic event), if available. Evaluation of a prior MR examination's susceptibility artifact of the region of the orbits may provide an experienced physician with important information on the ferromagnetic nature of the foreign body, but MR images alone are insufficient to clear orbits.

Patient Preparation/Gowning

Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices. This includes important on-planted devices such as external insulin pumps, external hearing aids, continuous glucose monitoring devices, and other similar items. Also, they should remove watches, jewelry, pagers, cell phones, body piercings, contraceptive diaphragms, cosmetics containing metallic particles (such as eye makeup, magnetic eyelashes, hair product), and clothing items that may contain metallic fasteners, hooks, zippers, or loose metallic components/threads or may have been treated with antimicrobial electrically conductive materials. Metallic drug-delivery patches should also be removed when appropriate (see section on Drug-delivery patches and pads). Many antimicrobial silver-impregnated wound dressings, bandages, and patches have been tested at 1.5 and 3 T and shown to demonstrate no significant heating risk in 3 prior studies [15-17]. Nevertheless, several vendors specify removal of their silver-containing products if located within the radiofrequency (RF) field of view [18]; therefore, appropriate screening should be performed. Patients with these silver-containing dressings should be instructed to alert the technologist if they experience heating. Patients or research participants must remove all clothing and wear site-supplied MR Safe pocketless garments in place of their own clothing (and undergarments if possible) in the region undergoing direct electromagnetic RF irradiation (see Chapter 8 for

thermal considerations). Face masks should not include metal in the form of nose pieces or fibers incorporated into the mask materials [19].

KEY POINTS

- Risk identification
  - Final determination to scan a patient is to be made the MRMD or by a designated Level 2 MR Physician responsible for the patient.
  - Accurate identification of the type, location, make/model of an implanted device is essential.
  - The most up-to-date conditions for safe scanning of a patient with an implant or device should be identified and followed.
- Gowning
  - Patients or research participants should remove all clothing, accessories, and jewelry and wear site-supplied MR Safe pocketless garments in place of their own clothing and undergarments in the region undergoing direct RF irradiation.
- Screening with ferromagnetic detection systems
  - Screening with an FMDS is recommended as an adjunct to other safety screening methods.
  - Use of more conventional nonspecific metal detectors is not recommended.

KEY ABBREVIATIONS

ACR: American College of Radiology

AIMD: active implanted medical device

B_0: static magnetic field

CIED: cardiac implantable electronic device

CT: computed tomography

CGM: continuous glucose monitor

EMR: electronic medical record

FMDS: ferromagnetic detection systems

ICD: implantable cardioverter defibrillator

IFU: instructions for use

MRMD: Magnetic Resonance Medical Director

MRSE: Magnetic Resonance Safety Expert

MRSO: Magnetic Resonance Safety Officer

RF: radiofrequency

SOP: standard operating procedure

T: tesla

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CHAPTER 6:
Full Stop/Final Check

"Full stop and final check" processes should be implemented. A tiered approach is suggested that appropriately addresses the different levels of anticipated MR safety risks:

- Routine. Typically, ambulatory settings where there is no obvious increased risk due to additional equipment and personnel.
- Augmented. Complex MR settings (e.g., hospitalized, emergent, anesthesia, interventional, etc.) that require an **augmented** process, including, in particular, when the patient is transported with support equipment and/or personnel.

Routine. A full stop and final check performed by the MR Technologist is recommended to review and confirm the satisfactory completion of MR safety screening for all patients before entering Zone IV. Elements of this include verification of the following:

- Patient identification and visual inspection.
- The examination to be performed includes potential use of contrast and completion of associated contrast risk assessment.
- Appropriately performed screening.
- Proper preparation, programming, or removal of implanted/on-planted devices.
- A lack of change in patient status while in Zone III.

If hearing aids have been left in place to ensure communication with the patient in Zone III, strict attention must be paid to ensure that these are removed and properly stored before entering Zone IV. Providing a graphic such as the one pictured in Figure 8 may be helpful to prompt a patient's memory of other items that have not been identified previously in the screening process.

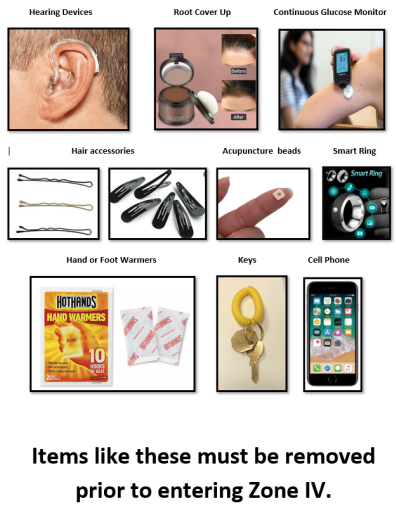

FIGURE 8. Examples of visual cards used during full stop/final check.

Augmented. The augmented full stop and final check process includes a verbal review by the supervising Level 2 MR Technologist and an acknowledgement by a second MR Personnel team member, modeled on elements of the Universal Protocol Final operating room/pre-procedure check. Elements of this verification include the following:

- Items included in the routine process above.
- Thorough screening for any support staff that will also enter Zone IV.
- Completion, as appropriate, of augmented screening of unconscious, unresponsive, altered-level-of-consciousness patients (as described in MR screening, unconscious, unresponsive, altered-level-of consciousness, mentally impaired patients).
- Completion of careful visual inspection of the patient as well as the transport/support equipment that will enter Zone IV for the presence of concealed or previously unrecognized potentially dangerous items that could pose a projectile risk (e.g., steel oxygen cylinders), burn risk (e.g., unconnected electrocardiogram electrodes and lead), or other safety issues (i.e., radiofrequency identification (RFID) tags in hospital linens).
- Identify the appropriate port/line to be accessed for potential gadolinium-based contrast agent injection.
- Ensure that the equipment that needs to be tethered in Zone IV is properly secured prior to allowing the patient to enter the MR system room.
- Ensure that there has been no change in patient and/or equipment status while in Zone III.

KEY POINTS

- Routine full stop and final check
  - Typically, ambulatory setting.
  - Performed by the MR Technologist to confirm the satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately prior to crossing from Zone III to Zone IV.
  - Hearing aids, external insulin pumps, continuous glucose monitoring devices, and other similar devices must be removed and properly stored prior to Zone IV entry.
  - Verbal review by Level 2 MR Technologist.
- Augmented full stop and final check
  - Typically, complex setting.
  - Helps ensure appropriate screening of patients in more complex environments (e.g., hospitalized, emergent, interventional, etc.).
  - Performed by the MR Technologist to confirm the satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately prior to crossing from Zone III to Zone IV.
  - Verbal review by Level 2 MR Technologist and second MR Personnel team member.

KEY ABBREVIATIONS

CGM: continuous glucose monitor

ECG: electrocardiogram

OR: operating room

CHAPTER 7:
Zone IV Examination Preparation and Completion

After appropriate screening and patient preparation as discussed in previous chapters, final steps that must be accomplished by MR Personnel prior to scanning include but are not limited to these elements:

1. Discuss the scan expectations with the patient (e.g., breath holding requirements, need to limit motion, etc.) to aid in obtaining a quality diagnostic examination. Discuss the need for the patient to disclose uncomfortable heating, pain, noise, etc. Concerns regarding claustrophobia or anxiety (see Claustrophobia, anxiety, and sedation section) can be discussed.
2. Provide hearing protection and ensure proper fit and function.
3. Position the patient, choose and place the radiofrequency (RF) coil appropriately, and plug the RF coil into the MR system securely.
4. Ensure proper RF burn prevention [1].
    a. Properly pad/insulate the patient from the scanner bore and RF transmission body coil, ensuring manufacturer's recommended separation/distance.
    b. Ensure no unsafe skin-skin contact points that would risk creating internal induced current loops (see Conducted tissue loop-related burns). Note, that skin-skin contact points outside the bore can also pose a burn risk and must be prevented.
    c. Ensure safety related to electronic cables (e.g., proper insulation, distance from edge of the magnet bore, central and straight coil positioning [1]).
    d. Ensure equipment such as MR Conditional electrocardiogram electrode pads are properly attached to the patient consistent with their use and product labeling.
5. Ensure that there is an effective means by which the patient/subject can communicate with the operating MR Technologist during the scan.
    a. Provide the patient/subject a technologist notification device such as a squeeze ball and have the patient test it. Provide a brief discussion on when it is appropriate to squeeze the ball (e.g., unanticipated heating, excessive noise, the need to move, pain, etc.).
    b. Other site-specific comfort methods (such as audio/video).
    c. Establish a 2-way intercom.
6. Reaffirm protocol, scanning conditions, and scan duration.
7. After obtaining localizers
    a. Check patient comfort, safety, and willingness to proceed.
    b. Check for concerning susceptibility artifacts associated with unanticipated objects.
    c. Confirm adequate hearing protection.

MR Personnel under direct Level 2 MR Personnel supervision must remove the patient/research participant from Zone IV.

KEY ABBREVIATIONS

ECG: electrocardiogram

RF: radiofrequency

Reference

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CHAPTER 8:
MRI Fields and Safety Concerns

The electromagnetic fields associated with MRI are generally the primary sources of safety considerations associated with routine use of the equipment. Therefore, these fields should be considered in terms of potential interactions and risks with respect to humans and objects exposed to the fields. The strong static magnetic field can induce torque and translational forces on ferromagnetic objects and devices that can lead to projectile events. The pulsed gradient magnetic fields can cause peripheral nerve stimulation and damage to implanted and on-planted devices as well as generate loud acoustic noise. Each of these phenomena will be discussed in turn. Additionally, time-varying radiofrequency (RF) magnetic fields are predominantly responsible for whole-body and localized heating of tissue and devices.

Static Magnetic Field

The static magnetic field, often denoted as B_0, is the strong, unchanging field in MRI that, for most superconducting systems, remains on at all times. Generally, the B_0 field is designed to be constant within the magnet bore central to the imaging system and taper off quickly outside this region. The MR environment is typically defined as the region with a magnetic field higher than 9 gauss, within which some medical devices, such as pacemakers, have been observed to malfunction and therefore present a threat for patients and personnel [1]. This spatial rate of change in the magnetic field from the center of the magnet to the fringes of the MR environment is referred to as the “spatial field gradient” (SFG).

As noted earlier, all projectile safety events are preventable. In terms of risk, torque on objects is determined primarily by the strength of the static magnetic field and is greatest within the bore where the field is at its maximum, while translational displacement forces tend to be greatest near the bore openings where the SFG is largest. As ferromagnetic objects approach the front or back of the bore of the scanner, the translational forces can easily turn them into dangerous projectiles, with forces increasing with proximity to the bore edge and with B_0 static magnetic field strength. This is a primary risk associated with MRI and a fundamental reason why access of personnel and objects into Zone IV is highly restricted (Figure 9).

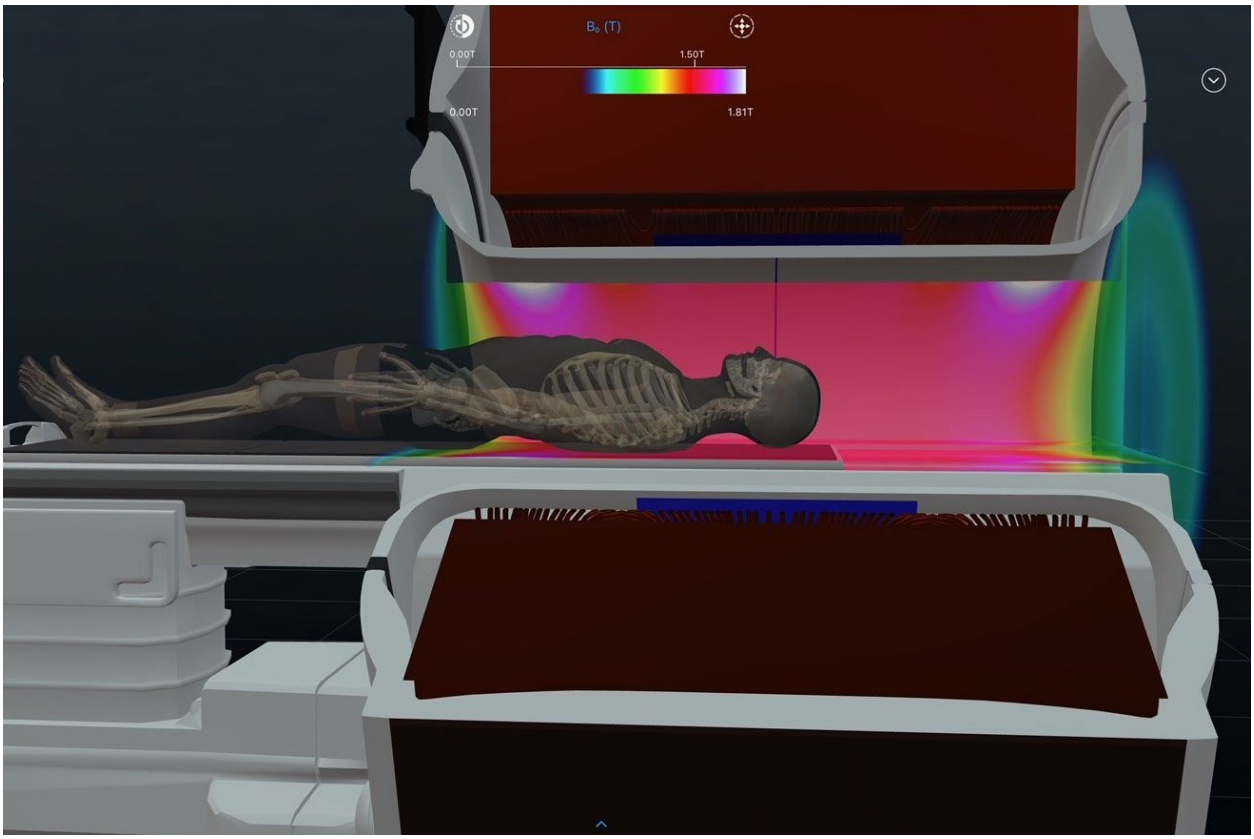


FIGURE 9. 3-D depiction of the static magnetic field in a 1.5 T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed 3-dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the static magnetic field B_0 are depicted. *(Courtesy of Dr. Emanuel Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC)*

Spatial field gradient. Strong magnetic fields can magnetize metallic objects placed within them, making the object itself interact with the magnetic field. The effect is strongest for objects with ferromagnetic content. The translational force on a metallic object in a magnetic field is proportional to the product of the induced magnetic field in the object and the SFG experienced by the object. The SFG (sometimes called the *static field gradient*) describes the rate of change in B_0 as a function of position around the MR system and is (typically cited in tesla per meter (T/m) or gauss per centimeter (G/cm), in which 1T/m = 100 G/cm). The translational forces experienced by ferromagnetic objects near the MR scanner are directly influenced by the SFG. MR magnets are designed to confine the magnetic field to the area of imaging as much as possible. For typical cylindrical, horizontal-field magnets, the maximal translational forces exerted by the system on objects occurs at the front or back of the bore of the MR system (Figure 10).

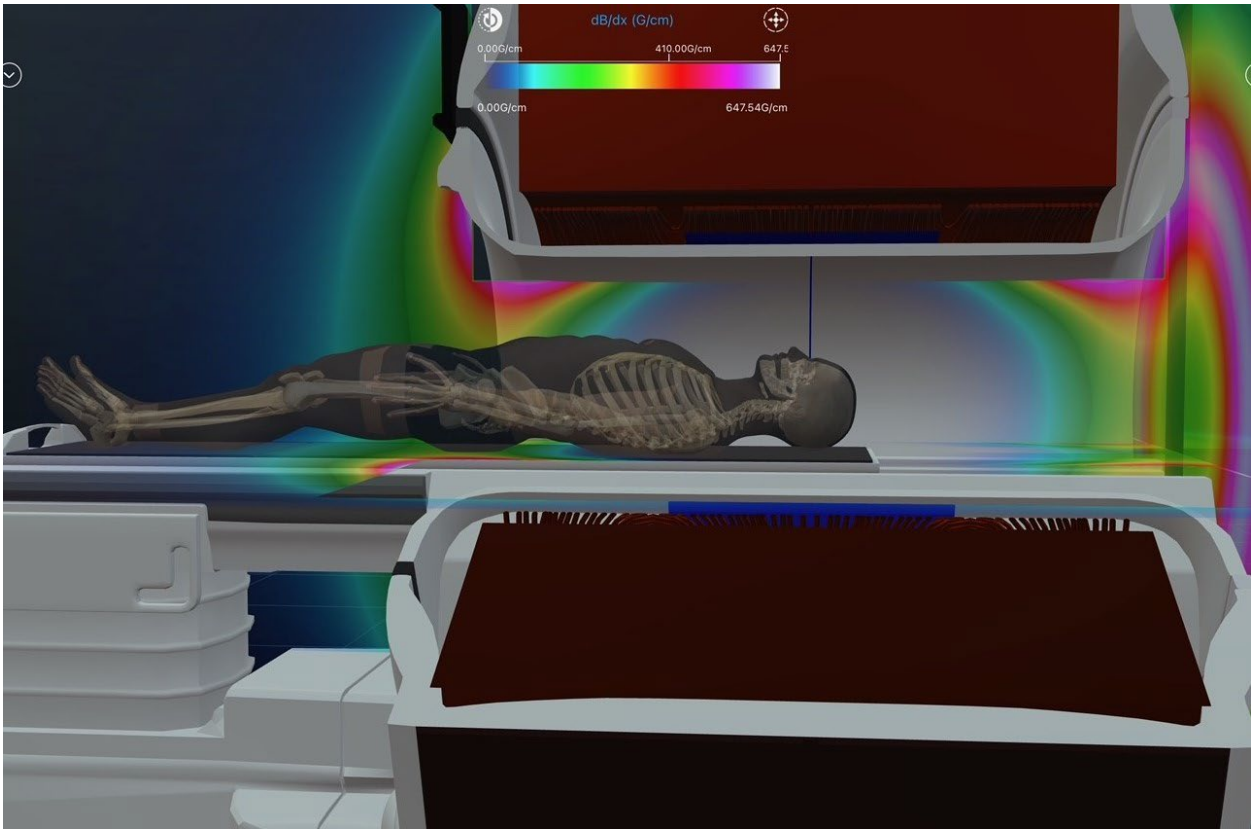
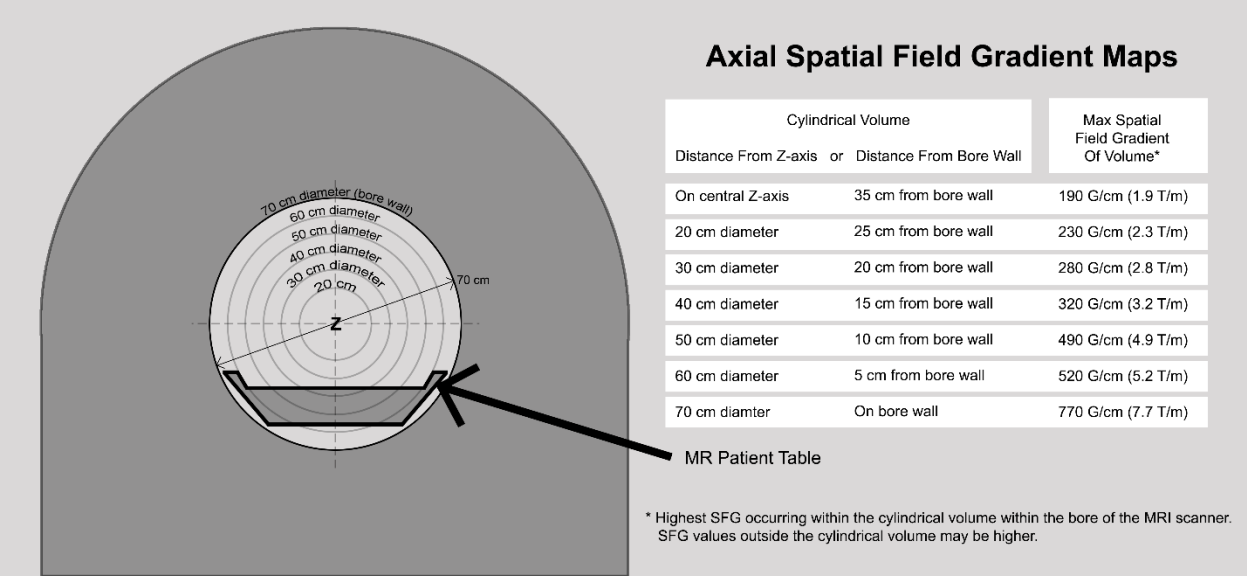


FIGURE 10. 3-D depiction of the SFG in a 1.5-T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed 3-dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the SFG is depicted. Notice that, in the homogeneous static magnetic field at the center of the MR scanner, the strength of the SFG and, therefore, potential translational forces on ferromagnetic materials and objects are minimal. The greatest translational forces scale with the SFG of this magnet, which maximizes near the radial extremes/borders at the entrance (and exits) to the MR scanner bore. *(Courtesy of Dr. Emanuel Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC)*

To aid in evaluating forces on specific objects in the MR environment, in particular medical implants, MR system manufacturers are required to provide a map of both B_0 and the SFG for their scanner(s) to demonstrate to the MR system operator the strength of these fields at specific locations. Some MR system manufacturers also provide the product of the SFG and B_0 at these locations.

These charts are designed to be used by the MR system operator to evaluate whether an object or implant will be exposed to fields exceeding the MR conditions described on the device labeling [2,3]. Typically, implant and device manufacturers will cite the MR system B_0 and magnet configuration (i.e., cylindrical bore) along with the SFG known to facilitate safe scanning of an implant as determined by nonclinical testing. The MR system operator must then determine the maximal SFG a device will be exposed to when entering/exiting the MR system to ensure that it is within the stated conditions for the implant or device. In a cylindrical bore magnet, the SFG that a device may be exposed to while traveling into or out of the magnet increases with proximity to the magnet bore as shown in Figure 11.

Further information on how to evaluate SFG information provided by MR system manufacturers for this purpose is provided in Appendix 5.



Axial Spatial Field Gradient Maps

Cylindrical Volume		Max Spatial Field Gradient Of Volume*
Distance From Z-axis or	Distance From Bore Wall	
On central Z-axis	35 cm from bore wall	190 G/cm (1.9 T/m)
20 cm diameter	25 cm from bore wall	230 G/cm (2.3 T/m)
30 cm diameter	20 cm from bore wall	280 G/cm (2.8 T/m)
40 cm diameter	15 cm from bore wall	320 G/cm (3.2 T/m)
50 cm diameter	10 cm from bore wall	490 G/cm (4.9 T/m)
60 cm diameter	5 cm from bore wall	520 G/cm (5.2 T/m)
70 cm diamter	On bore wall	770 G/cm (7.7 T/m)

* Highest SFG occurring within the cylindrical volume within the bore of the MRI scanner. SFG values outside the cylindrical volume may be higher.

FIGURE 11. Front view of an example SFG map of an MR system indicating maximum SFG values that may be encountered within each of the cylindrical volumes within the diameter of the bore as a patient with an implant or device enters/exits this particular magnet (black arrow, table top of the MR system).
(Image courtesy of Tobias Gilk of Gilk Radiology Consultants.)

Lenz effect. A conducting object experiencing a change in magnetic field will have a current induced within the object that generates a magnetic field resisting that change. This resistive effect can result in mechanical forces on the object. This has important consequences for MRI: if an electrical conductor (i.e., an aluminum tray) is moved through the SFG of the static magnetic field, voltages and currents will be generated within the conductor with a magnitude directly proportional to the rate of motion as well as the regional SFG value. The current will induce a secondary magnetic field oriented in opposition to the motion of the conductor, which will exert an opposing force on its motion. Note that this will occur even if the conductor is metallic but nonferromagnetic.

There are many scenarios in which these forces may pose concerns. For example, if a nonferromagnetic metallic device such as an MR Conditional oxygen tank is moved toward the bore of an MR scanner, as the scanner bore is approached, the force that arises from these Lenz effects can be sufficiently strong to virtually stop forward progress of the device. Further, the faster one moves the device into the bore, the greater the opposing force that is created to stop this motion. There are also potential consequences for large implanted metallic devices. Even if these devices do not pose projectile hazards, rapid motion of the patient/implant in a direction perpendicular to the static magnetic field orientation can result in forces on the implant opposing this motion that may be detected by the patient. If the patient were to complain of experiencing forces tugging or pulling on the implant, this might lead to the patient or health care personnel to erroneously conclude that the device has ferromagnetic components and possibly canceling the examination. Slowly moving a patient with a relatively large metallic

device into and out of the bore is a key factor in decreasing any Lenz effects that might be induced, decreasing the likelihood of a misunderstanding or unnecessary study cancelation.

As Lenz effects are proportional to the rate of the object's motion through an SFG, and as these effects may be substantially higher at 7 T than 1.5 T or 3 T, these might bear special reconsideration for metal objects or devices used in or around 7-T MR scanners such as metallic aortic or mitral valve replacements [4]. Electrocardiograms (ECGs) are significantly distorted within the bore of an MRI as a result of the magnetohydrodynamic (MHD) effect, rendering those ECGs nondiagnostic and potentially inappropriate for cardiac gating. Magnetic field–induced voltage in flowing blood in the descending aorta underlies the MHD effect. Maximum blood flow in the descending aorta coincides temporally with the T wave on the ECG. Due to this, ST segment elevation or depression in an ECG acquired while in the magnet bore could mimic or obscure cardiac ischemia. The MHD can be associated with trace resistance to cardiac output, not considered to be clinically significant [5-7].

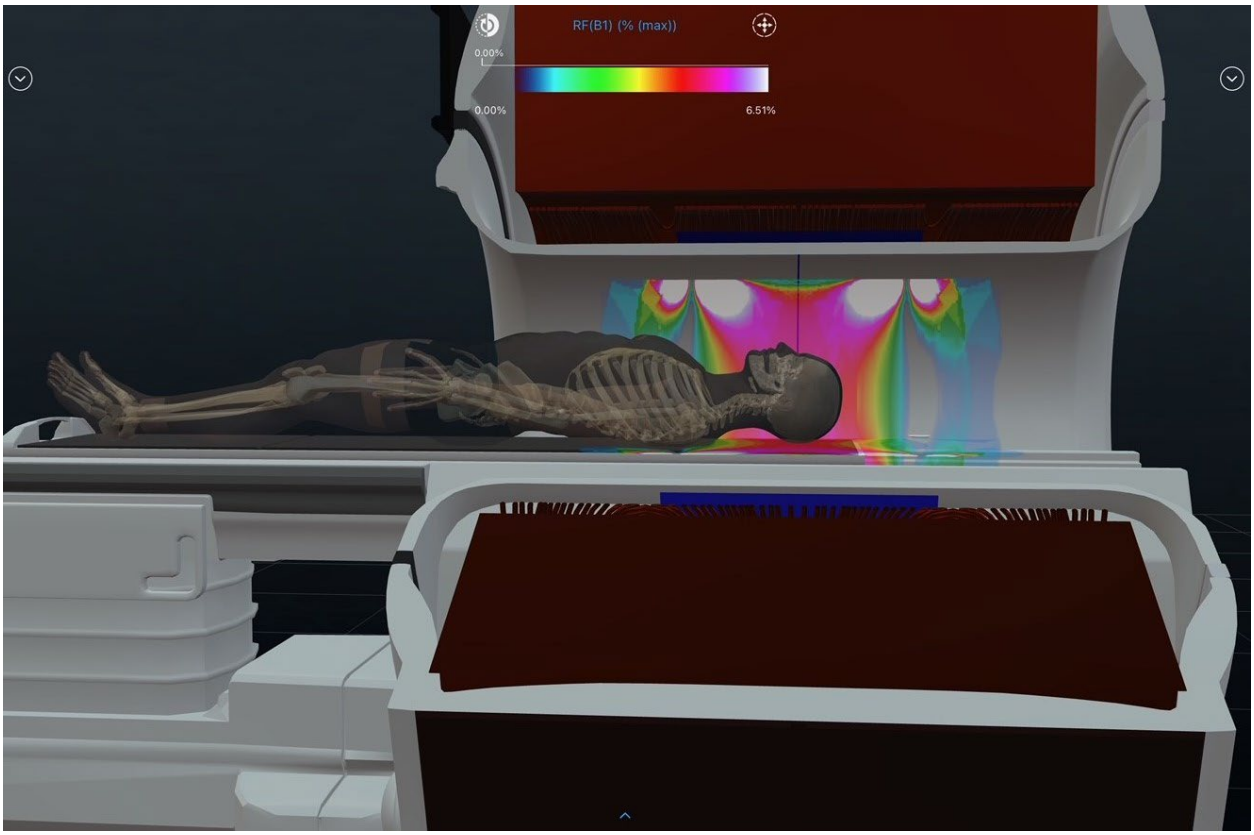
KEY POINTS

- Static magnetic field
  - The strong static magnetic field associated with MRI can interact with metallic objects, potentially turning ferromagnetic metals into dangerous projectiles. Access to these fields (Zone IV) must be strictly controlled. Personnel and devices entering this environment must be thoroughly screened by Level 2 MR Personnel.
  - The fringes of the static magnetic field above 9 gauss can interfere with implanted medical devices, such as pacemakers or implantable cardioverter defibrillators, resulting in potential injury or death. Access to these fields (Zone III and IV) must be strictly controlled. Personnel entering this environment must be screened by Level 2 MR Personnel.
  - Metal devices and medical implants have defined limits for exposure to maximal field strength and/or the SFG to prevent damage to the person and/or device. MR operators should have access to, and understanding of, vendor documents that describe these fields to safely manage both patients and devices in the MR environment.
  - The SFG changes markedly about the magnet bore edges (also see Appendix 5 for further discussion).
    - Translational forces are greatest near the edge of the magnet where the SFG is largest.
    - B_0 torque is greatest at the center of the magnet.

Time-Varying Radiofrequency Magnetic Field

Electric fields induced by RF transmission and the subsequent B_1 magnetic field in MR are the main sources of tissue heating and burns [8] (Figure 12).

Focal heating during the MR examination can result in tissue burns. Most thermal injuries occur on the skin of the upper extremities or torso, although they can occur virtually anywhere in the body. Direct communication between the patient and the MR Technologist during the examination is crucial because the patient may only experience minimal discomfort during the MR exam. Direct inspection of the area of discomfort may reveal only minimal skin redness, but thermal injury with blisters or even ulcers may yet develop within 24 hours after completion of the MR examination. Unconscious patients and those with limited capacity to communicate are at higher risk and require careful preparation prior to the MR exam.



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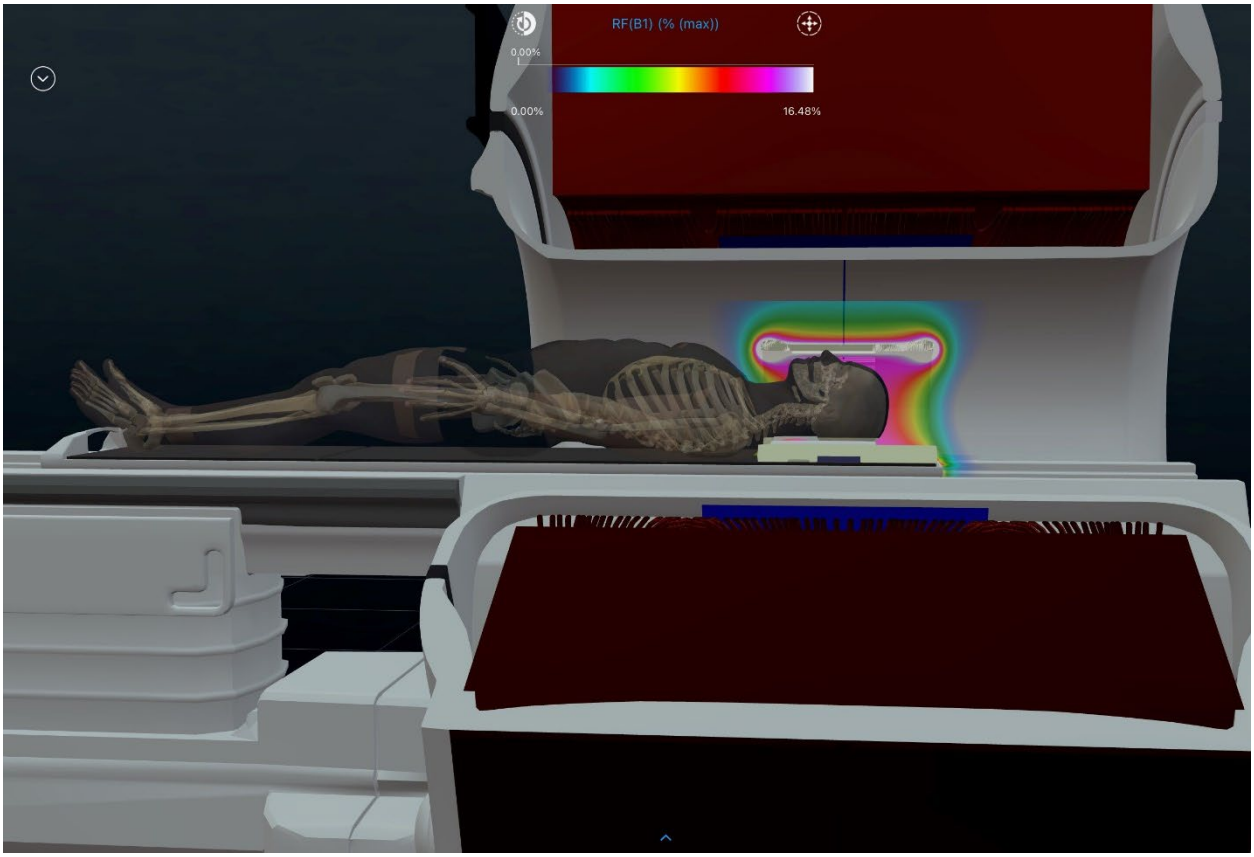


B.

FIGURE 12. 3-D depiction of the transmitted RF (B_1) oscillating magnetic fields in a 1.5-T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed 3-dimensionally throughout the MR scanner bore. (A) The spatial distribution of the transmitted RF (B_1) oscillating magnetic fields with the body RF coil of this scanner being used as the RF transmitter hardware is depicted. (B) The spatial distribution of the transmitted RF (B_1) oscillating magnetic fields with a transmit-receive head RF coil being used as the RF transmitter hardware is depicted. Note how the transmitted RF fields cover a smaller volume when a transmit-receive head RF coil is used for RF transmission in this same scanner.
(Courtesy of Dr. Emanuel Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC)

Whole-body heating: Quantitative considerations

Specific absorption rate, $B_1{+}_{rms}$, specific energy dose, and specific absorption. The dosimetric term used to estimate the rate of absorption of RF energy by human tissue in MR is the specific absorption rate (SAR), which is the mass-normalized rate at which RF power is coupled to biological tissue. It is expressed in units of watts per kilogram (W/kg) on the MR system [9]. The most commonly used SAR metric presented by the scanner is the whole body–averaged value [10-12]. SAR is an estimation of the rate of energy absorption by the patient, not a total dose of energy. The normal operating mode limits the whole-body SAR to less than 2 W/kg. The first level control mode whole-body SAR is limited to be less than 4 W/kg. The SAR is a conservative metric that is meant to estimate the dose received by the patient, which is extrapolated from the $B_1{+}_{rms}$, the root-mean-square value of the transmitted B_1 RF energy averaged over 10 seconds. Total energy absorbed by the patient over the course of an exam is referred to as the

specific energy dose (SED). The SED is commonly reported in units of joules per kilogram or kilojoules per kilogram. It is worth noting that recently the International Electrotechnical Commission (IEC) renamed SED to specific absorption (SA), and this term may begin to appear in MR safety literature and guidance documents [1].

The thermal load associated with an MR examination is a separate phenomenon from focal RF-related thermal injury [9]. Although discomfort related to a high thermal load during MR may be experienced by the patient, an actual burn does not occur if that load is sufficiently dissipated over time and/or space. Various health conditions may impair an individual's ability to manage a thermal challenge during MRI, including cardiovascular disease, diabetes, fever, and large body habitus. Medications, including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives, can alter the patient's thermoregulatory responses to a heat load [8,11]. Importantly, certain medications may have a synergistic effect with RF radiation with respect to tissue heating [8,11].

SAR limits are designed to avoid excessive RF-related tissue heating and burns, whereas SED limits are intended to protect a patient from experiencing an excessive elevation in core temperature or physiologic stress or discomfort related to inordinately high thermal loads from long-duration and/or high-SAR pulse sequences (e.g., total spine or body exams).

The SED of an exam may be reduced with shorter pulse sequences and/or reduced RF pulse strength, but sufficient rest and cooling-off periods between pulse sequences can ensure that it is possible to safely scan the patient even with high total SED values. It should be noted that although manufacturers have implemented SED limits on their MR scanners, limiting the SED of an MR examination does not necessarily reduce the risks of a thermal injury (burns have occurred in patients even when MR systems were operating within guidelines for RF power deposition) [13-16].

The IEC permits each MR system manufacturer to conduct its own risk assessment and structure criteria for MR system operator alerts, warnings, and/or "lockouts" as it deems appropriate [1]. Therefore, depending on the software operating on the MR system, the scanner may not present SED information (e.g., for older software versions); it may provide SED warnings at predetermined intervals with or without a lockout, or it may provide warnings and prevent additional scanning on a given patient for up to 24 hours if the MR system manufacturer–defined maximum SED threshold is reached. MR health care professionals should be aware of the SED procedure that a given MR system uses and understand the context of alerts and possible scanning restrictions. If restrictions exist, it may be necessary to modify the scanning protocol to successfully and safely complete the examination.

Specific thermal safety risks

Electrically conductive material–related burns. Electrical voltages and currents can be induced within electrically conductive materials that are within the bore of the MR scanner during the MRI exam. This might result in the heating of this conductive material by resistive losses. This heat might be of a magnitude sufficient to cause injury to human tissue. Among the variables that determine the amount of induced voltage or current is the consideration that the larger the implant and/or the diameter of conductive loops, typically the greater the potential for induced current that could result in a thermal injury to the patient.

Transmitting RF coil-related proximity burns. To help safeguard against thermal injuries or burns, pads meeting the MR system manufacturer's specifications ensuring adequate distance should be placed between the patient's skin and any transmit RF coil [8,11,17]. These pads ensure spacing between the transmit RF coil and the patient's tissue, protecting against proximity burns. Attention to the physical condition of insulating padding is recommended, as with time, pads can degrade and become overly compressible such that their insulating capacity is compromised, and a sufficient distance from the bore wall is not maintained. It is important to emphasize that insulating pads are necessary; a single-layer bedsheet is insufficient insulation or spacing to prevent burns (Figure 13).

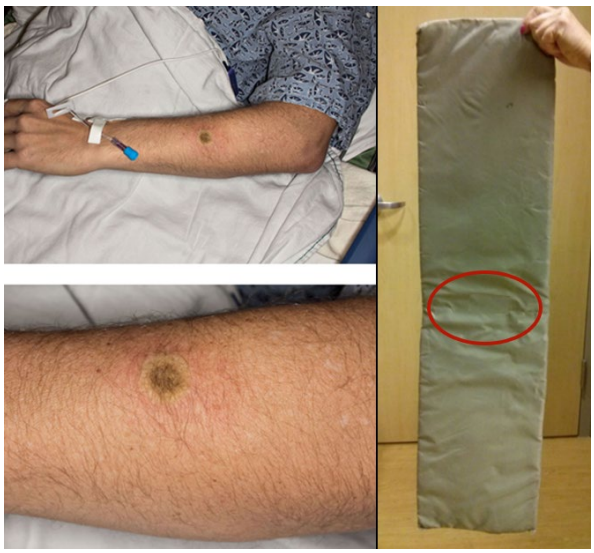


FIGURE 13. Example of a full thickness third degree burn that resulted from the MR bore proximity associated with use of a worn-out insulating pad that was overly compressed (central circled area).

Conducted tissue loop–related burns. RF deposition can be exacerbated by electrically conducting tissue loops within the patient's body. If there is significant current induction, burns can result when there are small areas of high resistance contact points where the energy is dissipated as heat. Therefore, it is important to prevent electrically conductive current loops that involve small areas of high resistance contact points such as between the patient's finger and a thigh, between small thigh-to-thigh contact areas, etc. The usage of supplied insulation pads to help prevent induced tissue current loops is recommended [18].

Electrically conductive wires/leads. The concern for induced current loops is even greater when electrically conductive wires or leads are involved. When electrically conductive material (wires, leads, implants, etc.) are required to be entirely or partially within the volume undergoing direct RF irradiation during MRI, care should be taken to ensure that no potentially dangerous electrically conducting loops (including the patient's tissue) are formed within the MR scanner during imaging. There are several reports of serious injury, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent MR examinations. The injuries in these instances resulted from excessive heating of the electrodes [19-23].

To avoid potential thermal issues and injuries associated with RF fields, all unnecessary or unused electrically conductive materials external to the patient should be removed from the MR system before the onset of imaging [8]. It is insufficient to merely disconnect and leave unused, unnecessary electrically conductive devices, such as surface RF coils or ECG leads and electrodes, in the MR scanner with the patient during imaging. All electrical connections, such as those used for surface RF coils or patient interfaces used for physiological monitoring systems, must be visually checked by the scanning MR Technologist prior to each use to ensure the integrity of the thermal and/or electrical insulation.

Resonant wavelength-related heating of conductors. The length, orientation, shape, position, and inductance of any electrical conductor may be heated by the transmitted RF energy during an MRI exam. Even if only part of a conductor is within range of the transmitted RF radiation, substantial unsafe heating can result. While heating concerns generally increase with stronger magnetic fields and longer conductors, specific conductor lengths, orientations, and other settings can lead to resonant spikes in induced current.

Virtually any conductor lengths of more than a few centimeters can produce substantial heating under certain conditions [24].

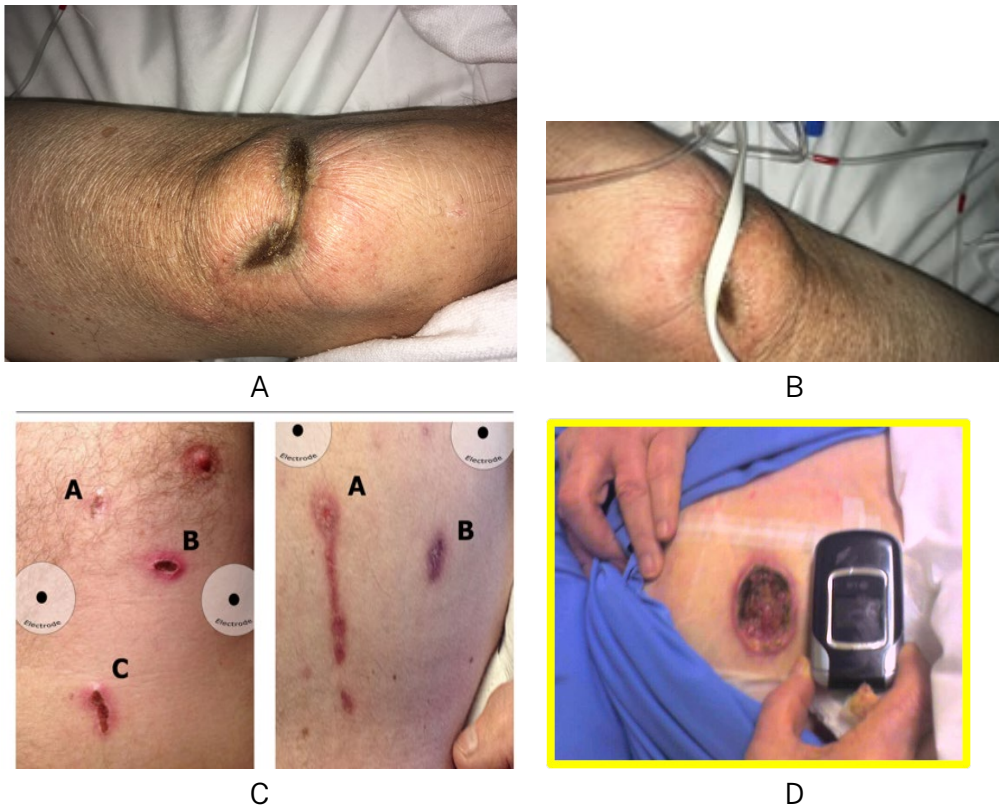
Internal. Very rapid and clinically significant internal lead heating can occur due to RF deposition. Especially at the uninsulated lead tips, this can occur in a matter of seconds with a magnitude sufficient to result in serious thermal injury [8]. Residual or abandoned implanted leads or wires that are not connected to any other device are also prone to substantial heating under certain conditions [25]. For example, while it has been demonstrated in vitro that the heating of certain implants or wires may be clinically insignificant at 1.5 T but quite significant at 3 T, the converse can also be true in some circumstances in which specific implants might demonstrate no significant heating at 3 T/128 MHz but may heat to clinically significant levels in seconds at 1.5 T/64 MHz [25]. Thus, it is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to the static magnetic field strengths and frequencies at which they have been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating in which no or insignificant heating had been observed at the tested field strength(s). **For example, if MR Conditional labeling specifies 3 T, it cannot be assumed that similar scanning parameters at 1.5 T are safe for the patient.**

It is possible to substantially reduce RF exposure to implanted leads with the use of transmit-receive RF coils located at distant anatomic sites relative to implanted devices. For example, a patient with an abandoned spinal cord stimulator lead located a sufficient distance from the head is likely able to safely undergo a head MRI using a transmit-receive head RF coil without risk of RF heating of the stimulator. Other transmit-receive RF coils, including wrist, knee, ankle, etc., may be used in similar situations to limit RF deposition to implanted devices and leads [26].

There are devices available that can be used to shape the RF-field, such as RF-shielding blankets or RF shim pads. These can be potentially unsafe since electric fields are shifted to their edges where there could be interaction with adjacent tissue (heating). These devices should be used with caution and in accordance with their FDA approved instructions for use.

External. When any portion of electrically conductive materials external to the patient are required to be within the volume of the transmitting RF coil during imaging, thermal insulation

(including air, pads, etc.) should be placed between the patient and the electrically conductive material to minimize any contact with the patient. It is also appropriate to position the leads or wires as far as possible from the inner bore walls along the midline central long axis of the MR scanner if the body RF coil is being used for RF transmission [27]. When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or sealed ice packs to such contact areas. If using detachable transmit-receive coils (e.g., head, wrist, knee, etc.), the risk of the heating of external leads can be substantially diminished [26,28].



Examples of RF field–associated burns are provided in Figure 14.

FIGURE 14. Examples of serious tissue burns resulting from RF-related heating during MRI exams. (A) Healing third degree burn at patient's knee. (B) Reenactment of path of an arterial pressure transducer extension cable within the RF field that crossed an anesthetized patient's knee during an interventional MR procedure. Subsequent testing with the cable in that configuration demonstrated that the turbo spin-echo pulse sequences with whole body–averaged SARs of approximately 2 W/kg produced localized heating approaching 30° Celsius. (C) Skin burns caused by ECG electrode lead heating during MRI. The reader is referred to [25] for details. Figure used with permission. (D) Third degree burn resulting from RF-related heating of a material (i.e., cell phone) *courtesy of Frank G. Shellock, PhD.*

Special considerations for RF field–related thermal issues

Electrically conductive clothing. Some materials used in clothing have been increasingly associated with thermal injury and/or burns in patients undergoing MRI. Recent trends in the manufacturing of clothing and other related products have incorporated metallic and conductive materials (e.g., antimicrobial silver and copper) that are not reliably disclosed in labeling [29]. Such clothing products include, but are not limited to, sportswear (including

underwear), brassieres, orthotic-related items (e.g., stump covers or stump shrinkers), and blankets [8,30]. Reliance on clothing labeling is not sufficient, as the Federal Trade Commission guidelines allow clothing to contain impurities at levels as high as 5%, which could be significant for a patient undergoing an MR examination [31]. For anatomic regions within or near the volume undergoing direct RF (B_1) field irradiation, to avoid such thermal concerns, we recommend gowning patients to skin, wearing only MR Safe pocketless garments supplied by the imaging facility.

Skin staples, multiple dermal implants, or piercings in proximity to each other. In general, although the thermal risks associated with individual small dermal implants (i.e., skin staples, superficial metallic sutures, piercings that cannot be removed) are quite small, dermal implants that are in close proximity or directly contact one another may increase the risk of thermal injury. If the items are inside the MR bore and the built-in body coil is being used for transmission, several precautions are recommended.

a. The patient should be instructed to report immediately if they experience warmth or burning sensations during the study by verbally alerting the technologist or using the technologist notification device (i.e., squeeze ball) and not wait until the end of the MR sequence.
b. The application of cold compresses or sealed ice packs may be helpful.

Alternatively, the use of a transmit-receive RF coil may be used to avoid RF irradiation of the dermal implants in a different part of the body inside the bore of the scanner (e.g., transmit-receive RF head coil for a brain MRI exam in a patient with unremovable umbilical piercings).

Patients with tattoos within range of RF transmission. Extensive, dark, or loop-shaped tattoos or tattooed eyeliner may increase the potential for RF heating. Patients should be instructed to immediately report any discomfort during scanning. If appropriate, the placement of cold compresses or sealed ice packs should be considered. Parenthetically, although not an RF thermal concern, patients with tattoos that had been placed within 48 hours prior to the pending MR examination should be advised of the potential for a smearing or smudging of the edges of the freshly placed tattoo [32-36].

Drug-delivery patches and pads. Some drug-delivery patches contain metallic components. Scanning patients with such medication patches may result in thermal injury or alteration in drug-delivery rate by heating if the patch is within the volume of RF irradiation [37]. Options are to remove the patch, use a transmit-receive RF coil to scan a different anatomic region, or perform the MRI exam using low whole-body average SAR pulse sequences. Clinical implications of patch removal need to be assessed and reviewed by a Level 2 MR Physician.

In the case of clinically important drug-delivery patches, removal or repositioning may be considered following a consultation with the patient's prescribing physician. If the patch for a prescription medication is removed, an appropriate process must be in place to replace the medication (particularly for drugs that may cause undesired clinical symptoms or complications if not replaced in a timely manner).

An option to consider could include placing a cold compress or sealed ice pack directly on the medication patch, recognizing this could substantially alter the rate of delivery or absorption of the medication and possibly be less comfortable for the patient.

KEY POINTS

- Time-varying RF magnetic field
  - RF burns are the most commonly reported adverse events in MR.
  - Remove all removable electrically conductive materials from the patient prior to imaging.
  - Insulation and appropriate distance should be placed between the patient and any external conductive material, including the bore wall.
  - Avoid large diameter electrically conducting loops, including patient tissue.
  - Avoid skin-to-skin contact, especially small contact areas, completing large caliber body loops.
  - Currents can be induced within conductive materials.
    - Any conductor of more than a few centimeters may produce substantial heating, which may increase rapidly depending on its specific length, orientation, and position due to resonant heating.
      - Follow established product MR Conditional labeling and safety guidelines carefully and precisely.
      - Position any leads or wires as far as possible from the inner bore walls along the midline central long axis of the MR scanner if the body coil is being used for RF transmission.
    - Metallic clothing can cause injury.
      - Reliance on clothing labeling is not sufficient.
      - MR Safe pocketless garments supplied by the facility are recommended.
    - Dermal implants that are in close proximity or directly contacting one another may increase the risk of thermal injury.
      - Tattoos can heat.
      - Consider cold compresses.
    - Drug-delivery patches can contain metallic components, which may result in thermal injury and/or alterations in drug-delivery rate.
    - MR Conditional labeling at a specified field strength does not imply MR conditions at other field strengths.
    - Detachable transmit-receive coils can reduce the risk of heating in specific clinical scenarios.
  - SAR estimates the rate of absorption of RF energy.
    - SAR limits are designed to manage RF heating of tissue.
    - Normal Operating Mode can reduce the risk of whole-body heating but does not necessarily eliminate the risk of burns.
    - First Level Controlled Operating Mode may increase risk and requires medical supervision (see discussion of Operating Modes in PNS)
  - SED refers to total energy absorbed.
    - SED limits are a means to protect a patient from adverse events related to core temperature elevation over time.
    - Shorter sequence length and cooling-off periods between sequences can reduce risk.
    - SA is a newer synonymous term that may replace SED.

Time-Varying Gradient Magnetic Field

Spatial localization of MR signal employs time-varying gradient magnetic fields that are rapidly alternated and varied over time and are often described by their temporal rate of change, dB/dt. A sample time-varying gradient magnetic field is shown in Figure 15; these fields can vary with pulse sequences employed, and so associated safety considerations should be recognized on an exam-specific (and implant-specific) basis.

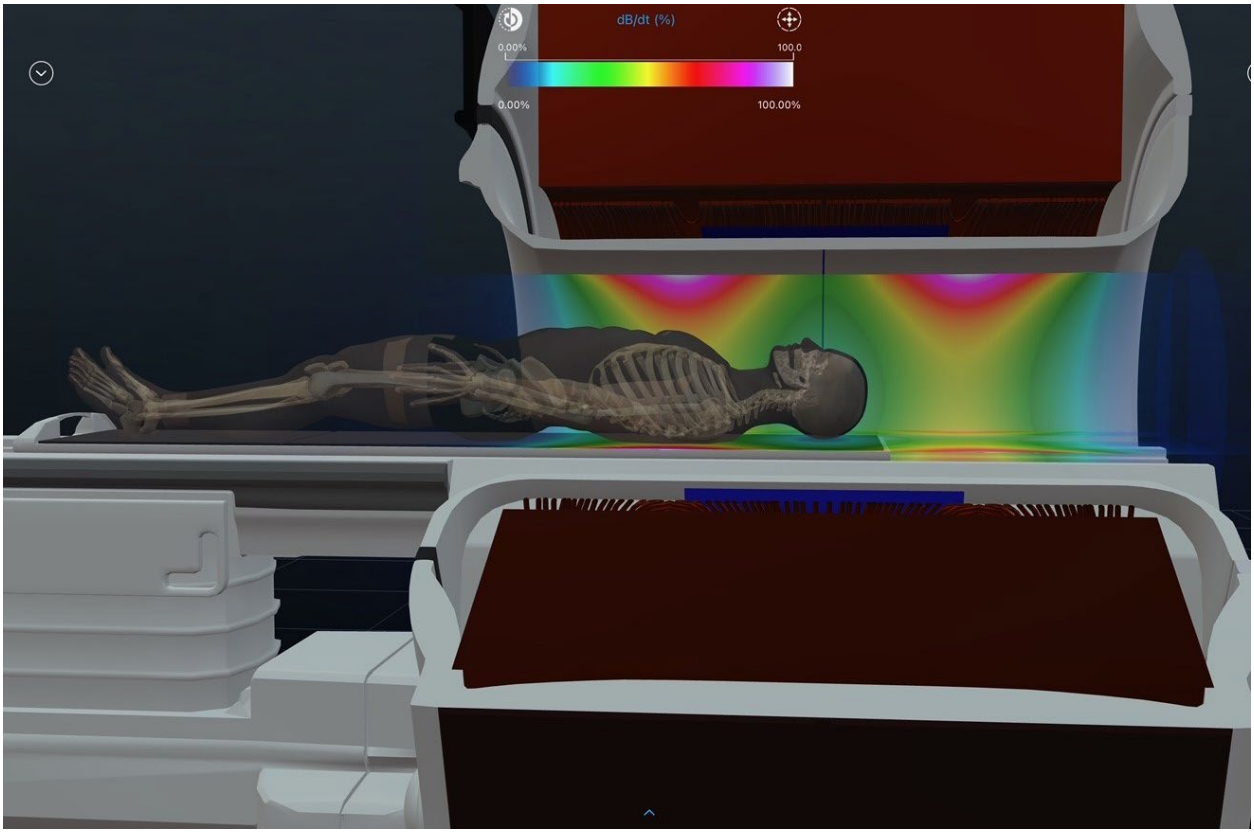


FIGURE 15. 3-D depiction of the time-varying gradient magnetic fields dB/dt in a 1.5-T MR scanner. The near side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed 3-dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the time-varying gradient magnetic fields dB/dt is depicted. Note that when the patient's brain is positioned at the MR isocenter, the greatest dB/dt values are over the chest of this patient, right where a cardiac pacemaker might be positioned. *(Courtesy of Emanuel Kanal, MD, created using MagnetVision, Advanced Magnetic Analytics, LLC)*

Auditory considerations. Acoustic noise is generated by the switching of the time-varying gradient magnetic fields. It is recommended that all patients and research volunteers use hearing protection when appropriate [38]. MRI sequences that are not FDA cleared should not be performed on patients or research volunteers without hearing protection in place. The FDA considers MRI systems capable of producing sound pressures that exceed 99 A-weighted decibels (dB(A)) with hearing protection in place as a significant risk [12]. The IEC standard on this issue (IEC 60601-2-33:2022) [1] also states that, for all equipment capable of producing more than an A-weighted root-mean-square sound pressure level of 99 dB(A), hearing protection should reduce the sound pressure level below that threshold for the safety of the

patient. Hearing protection frequently needs to be in excess of 28 to 30 dB(A) given the loudness of some contemporary magnets and sequences. Manufacturer instructions for use should provide at least the minimum appropriate level of hearing protection.

It is important that staff are thoroughly trained on the proper placement of ear plugs and use of other types of hearing protection. Staff should work with all persons receiving the hearing protection to ensure proper placement and to verify fit and function of the hearing protection prior to the MR examination. Hearing must be adequately protected concurrent with being able to adequately hear patient instructions, etc. In the event a patient refuses hearing protection, sites should have a process and procedure in place to discuss the risks of proceeding without the protection and may consider canceling the examination.

All patients or research volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been cleared by the FDA) should also have hearing protective devices in place prior to initiating any MR sequences.

Peripheral neural stimulation. Nerve and muscle cells can be stimulated by currents induced by the time-varying gradient magnetic field. The resulting sensation ranges from tingling to muscle contractions and generally presents minimal discomfort or danger to the patient. The magnitude of the stimulation is a function of the pulse characteristics and repetition rate. Concerns related to this are addressed in the IEC standard 60601-2-33 [1], which defines different scanning modes. Clinical scanners are usually restricted to the Normal Operating Mode and the First Level Controlled Operating Mode.

The IEC standard 60601-2-33 [1] defines 3 modes for scanning:

1. Normal Operating Mode: mode of operation of the MR equipment in which none of the outputs has a value that may cause physiologic stress to patients. (Outputs refer to the magnitude of the magnetic fields.)
2. First Level Controlled Operating Mode: mode of operations of the MR equipment in which 1 or more outputs reach a value that may cause physiologic stress to patients that needs to be controlled by medical supervision.
    a. Software allowing access to this mode must require specific acknowledgement by the operator that the First Level Controlled Operating Mode has been entered.
3. Second Level Controlled Operating Mode: mode of operation of the MR equipment in which 1 or more outputs reach a value that may produce significant risk for patients in which explicit ethical approval is required (i.e., a human subject research protocol approved to local requirements).

In Normal Operating Mode, the gradient system shall operate at a level that does not exceed 80% of the mean threshold for peripheral neural stimulation (PNS), in which the threshold for PNS is defined as the onset of sensation.

In First Level Controlled Operating Mode, the gradient system shall operate at a level that does not exceed 100% of the directly determined mean threshold for PNS.

Induced voltages. Patients with implanted or retained wires and leads in anatomically or functionally sensitive areas (e.g., myocardium, implanted electrodes in the brain, adjacent to the spinal cord, etc.) should be considered higher risk, especially from faster MRI pulse sequences

such as echo-planar imaging (i.e., often used with diffusion-weighted imaging), functional imaging, perfusion-weighted imaging, MR angiographic imaging, etc. that require a rapid variation of the gradient magnetic fields. These risks include whether the lead/wire is directly exposed to the time-varying gradient magnetic fields or may be part of an anticipated induced current pathway. The decision to alter the rate of magnetic field change (dB/dt) and the maximum strength of the magnetic field of the gradient subsystems during the imaging of such patients should be reviewed by the Level 2 MR Physician supervising the patient with attention to the MR conditions of scanning.

Additionally, time-varying gradient magnetic field–induced voltages can potentially be induced in implanted devices, possibly causing implant vibration, active device damage/malfunction/incorrect sensing, or even device and tissue heating [39-41].

KEY POINTS

- Time-varying gradient magnetic field (dB/dt)
  - The rapidly switched magnetic field gradients used during imaging may result in uncomfortable or painful PNS. MRI operators can reduce the probability of PNS by employing Normal Operating Mode for dB/dt versus First Level Controlled Operating Mode.
  - The rapid switching of this field can also result in peak acoustic noise in the MR suite, requiring appropriately positioned hearing protection to minimize discomfort and the potential for auditory damage.
  - Additionally, devices and implants in this field may experience induced voltages, vibration, damage, and (in some cases) additional heating. MR operators should be able to understand and apply recommended dB/dt limits for devices using information provided by the MR vendor.

KEY ABBREVIATIONS

B_0: static magnetic field

B_1: time-varying radiofrequency magnetic field

B_1+_{rms}: radiofrequency magnetic field + root mean square

dB(A): A-weighted decibels

dB/dt: time-varying gradient magnetic field

ECG: electrocardiogram

FDA: Food and Drug Administration

G/cm: gauss per centimeter

IEC: International Electrotechnical Commission

MHz: megahertz

MHD: magnetohydrodynamic

PNS: peripheral nerve stimulation

RF: radiofrequency

SA: specific absorption

SAR: specific absorption rate

SED: specific energy dose

SFG: spatial field gradient

T/m: tesla per meter

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CHAPTER 9:
MR Contrast Agents

No patient is to be administered prescription MR contrast agents, typically gadolinium-based contrast media (GBCM), without orders from a licensed physician or advanced practice provider practicing under a supervising physician [1]. Research study participants may receive MR contrast agents as directed by the study protocol after they agree to enroll in the study that has undergone ethics committee (i.e., institutional review board) approval and sign the appropriate informed consent (and assent, as appropriate). Qualified MR Personnel may establish and attend peripheral intravenous (IV) access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area. IV injection–qualified MR Personnel may administer MR GBCMs via peripheral IV routes as a bolus or slow or continuous injection as directed by the orders of a licensed site physician or advanced practice provider.

Practices relating to the administration of these agents and recommendations regarding GBCM usage, adverse reactions, nephrogenic systemic fibrosis, and retained or residual gadolinium in the body should follow the ACR Committee on Drugs and Contrast Media [2]. The most recent version of the ACR Manual on Contrast Media may be downloaded from the ACR website at Contrast Manual | American College of Radiology (acr.org).

KEY POINTS

- No patient is to be administered prescription MR contrast agents without orders from a licensed physician or advanced practice provider.
- Practices relating to the administration of these agents and recommendations regarding GBCM usage, adverse reactions, nephrogenic systemic fibrosis, and retained or residual gadolinium in the body should follow the Contrast Manual | American College of Radiology (acr.org).

KEY ABBREVIATIONS

ACR: American College of Radiology

APP: advanced practice provider

GBCM: gadolinium-based contrast media

IV: intravenous

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CHAPTER 10:
Classification of Objects and Medical Implants and Devices in The MR Environment

This chapter will focus on the classification of materials/objects in the MR environment and ensuring safety. These fall into 2 major categories:

1. Patient support equipment and portable items such as ventilators, physiological monitors, anesthesia machines, infusion pumps, intravenous poles, wheelchairs, step stools, and others. Chapter 11 provides additional information on these objects and equipment.
2. Medical devices directly related to the patient, including implanted devices (e.g., cardiac pacemakers, aneurysm clips, etc.) as well as on-planted devices (external insulin pumps, continuous glucose monitoring devices, etc.). Several implanted devices are discussed in detail in Chapter 12.

Items that are not required for the care of a patient during the acquisition of their MRI examination should not enter Zone IV until the patient has been removed fully from the scanner room.

Recognizing the manufacturer's MR safety labeling, as part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (>1000 G) and/or a ferromagnetic detection system. This will enable the site to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces. The use of conventional metal detectors that do not differentiate between ferromagnetic and nonferromagnetic materials is not recommended.

MR Safety Labeling Classifications

Throughout this manual, the standard MR labeling terms (*MR Safe*, *MR Conditional*, and *MR Unsafe*) designated by American Society for Testing Materials (ASTM) International, *ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment*, [1] and adopted by the FDA (Figure 16) are used. These designations can apply to objects peripheral to the patient as well as implanted/on-planted devices.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as *nonmagnetic* or outdated classifications such as *MR compatible* should not be presumed to conform to a particular current ASTM International and FDA classification. Similarly, any product with metallic construction or components cannot by definition be MR Safe and must be considered as MR Unsafe or possibly MR Conditional. Objects intended for use in Zone IV, including nonclinical incidental products such as step stools or ladders, which are not accompanied by manufacturer or third-party MR safety test results under the ASTM International Standard F2503 criteria, should be site tested as described in MR Conditional.

FIGURE 16. FDA labeling criteria developed by ASTM International for objects and devices taken into Zone IV [1,2]. The square green MR Safe label is for nonmetallic, nonconducting objects; the triangular yellow label is for objects with MR Conditional labeling; and the round red label is for MR Unsafe objects. Alternatively, these symbols may be printed as black and white icons [1,2].

MR Safe  . *A designation indicating that the object or device is safe in all MR environments, without conditions*. The term "MR Safe" is reserved for items that are composed of materials that are nonmetallic, nonconducting, and nonmagnetic; such objects pose no known hazards during or resulting from exposure to any MR environment.

MR Conditional  . A designation indicating that the object or device has been demonstrated to be safely used within the MR environment, provided the specified conditions for safe use (as provided by the manufacturer) are met. When making decisions based on published MR Conditional or safety claims, one should recognize that all such claims only apply to the tested precise model, make, and identification of the object/item as tested to be safe under the specified conditions within the MR environment; these include the defined conditions for the tested static magnetic field strength (B_0) and spatial field gradient strengths, the radiofrequency fields (B_1), and the time-varying gradient magnetic fields (dB/dt). An example is provided in the statement, "MR Conditional having been tested to be safe at 3 T for a maximum spatial field gradient of 30 T/m (3000 G/cm) or less and the Normal Operating Mode (regarding RF output)."

Implant or device MR safety information must be documented in writing or in the medical record. Decisions based on published MR safety information should recognize that all safety claims regarding MR Conditional devices apply only to specifically tested conditions, such as the static magnetic field strength (B_0), the exposure of the device to the spatial field gradient, the strength and duration of the transmitted radiofrequency field (B_1), and the rate of change of the time-varying gradient magnetic fields (dB/dt).

TABLE 4. A summary of common MR safety conditions specified in the device vendor instructions for use

Example specified conditions	Example values for generic active implanted medical device (whole-body transmit)
Device	
Allowed devices	Implantable pulse generator (IPG) and lead model(s)
Allowed configurations	Allowed IPG and lead model combination(s) for all conditions that follow
Implant configuration	IPG in upper buttock, low back, flank, abdomen, or midline Lead tip in the epidural space between the T7 and T12 vertebrae
Device status	Make sure IPG and patient controller fully charged
	No broken leads and lead impedance within specified parameters
Device mode	Set device to the MRI Mode
MR system	
Configuration	Cylindrical bore with horizontal field
Field strength(s)	1.5 T or 3.0 T
Maximum spatial field gradient	25 mT/m (2500 gauss/cm)
Maximum gradient slew rate	200 T/m/s (per axis)
Radiofrequency (RF) transmit equipment	
Frequency	Hydrogen (^{1}H) nuclei only
RF coil(s)	Integrated whole-body transmit
RF transmit mode	Circularly polarized or Multichannel-2 (MC-2)
Scan regions	Any landmark acceptable
RF exposure	(For specific IPG and lead model combinations)
Anatomic scan region A	Isocenter superior to C7
RF output limits	For 1.5-T MR scanner: Normal Operating Mode (whole-body specific absorption rate (SAR) $\leq$2 W/kg)
	For 3.0-T MR scanner: Normal Operating Mode (whole-body SAR $\leq$2 W/kg)
Anatomic scan region B	Isocenter inferior to C7

RF output limits	For 1.5-T MR scanner: Normal Operating Mode (whole-body SAR ≤2 W/kg) For 3.0-T MR scanner: $B_1^+{}_{rms}$ ≤1.7 mT or whole-body SAR ≤1.2 W/kg
Scan duration	Active scan time ≤30 minutes per session with 30 minutes between sessions
Receive RF coil	Any
Image artifacts	Signal loss expected up to 5 cm from IPG using a spin-echo acquisition Some manipulation of scan parameters may be needed to compensate
Patient	
Positioning/orientation	Supine or prone
Thermoregulatory status	Patient should not have a fever. Do not cover patient with a blanket
Cognitive status	Patient can notify MR Personnel immediately if any discomfort, pain, heating, stimulation, or vibration is experienced
Monitoring	Visually and audibly monitor the patient, including verbal communication

NOTE: The table is populated with example values for safely scanning a patient with a generic active implanted medical device that has leads (e.g., neuromodulation system, pacemaker, defibrillator, etc.) that has conditions for full-body imaging. This example is intended to highlight key conditions and not represent any specific device [2].

MR Unsafe  . An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

Object/device alteration. Alterations performed by the facility on MR Safe, MR Unsafe, and MR Conditional equipment or devices may change the MR safety properties of the device. For example, tying a ferromagnetic metallic twisting wire/binder onto a sign labeling the device as MR Conditional or MR Safe might result in safety issues or image artifacts if introduced into the MR scanning environment. It is critical to always establish that immediately following repairs or modifications or maintenance of MR Conditional object/items/devices, these items are again confirmed to be safe within the MR environment as defined under the originally specified testing conditions. Hence, maintenance and repair of MR Conditional devices must include reconfirmation of the MR Conditional labeling information.

KEY POINTS

- Classifications
  - MR Safe: the object or device is safe in all MR environments (must be nonmetallic, nonconducting, and nonmagnetic).
  - MR Conditional: the object or device may be safe in the MR environment if conditions for safe use are met.
  - MR Unsafe: the object or device presents safety risks in the MR environment.

KEY ABBREVIATIONS

ASTM: American Society for Testing Materials

B_0: static magnetic field

B_1: time-varying radiofrequency magnetic field

B_1+_{rms}: radiofrequency magnetic field + root mean square

dB/dt: time-varying gradient magnetic field

FMDS: ferromagnetic detection systems

FDA: Food and Drug Administration

G: gauss

G/cm: gauss per centimeter

IFU: instructions for use

IPG: implantable pulse generator

MC: multichannel

mT: millitesla

References

1. American Society for Testing Materials International. Standard practice for marking medical devices and other items for safety in the magnetic resonance environment. Published October 24, 2023. Accessed April 22, 2024. doi: 10.1520/F2503-23E01
2. US Food and Drug Administration. Testing and labeling medical devices for safety in the magnetic resonance (MR) environment: guidance for industry and Food and Drug Administration staff. Published October 10, 2023. Accessed April 22, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment

CHAPTER 11:
Introducing Portable Metallic Objects and Equipment Into Zone III and Zone IV

Labeling and Testing

All sites should have ready access to a strong handheld magnet (>1000 G) and/or a ferromagnetic detection device for testing purposes.

All *portable* metallic or partially metallic objects intended to be stored/located in Zone III/IV are to be properly labeled as MR Unsafe  or MR Conditional  prior to permitting them into Zone III when practical based on size/mass (e.g., pens, paperclips).

Never assume an MR Conditional or MR Safe status of an object unless it has been tested. The results of such testing, as well as the date, time, name of the tester, and methodology used for that particular object, should be documented in writing. If an object has not been tested or if its MR safety status is unknown, it should not be permitted unrestricted access into Zone III.

Zone III areas typically house electrically active stationary computers, printers, etc., that are not intended to enter Zone IV. MR safety testing and labeling are not required for such stationary items.

The testing of objects that are not electrically activated (e.g., fire extinguishers, intravenous poles, oxygen tanks, step stools) is to be accomplished by MR Personnel exposing the object to a handheld magnet (>1000 G) or ferromagnetic detector. If grossly detectable ferromagnetic properties are observed, it is to be labeled with a circular red MR Unsafe label  . If none are observed, the object may be a candidate for a triangular yellow MR Conditional label  , which can be used in specific locations and scenarios in the room that do not adversely impact the function of the device nor introduce other safety hazards (i.e., conducting materials). It is only when the composition of an object and its components are known to be nonmetallic, nonconducting, and nonmagnetic that the green MR Safe label  is to be affixed to a device or object.

MR Unsafe Transport Equipment — Temporary Provisions

MR Unsafe transport equipment (e.g., wheelchairs, gurneys) may be brought into Zone III under specific **temporary** circumstances if they are deemed by MR Personnel to be necessary and appropriate for patient care (e.g., minimize patient transfers in medically compromised patients, etc.) and conscientiously secured to ensure that they do not pose a projectile risk. This equipment should only be brought into Zone III if it is under the direct supervision of specifically designated MR Personnel who are thoroughly familiar with the equipment, its function, and the reason supporting its introduction into Zone III. These devices must be appropriately physically secured, tethered, or restricted at all times within Zone III to ensure that they never pose a projectile risk (as in Figure 17 and Figure 18).

FIGURE 17. Tethering of an MR Unsafe gurney to a fixed anchor point in Zone III.

FIGURE 18. An example of a stop sign reminder that the tethered equipment cannot be taken into the magnet room.

Portable Objects in Zone IV

In general, objects that are not required for the immediate care of a patient should not enter Zone IV if a patient is occupying the room. For example, introducing an MR Conditional ventilator into Zone IV should be done prior to a patient occupying the room. To the extent possible, it may be beneficial for the patient to be last in and first out of Zone IV with respect to external objects.

All portable metallic objects that are to be brought into Zone IV must be properly labeled as MR Conditional or MR Unsafe. MR Conditional objects should be obtained instead of MR Unsafe objects when necessary for use within Zone IV. Items that are clearly made of ferrous materials or otherwise deemed unsafe should be identified as MR Unsafe and labeled appropriately with the corresponding round label. Proper precautions including tethering must be taken to prevent an MR Unsafe object from becoming a dangerous projectile (see MR Conditional External Nonimplanted Devices (Zone IV) in Appendix 2). It is advisable to position these objects in Zone IV when patients and staff are not occupying the room. If the patient is already in the MR scanner, if feasible, remove the patient from the bore of the magnet prior to object transport. Objects with an MR Conditional status should be affixed with a triangular MR Conditional label prior to being brought into the scan room/Zone IV (Figure 19 and Figure 20) and the conditions clearly documented and communicated.

FIGURE 19. Tethering and placement of anesthesia equipment in Zone IV. Note the tether (black arrow) and the 200-gauss line (yellow arrow).

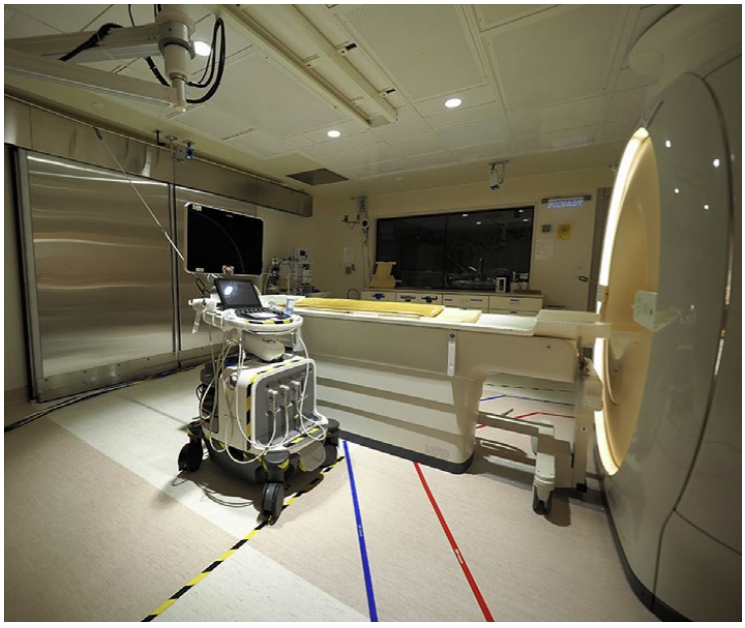

FIGURE 20. Tethering of an appropriately labeled MR Unsafe ultrasound equipment in a hybrid procedural suite, preventing it from crossing the black and yellow striped line. The ultrasound system is positioned beyond the 100-gauss (blue line) and 300-gauss (red line) areas. The intention of the tether is to prevent the ultrasound system from entering a fringe field that would cause it to become a projectile. Extensive physics testing was performed on the ultrasound equipment, verifying its safe location as pictured, prior to its deployment in Zone IV. (Figure used with permission of the Mayo Clinic Foundation for Medical Education and Research, all rights reserved.)

FIGURE 21 illustrates a typical configuration of an MR system and associated equipment in an inpatient facility.

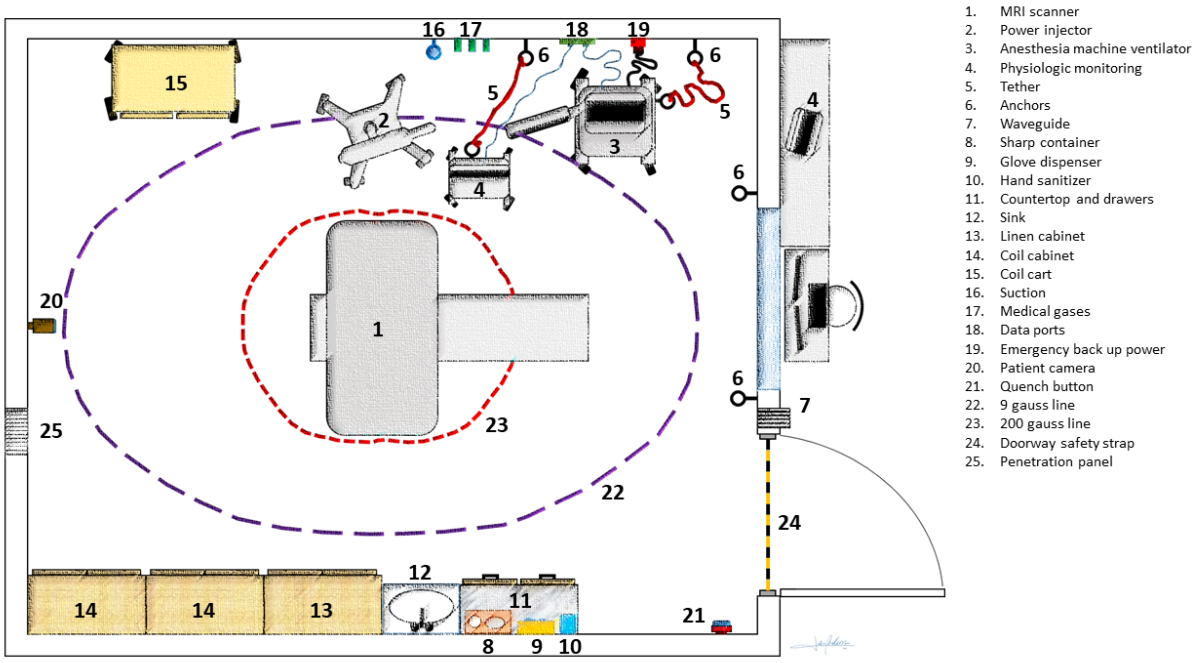

FIGURE 21. Typical configuration of an MR system in an inpatient facility. The design of Zone IV should consider the optimal workflow during more complex MR examinations, such as those requiring anesthesia. It is recommended that dedicated space is devoted to the anesthesia ventilator and physiologic patient monitoring equipment, typically away from the door. Similarly, anesthesiologists, nurses, respiratory technicians, and other personnel supporting the patient must have dedicated space to perform their functions. A clear path between the scanner door and the patient ensures easy access to the patient by the MR Technologist and nursing and a route for fast transportation of the patient out of Zone IV in the event of a medical emergency. In addition to the 9-gauss line marking on the floor, a 200-gauss line is recommended since this limit is often stipulated in labeling for MR Conditional equipment frequently used in Zone IV. Reliable tethering prevents this equipment from crossing the 200-gauss line. This is an example configuration, and appropriate physics testing may be required for specific devices at any given facility.

MR scanning of hospitalized, higher-risk, or nonambulatory patients presents additional challenges. In many instances, these patients are too sick to enter Zone IV by themselves and must be transported into the MR scanner using an MR Conditional wheelchair or stretcher. Similarly, metallic objects used for patient care (e.g., needles, small oxygen tanks, sandbags with metal shot, etc.) may be inadvertently transported after being used at other locations in the facility and hidden around the patient (e.g., underneath sheets or within pillow covers). The full stop/final check is intended to mitigate these potential projectile risks. (Refer to Chapter 6: Full Stop/Final Check). Whenever possible, the transfer of these patients to the MR table should be done in Zone III (e.g., via a detachable MR table).

Cellphones. Cellphones in Zone III represent a particular challenge because they can become projectiles if brought into Zone IV and are ubiquitous and commonly used for routine work in Zone III. Facilities should develop policies and procedures to ensure that cellphones do not enter Zone IV (including potential use of pocketless scrubs, dedicated secured locations for their storage in Zone III, etc.).

Pocketless attire. Items commonly found in the pockets of personnel (cellphones, scissors, stethoscopes, and other small metallic objects without MR safety labeling, etc.) present additional projectile risks. MR Safe pocketless garments should be strongly considered for use by all individuals entering Zone IV to mitigate projectile risks (Figure 22). Pocketless attire is recommended for those MR Personnel that regularly work in Zone IV on a daily basis. Existing attire can be made functionally pocketless by oversewing the pockets. Due to potential issues at institutional laundries in accurately separating pocketless from pocketed attire, having them uniquely colored or conspicuously labeled/emblazoned will ensure the ability to readily identify these garments. Unique MR Personnel attire would also be anticipated to aid rapid identification of MR Personnel from non-MR Personnel.

FIGURE 22. Example of pocketless scrub attire.

KEY POINTS

- Processes/procedures to decrease projectile risk from portable equipment/devices:
  - Employ a ferromagnetic detection system.
  - Employ Zone IV doorway protection closed/strap/other barrier.
  - Incorporate full stop/final check standard operating procedure.
  - Deploy MR Safe or MR Conditional equipment/devices in Zone IV when possible. The use of MR Conditional equipment must follow the specified conditions.
  - Tether MR Unsafe items in Zone III and Zone IV.
  - Provide MR Safe pocketless attire to patients/research participants, MR Personnel, and any other personnel required to work in Zone IV.
  - Employ proper American Society for Testing Materials MR safety labeling of equipment in Zone III and Zone IV.
  - Employ proper and effective screening of all staff, research subjects, and patients, including MR Personnel, before crossing into Zone IV.
  - Ensure that all non-MR Personnel granted access to Zone III are closely monitored by and remain the consistent responsibility of Level 2 MR Personnel.
  - Ensure that entry into Zone IV is appropriately secured when the area is unsupervised.
  - Position external objects prior to patient entry to Zone IV.
  - Remove the patient from Zone IV prior to removing or manipulating objects whenever possible.

KEY ABBREVIATIONS

ASTM: American Society for Testing Materials

G: gauss

Chapter 12:
Managing Patients and Research Subjects With Medical Implants and Devices In The MR Environment

Some devices, both active and passive, may require adjustments before and after the MRI to ensure a safe completion of the MR examination and adequate functioning of the device. The number of such devices continues to increase and requires MRI facilities to develop specific standard operating procedures (SOPs), frequently in conjunction with the referring physicians. Adequate management during and after the MR scan should include an assessment of the device, programming for MR scanning, and a post-scan reprogramming or check. Facilities must ensure access to properly trained personnel both inside and outside radiology (i.e., cardiology, electrophysiology, pain medicine, vendor representative, etc.) to meet the MR safety conditions as specified by the instructions for use (IFU).

Active Implanted/On-planted Devices

Active implanted medical devices (AIMDs) contain an energy source such as a battery or have the ability to be inductively coupled [1,2]. In contrast to implanted devices, on-planted or external devices (e.g., external insulin pump, continuous glucose monitoring device, etc.) are located, at least partially, external to a patient's body.

An exhaustive discussion of the large number of AIMDs currently available is beyond the scope of this Manual. However, this Manual will summarize information for several AIMDs due to their frequency in the clinical environment and the important MR safety considerations related to these items.

All elements of an MR Conditional system must be present for the system to be MR Conditional. For example, an MR Conditional neurostimulation system is comprised of a MR Conditional pulse generator and MR Conditional leads. If any element of the system is not MR Conditional, the entire system is not MR Conditional.

Cardiac implantable electronic devices. Cardiac implantable electronic devices (CIEDs) have expanded in number and complexity since their introduction in 1958 and now include cardiac pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, cardiac contractility modulation therapy devices, implantable cardiovascular monitors (ICMs), and implantable loop recorders (ILRs). Cardiac pacemakers, which include implantable pulse generators (IPGs) and leads that are approved by the FDA and are labeled MR Conditional, became available in the United States in 2011. Since then, other commercially available CIEDs have been labeled MR Conditional, including ICDs, CRT devices, ILRs, and ICMs. IFU product inserts, identification cards for patients, manufacturer-maintained databases, lead and IPG identifiers visualized on plain radiographs, and operative notes may assist in the proper identification of MR Conditional CIEDs.

In patients who have implanted cardiac devices that have not been labeled MR Conditional, guidance regarding the performance of MR examinations is deferred to recommendations from the Heart Rhythm Society [3]. Key elements included in the document related to the scanning of

patients with CIEDs that have not been labeled MR Conditional include, but are not limited to the following:

- Institutional workflow/SOP with responsible MR Medical Director (MRMD) and CIED MD and a radiology/cardiology team approach.
- Medical necessity of the MR exam.
- Evaluation for fractured or abandoned leads. At times, the documentation in the electronic medical record for a patient with a history of a removed implanted CIED may not be entirely clear. A chest radiograph may be useful to determine the presence of abandoned leads.
- Electrocardiogram and pulse oximetry monitored during the MR examination.
- Defibrillator/monitor with external pacing available (outside Zone IV).
- Advanced cardiac life support personnel in attendance during the MR exam until the CIED is reprogrammed following the examination.
- CIED evaluation/programming immediately pre- and post-MRI.

Further information related to MRI scanning of patients with CIEDs has been provided by the ISMRM. [4]

Epicardial pacing wires. A distinction of the type, MR safety labeling, and location/alteration associated with epicardial leads is important for MR safety decision-making considerations. In the majority of cases, epicardial leads are associated with 2 major scenarios:

1. **Temporary epicardial pacing leads and remnants.** After cardiac surgery, these typically short, small caliber leads (wires) are placed and are tunneled through the mediastinum to traverse the chest wall to permit attachment to an external pulse generator in the event that it is necessary to support the patient with temporary pacing. While frequently these are completely extracted prior to patient discharge, not infrequently, some remnant remains, often cut/snipped and often extending to just below the skin surface (Figure 23). Previous publications have addressed performing MRI exams in this patient group [5,6]. In the typical clinical setting of a patient with a retained temporary epicardial lead fragment, the relatively short length together with lack of large conducting loops has not been shown to pose a barrier to scanning, with no adverse outcomes associated with this scenario reported to date. Postsurgical temporary epicardial leads that have been partially removed are not considered to be abandoned pacing leads according to the Heart Rhythm Society [3].

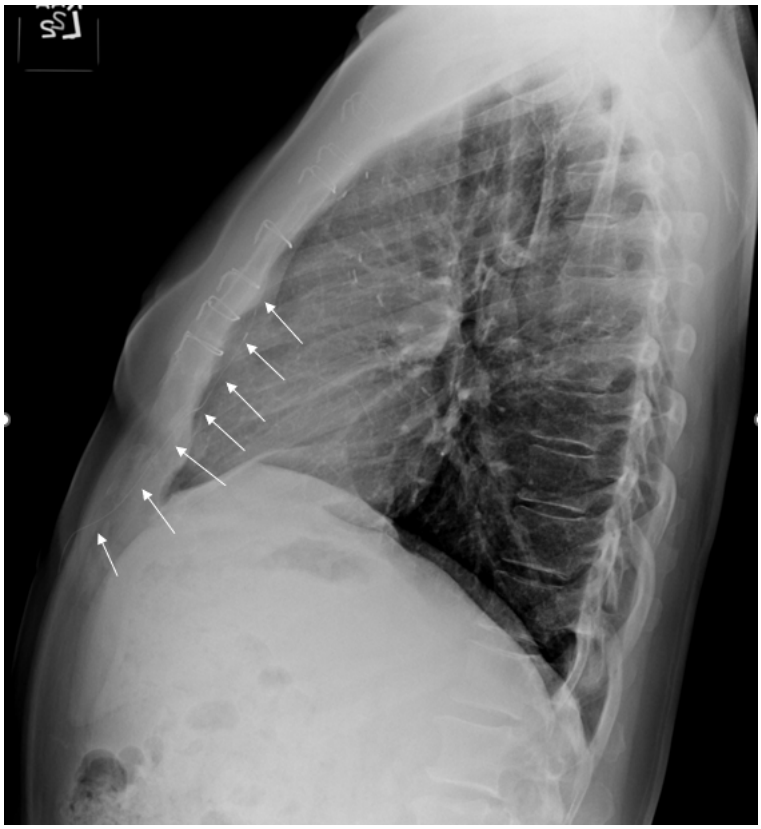

FIGURE 23. Lateral chest radiograph demonstrating a relatively short, temporary epicardial pacing lead (wire) remnant (white arrows). These have not been shown to be a barrier to scanning, without reported adverse events associated with these.

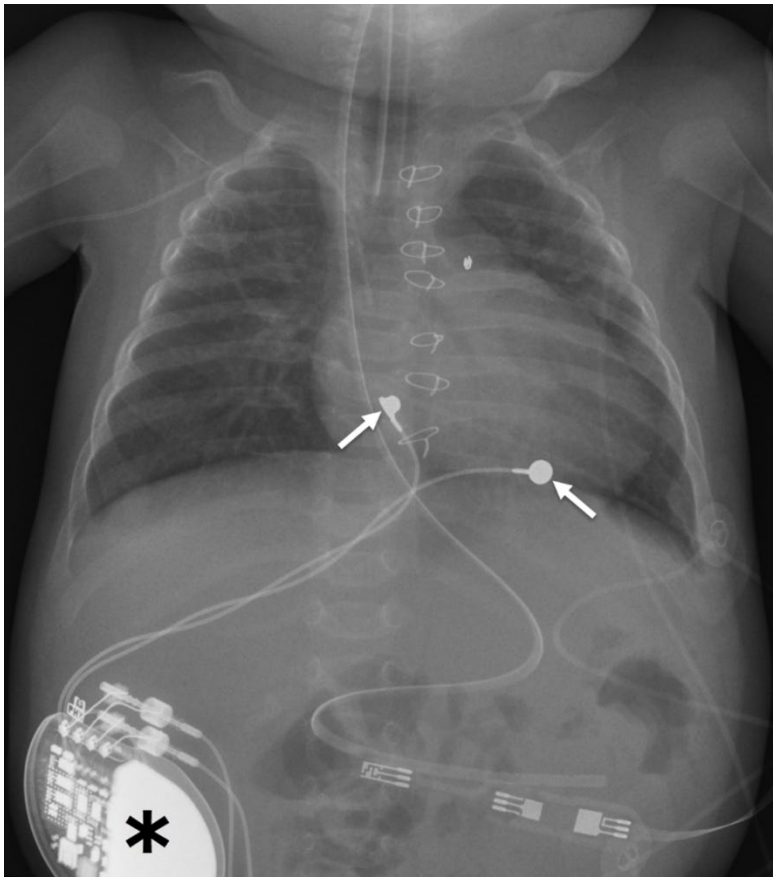

FIGURE 24. Typical appearance of permanent epicardial leads (white arrows). Note that these are typically larger caliber than the finer temporary epicardial leads that are used commonly in cardiac bypass and related surgeries as shown in Figure 23.

2. **Permanently implanted epicardial leads/CIEDs.** These permanent epicardial leads/CIEDs are often implanted in children or infants with congenital heart defects in whom endovascular access would be difficult or impossible (Figure 24 and Figure 25). Other applications are in those with infected endovascular CIEDs or endocarditis. Permanently implanted epicardial leads are typically of a larger caliber than temporary epicardial pacing leads, and these are combined with IPGs. As noted in the Heart Rhythm Society document, there are presently insufficient data to comment on the safety of MRI performance in the presence of permanent epicardial leads [3], although some recent studies have addressed this question [7,8].

Retained or abandoned endovascular and intracardiac leads. A typical appearance of abandoned endovascular and intracardiac leads is demonstrated in Figure 26. Also as noted in the Heart Rhythm Society document, there is insufficient data to comment on MR safety considerations in the presence of retained or abandoned endovascular and intracardiac leads [3]. A prior study demonstrated the possibility of substantial length-dependent lead tip heating. In addition, the attachment of leads to the pulse generator substantially affects heating at the lead tip [9]. Recent studies have investigated safety in patients with abandoned leads undergoing MRI with careful monitoring and other precautions [10,11]. As other studies emerge on abandoned leads, the recommendations in this manual may be modified.

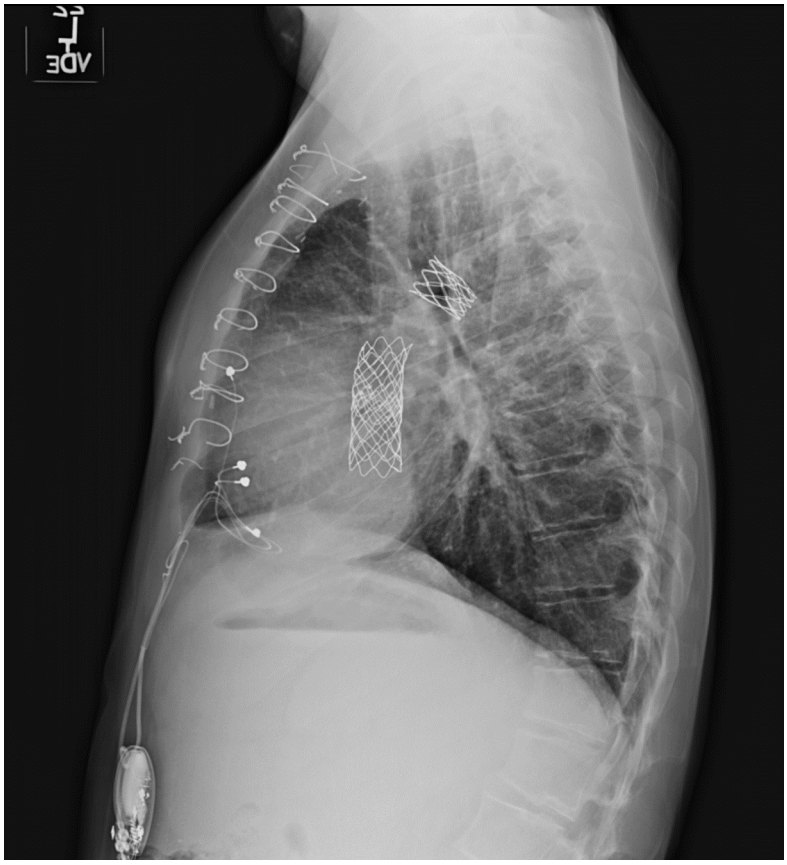

FIGURE 25. Lateral chest radiograph demonstrating relatively long permanently implanted epicardial leads (white arrows) and attached to a pulse generator.

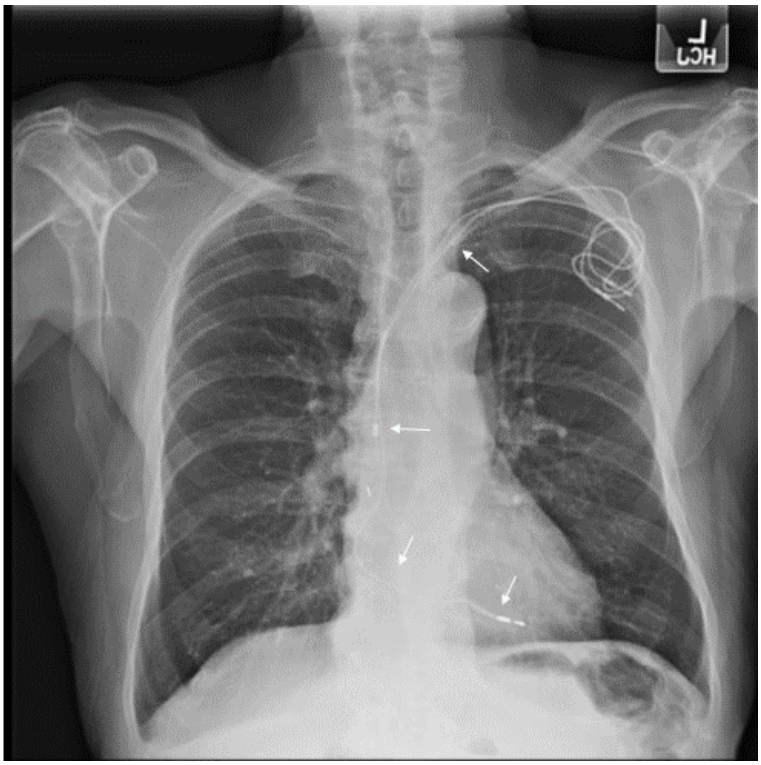

FIGURE 26. Radiograph demonstrating abandoned transvenous intracardiac leads (white arrows). For patients with a history of revision or removal of implanted electronic devices, cardiac or otherwise, radiographic screening prior to MR examination should be considered to evaluate for abandoned leads.

Neuromodulation systems. An increasing number of AIMDs used for neuromodulation are now available, designed to stimulate the central nervous system and peripheral nervous system targets for clinical benefit. These include deep brain stimulators, responsive neurostimulation systems, cochlear implants, spinal cord stimulator systems, vagus nerve stimulator systems, hypoglossal nerve stimulator systems, sacral nerve stimulator systems, and peripheral nerve stimulator systems [12].

Careful attention to the accurate identification of the precise make, model, and manufacturer as well as location of implantation of the leads and IPG for the AIMD is mandatory to ensure patient safety. Subtle differences in model numbers within a particular class of neurostimulation systems or a modification in how or where it is or was implanted can markedly change the scanning conditions, including a device changing from being MR Conditional to being MR Unsafe and posing a serious risk to the patient. Different model numbers within a particular type of neurostimulator class can be associated with the ability to use the transmit body RF coil as opposed to being restricted to transmit/receive RF coils such as those used for the head or knee.

It is frequently necessary to have current imaging to accurately confirm the location of IPG and lead systems as well as to evaluate for possible broken or abandoned leads. Increasingly, patients can present with more than 1 active implanted device, requiring thoughtful considerations of the conditions for safe scanning and frequently benefiting from a coordinated evaluation by the MR Safety Officer (MRSO), MR Safety Expert, and MRMD safety team. For MR Conditional neurostimulation systems, it is useful to contact the patient prior to their arrival to ensure that they bring the device programmer to allow the device to be programmed appropriately for scanning as needed. Facilities should incorporate SOPs, often including

Patient Eligibility forms or Patient Checklists, to ensure that all the necessary conditions for safe scanning are being met. Coordination with nonradiology subspecialty clinical teams can also be beneficial for post-MRI reprogramming of certain devices (e.g., vagus nerve stimulators).

Implantable infusion pumps. Implantable infusion pumps provide controlled delivery of medications primarily into the spinal subarachnoid space, with morphine and baclofen and their derivatives the most commonly infused agents for control of pain and spasticity, respectively. If MR conditions for safe scanning are not followed carefully, there is potential for patient injury or death that can be related to drug overdosage or potentially from interrupted drug infusion. Safety issues related to implantable infusion pumps in MRI were the subject of a 2017 FDA alert [13].

A number of deaths have occurred in association with MRI related to drug overdosing that are apparently attributable primarily to not adhering to MR conditions for safe scanning [14]. The drug reservoirs for some implantable infusion pumps must be entirely emptied of their contents prior to scanning, as the drug can be subject to uncontrolled release while in MRI, with potentially catastrophic results. For other devices, the motors are expected to stall in MRI, temporarily interrupting drug infusion, but occasionally the pump motors may not restart as expected following removal of the patient from the MR environment. This can pose significant clinical problems associated with unanticipated opioid withdrawal or clinically more dangerous baclofen withdrawal syndrome, which is associated with approximately 20% mortality [15]. For this reason, these infusion pumps must be evaluated to ensure they are operating properly following scanning. Other infusion pumps exist, including hepatic artery infusion pumps, that are MR Conditional primarily for the administration of chemotherapeutic agents.

Implantable and external insulin pumps. Due to increasingly widespread use, practices should be particularly vigilant for the presence of insulin pumps that can be implanted or worn externally (on planted). Presently, these devices are considered MR Unsafe due to the presence of ferrous materials and/or electronics that can be adversely impacted by the electromagnetic field used for MR. Importantly, if exposed to the MR environment, sensing and insulin delivery circuits may be temporarily or permanently damaged such that there may be dangerous physiologically unsafe insulin delivery that could lead to life-threatening hypo- or hyperglycemia [16]. For this reason, it is critical to positively identify diabetic patients in the screening process in an effort to further ensure reliable detection of these devices. If the patient has an implantable insulin pump, MRI is contraindicated. If the patient has an external insulin pump, the device must be removed from the patient prior to allowing the patient into the MR system room. Additionally, MR Personnel should be aware that internal and external insulin pumps are often used in association with continuous glucose monitoring devices, some of which are MR Unsafe and therefore require removal from the patient prior to entry into Zone IV.

Passive Implanted Devices

Passive implants and devices, unlike active devices, do not contain an intrinsic electrical power source. All passive implants that contain metal are by definition either MR Conditional or MR Unsafe. Common passive implants and devices include aneurysm clips, intravascular stents (vascular, ureteral, tracheal, esophageal, etc.), heart valve prostheses, orthopedic implants (plates, screws, pins, total hip prostheses, mesh, etc.), intraocular lens implants and glaucoma shunts, programmable and nonprogrammable ventricular shunts, and prostheses. The major

risks in MRI of these devices relate to the potential for electrical current induction, RF-associated heating, gradient-associated vibration or heating, magnetic field–associated translation and torque, and possible Lenz-related forces. Some devices, such as certain programmable ventricular shunts, may require confirmation of setting with possible setting reprogramming after exposure to the MR environment. A nonmetallic, nonconducting, nonmagnetic passive implant, such as hernia mesh, can be considered MR Safe [17].

Intracranial aneurysm clips. If it is unclear whether a patient has an implanted intracranial aneurysm clip, if available, recent cranial radiographs or CT or MR examinations should be reviewed to identify a possible intracranial aneurysm clip. If unavailable, radiographs or CT should be obtained.

In the event that a patient has an intracranial aneurysm clip, the MR examination should not be performed until the specific manufacturer, model, and type of aneurysm clip within that patient is identified. Next, it should be determined if the aneurysm clip is MR Unsafe or MR Conditional [18]. All documentation of types of implanted clips, dates, etc., must be in writing and signed by/attributable to a licensed physician. Electronic copies of operative reports, physician statements, etc., are acceptable as long as a legible physician signature or other electronic attestation accompanies the requisite documentation. Blanket letters indicating the safety of all clips implanted by a practice are not acceptable. A written history of the clip describing appropriate ferromagnetic testing methods (as specified for appropriate labeling in American Society for Testing Materials (ASTM) International F2503) [17] used to characterize the clip prior to implantation by the operating surgeon is also considered acceptable.

A patient with a previously unrecognized MR Unsafe aneurysm clip (or another implant) may have undergone a prior MR examination without a known adverse event. This fact is insufficient evidence of the safety of the implant and should not be relied on solely to determine the MR safety status of that aneurysm clip (or other implant) for future MR examinations.

For these previously scanned patients with unknown or unsafe aneurysm clips, it is important to note that variations in static magnetic field strength, static gradient magnetic field, orientation of the aneurysm clip (or other implant) relative to the direction of the static magnetic field or its static magnetic field gradient, and rate of motion through that static magnetic field gradient, as well as other factors, are presumably unknown variables that are impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance but could potentially result in significant injury or death on a subsequent MR exposure. By assessing the size of the artifact associated with the clip relative to the static field strength on which it was studied, the MRI pulse sequence type, and the MRI parameters selected, an opinion may be issued by one of the facility's Level 2 MR Physicians as to whether or not the aneurysm clip demonstrates substantial ferromagnetic properties. Access to the MR scanner could be based on that opinion.

Barring the availability of either pretesting or prior MRI-related data for the aneurysm clip in question, the supervising physician in each case must perform a risk versus benefit assessment and review. Furthermore, for patients with intracranial aneurysm clips with no available ferromagnetic or imaging data, should the risk-benefit ratio favor the performance of the MR examination, the patient or guardian should provide written informed consent that includes death as a potential risk of the MR procedure prior to permitting that patient to undergo an MR

examination. Because research scans in general do not offer benefit for the research participant, scanning patients without written information about the specific device is strongly discouraged.

Figure 27 depicts CT and 1.5-T MRI appearance of MR Conditional aneurysm clips and aneurysm embolization coils.

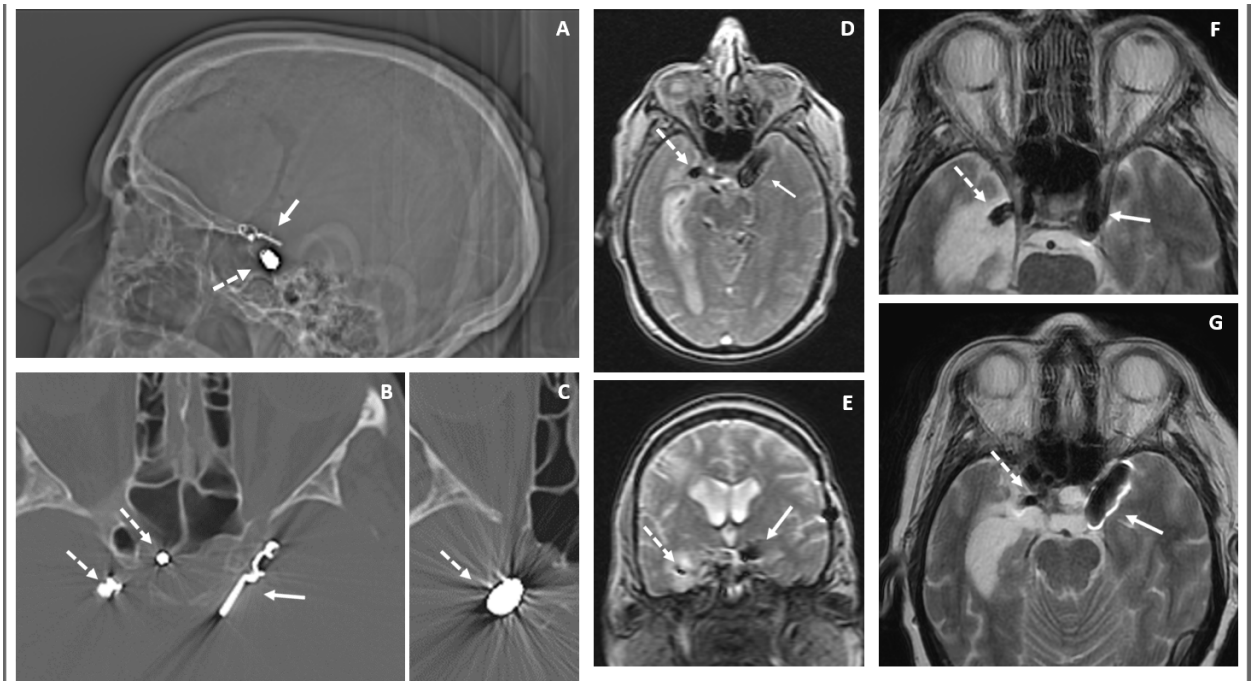

FIGURE 27. CT and 1.5-T MRI appearance of MR Conditional aneurysm clips and aneurysm embolization coils. (A) CT topogram appearance of MR Conditional aneurysm clip (arrow) and aneurysm embolization coil mass (dashed arrow). (B and C) CT appearance of aneurysm clip and embolization coil mass. (D and E) 1.5-T T2* gradient-echo axial and coronal localizer images. Note the limited susceptibility artifact associated with the nonferromagnetic aneurysm clip and embolization coil mass and compare this with the pronounced artifact associated with the MR Unsafe ferromagnetic clip seen in Figure 28. (F and G) Relatively limited susceptibility artifact on T2 fast spin-echo images associated with the MR Conditional nonferromagnetic aneurysm clip and embolization coil mass.

Implant, Device, or Object Discovered During an MR Examination

During an MR examination, it is possible that an unanticipated ferromagnetic implant or foreign body is discovered within a patient or research participant. This is typically suspected or detected on localizer images by observing a sizable image distortion and/or signal-loss artifact that grows with increasing echo time and is more prominent on gradient-echo relative to spin-echo imaging sequences. In such cases, it is imperative that further image acquisition is put on hold and that the Level 2 MR Physician (and/or MRMD or MRSO when appropriate) responsible for the patient be immediately notified of the suspected ferromagnetic object. This Level 2 MR Physician should then assess the situation, review the imaging, and decide the best course of action.

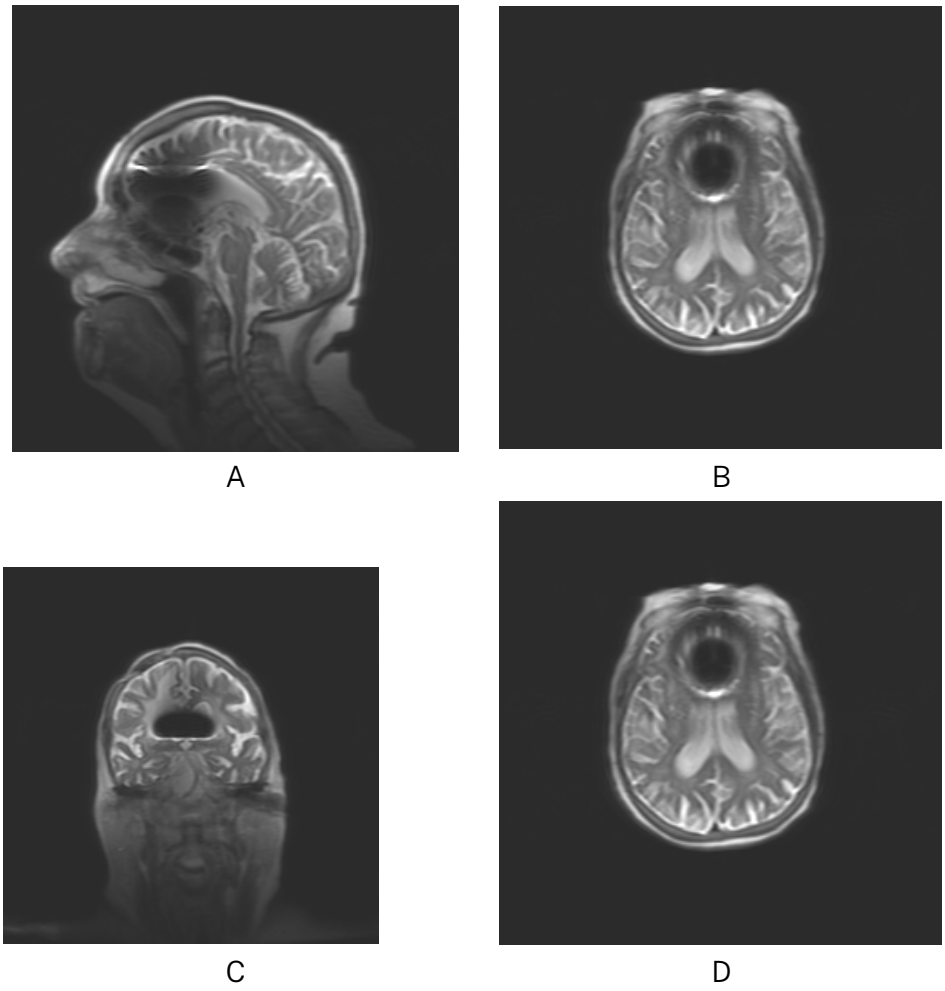

FIGURE 28. Examples of pronounced susceptibility artifact on 1.5-T localizer images associated with ferromagnetic intracranial aneurysm clip (A, B, C). The ferromagnetic clip is seen on the CT images (D). In this case, the patient was removed safely from the scanner using slow table speed, and the table was detached and wheeled out of the room slowly without the patient sitting up.

It should be noted that there are numerous potentially acceptable courses of action that might be recommended that are dependent on many factors, including the status of the patient, the location of the suspected ferromagnetic implant/foreign body relative to local anatomic structures, the mass of the implant, the length of the object, the strength of the static magnetic field, and other factors. Appropriate courses of action might include proceeding with the scan underway, immobilizing and slowly removing the patient from the scanner, or other intermediate steps. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the patient from the scanner bore. Further, the greater the rate of motion of the patient/device through the magnetic field near the scanner bore (spatial field gradient), the greater the forces acting on that device will likely be. In general, slow table speed and slow patient movement should be beneficial. Efforts to immobilize an unrecognized on-planted device can be helpful.

Figure 28 illustrates discovery and subsequent safe removal of a patient after identification of susceptibility artifact associated with an aneurysm clip on the anatomical localizer. Reinforcing this critical need to carefully review patient localizer images to assess for the presence of ferromagnetic objects, a case reported in 1986 in the literature documented a patient that went blind from interactions between an undetected metallic foreign body in his retina and the static magnetic field of the MR system after both entering the scanner and undergoing the entire MR examination without reported incident. Notably, this patient only went blind on exiting the MR system at the completion of the examination [19].

The detection of an unexpected focus of susceptibility artifact in MR examinations of the torso can be particularly challenging because of the multitude of devices that are implanted during surgical and interventional procedures (e.g., staples, stents, inferior vena cava filters, hemostatic clips, embolization coils, etc.). The Level 2 MR Personnel should be aware that some commonly used devices, such as certain clips used in endoscopic procedures, are indeed MR Unsafe [20]. Furthermore, ingested iron supplements within the bowel can cause substantial susceptibility artifacts mimicking metallic clips on MRI [21]. Also, due to their ferromagnetic content, some hemostatic clips deployed during endoscopy impart susceptibility artifacts that could adversely affect the diagnostic quality of the images.

When an unexpected artifact is encountered in a patient undergoing MRI, the Level 2 supervising physician should be contacted before proceeding with the rest of the MR examination. The magnetic fields associated with the MR scanner are 3-D. Thus, especially for superconducting systems, one should avoid the temptation to have the patient sit up as soon as they are physically out of the bore. Doing so may expose the ferromagnetic object to significant torque- and translation-related forces despite its being physically outside the scanner bore.

> *Therefore, it is advisable to continue to extract the patient along a straight-line course parallel to the center of the MR system while the patient remains immobilized until they are as far as physically possible from the MR scanner in Zone IV and continuing directly into Zone III, if possible, before having the patient sit up.*

If the table is dockable, detach the table and move the patient into Zone III before allowing the patient to sit up. If the table is fixed, it is recommended to slowly horizontally transfer the patient to an MR Conditional stretcher in Zone IV and then move the patient into Zone III. If there is determined to be a strong likelihood of producing or worsening patient injury by attempting to remove the patient from the MR system, quenching could be a consideration. Additionally, having emergency medical assistance readily available (with proper safety precautions) is also a consideration.

Should an implanted device that may be altered by the magnetic field (e.g., programmable shunt, implantable infusion pump, tissue expander, continuous glucose monitor, etc.) inadvertently be discovered while the patient is in Zone IV, the physician responsible for the maintenance of the device(s) should be contacted prior to the patient's discharge from the MRI facility. Significant injuries have resulted from such partial exposures to powerful static magnetic fields, and thus, the functionality of the device should be verified and never assumed for critical devices such as internal or external insulin pumps or AIMDs.

KEY POINTS

- External (nonimplanted) devices, objects, and equipment
  - Portable metallic devices should be properly labeled prior to entry to Zone III.
  - MR Unsafe equipment necessary for patient care in Zone III must be responsibly managed by physically securing/tethering or other means.
  - Pocketless scrubs attire should be strongly considered for personnel entering Zone IV to decrease projectile risks.
- Active implanted/on-planted devices
  - Active medical devices contain an energy source or can be inductively coupled.
  - Careful attention to MR conditions for safe scanning of specific devices is essential.
    - CIED systems without MR Conditional labeling can be scanned provided a program is employed in accordance with the recommendations of the Heart Rhythm Society.
  - Identify patients with CIED, neurostimulators, insulin pumps, and infusion devices early in the screening process to confirm whether and how the patient can be safely scanned.
- Passive implanted devices
  - Passive implanted devices do not contain an intrinsic electrical power source.
  - Metal-containing passive devices cannot be MR Safe, only MR Conditional or MR Unsafe.
  - Lack of a known adverse event in a patient scanned with an implanted device of unknown safety labeling does not ensure its safety in any way with future MR exams.
- Implant, device, or object discovered during MR examination
  - Extensive susceptibility artifacts can be an indicator of potentially unsafe ferromagnetic content in an implant.
  - Sites should have SOPs in place on processes/procedures to remove a patient from the magnet if potentially unsafe metal is identified.
    - Slow table speed and keeping the patient recumbent until well away from the bore are important elements.

KEY ABBREVIATIONS

ACLS: advanced cardiac life support

AIMD: active implanted medical device

ASTM: American Society for Testing Materials

CCM: cardiac contractility modulation

CIED: cardiac implantable electronic device

CRT: cardiac resynchronization therapy

CT: computed tomography

FDA: Food and Drug Administration

ICD: implantable cardioverter defibrillator

ICM: implantable cardiovascular monitor

IFU: instructions for use

ILR: implantable loop recorder

IPG: implantable pulse generators

MRMD: Magnetic Resonance Medical Director

MRSE: Magnetic Resonance Safety Expert

MRSO: Magnetic Resonance Safety Officer

RF: radiofrequency

SOP: standard operating procedure

B_0: Static magnetic field

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CHAPTER 13:
Physiological Monitoring of Patients

Visual and audio monitoring are basic required monitoring processes used for patients and research subjects. Additional physiological monitoring for patients during MR examinations is often necessary. Physiological monitoring techniques should be carefully selected, primarily because of the risk of thermal injury associated with monitoring equipment in the MR environment. While not all radiofrequency-induced thermal injuries can be detected as they are developing, sedated, anesthetized, or unconscious patients are especially vulnerable to such injuries, as they are unable to provide the operator with adequate warning of developing thermal injuries. The potential for heating scales with the magnetic field exists, at least theoretically, at all MRI field strengths. When needed, MR Conditional electrocardiogram (ECG) and electroencephalogram electrodes should be used, and leads should be positioned per the manufacturers' direction during the scan [1].

Distortion of the ECG within the magnetic field, particularly during sequence acquisition, can make interpretation of the ECG unreliable, even with filtering used by contemporary monitoring systems. For example, T-wave elevation is frequently noted [2]. ECG recordings in MRI are unreliable and may demonstrate ST segment elevation or depression due to the magnetohydrodynamic effect. This may simulate or mask cardiac infarction (discussed in Lenz effects).

Routine monitoring of the patient's heart rate and rhythm may also be accomplished with an MR Conditional pulse oximeter, with careful attention to the instructions for use.

Additional physiological monitoring devices exist, including indwelling temperature probes and intracranial pressure monitors, and their conditions for safe scanning should be followed carefully in accordance with MRI labeling.

KEY POINTS

- Monitoring techniques should be selected and carefully implemented following manufacturer's MR Conditional instructions because of the risk of thermal injury.

KEY ABBREVIATIONS

ECG: electrocardiogram

EEG: electroencephalogram

IFU: instructions for use

MHD: magnetohydrodynamic

T: tesla

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CHAPTER 14:
Emergency Situations

This section discusses several MR safety switches that can be used in the case of an emergency as well as emergency response–related issues such as fires, codes, and entrapment by ferromagnetic objects. Facilities should have policies and procedures to ensure appropriate communication and chain of authority during after-hours emergencies [1]. For the safety of firefighters, code or rapid-response teams, and other emergent services responding to an emergent call at the MR facility, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR facility should be forwarded simultaneously to a specifically designated individual from among the facility's MR Personnel. This individual should, if possible, be on-site prior to the arrival of the firefighters or emergency responders to ensure that they do not have free access to Zones III or IV. The facility might also consider assigning appropriately trained security personnel, who have been trained and designated as MR Personnel, to respond to such calls. For firefighter or police responses, clear lines of authority for screening, access restrictions, and Emergency Magnet Off procedures are essential.

Given differences in the design of MR facilities and between MR system manufacturers, it is strongly advised that all MR facilities perform regular training and drills to reinforce knowledge of where key safety switches reside and their use as well as to rehearse and refine emergency response protocols to protect patients, MR staff, and first responders.

Emergency Table Stop and Emergency Power Off

Two safety switches that do not ramp down the magnetic field are the Emergency Table Stop and the Emergency Power Off buttons. MR system manufacturers may give different names to these switches, but the MR operator/Level 2 MR Personnel needs to be aware of where they are, when to use them, and how to recover the system after using these switches.

The Emergency Table Stop button is generally designed to immediately stop MR scanning and table motion. Emergency Table Stop buttons (Figure 29) are usually found on or near the MRI console and on the MR bore front cover or the patient table. The Emergency Table Stop button should generally be used when something is caught on the table and further table motion may result in damage or injury to the patient.

The Emergency Power Off button is generally used to stop electrical power to the entire suite and computer room, including an uninterrupted power supply if present. Use of the Emergency Power Off may require an electrician and access to the main breaker to reset and so should be used with caution and only in emergent situations only. The Emergency Power Off button is generally present in the MR control room or on the wall inside Zone IV. In some cases, it may be covered with a plastic guard to avoid accidental activation (i.e., if situated next to the electronically active door seal switch). The Emergency Power Off may be used in cases of fire, flooding, or voltage accidents. Example scenarios for deploying an Emergency Power Off could include detecting smoke or having an uncontrolled water pipe burst in the MR environment.

In the case of Emergency Table Stop or Power Off, if a patient needs to be quickly removed from the scanner, the operator must be familiar with the manual process for moving the table

and/or undocking the table. Fast and safe patient removal from the room is often a key component in any emergency response scenario.

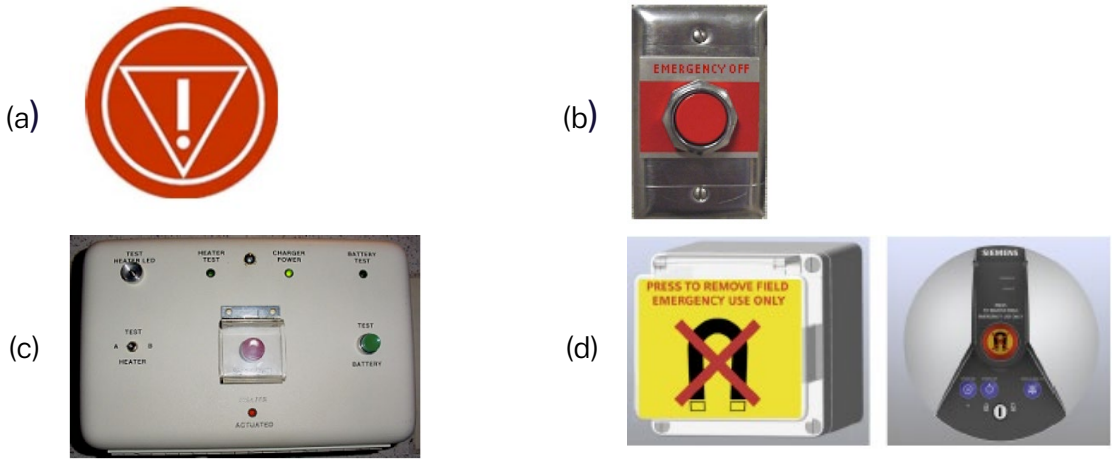

FIGURE 29. (a) Universal symbol used for emergency stop safety switch. (b) Example of an Emergency Power Off safety switch. (c and d) Examples of Emergency Magnet Off units for quenching superconducting units (Source: GE and Siemens Operator Manuals)

Emergency Magnet Off (Quench)

Another primary safety switch in the MRI suite is the Emergency Magnet Off unit for rapidly shutting down the magnetic field. Emergency Magnet Off is usually activated by a button or lever in the MR operator room and/or Zone IV. Buttons are usually protected by a plastic cover to avoid inadvertently deactivating the magnet. MR Personnel should be aware that MR fields may change unexpectedly during a quench. Different magnet designs will have different rates for the field to be shut down. Electromagnets will usually take much longer than superconducting magnets. The MR operator should be familiar with the vendor safety manual concerning their Emergency Magnet Off procedure and safety considerations.

Traditional superconducting magnets used for MRI use large volumes of liquid cryogens to remain in superconducting mode. The Emergency Magnet Off, often referred to as the “Quench button” for superconducting magnets, involves “quenching” the magnet, whereby a tremendous amount of energy is dissipated as the cryogen undergoes rapid expansion and is released as gas through the cryogen vent. This procedure carries its own safety considerations. Because of the risks involved with quenching these magnets, the decision to quench a magnet should be deliberate. Alternatively, some newer generation human MR systems now on the market use lower volumes of cryogen liquid and do not require an externalized venting pipe during installation. The Emergency Magnet Off switch in such systems also quenches the magnet, with the release of a relatively small volume of cryogen material into the room.

If a situation arises in which emergency responders must enter a Zone IV containing an MR system with a superconducting magnet without undergoing screening or elimination of ferromagnetic items, deliberate quenching must seriously be considered. For superconducting systems, it is imperative that all personnel and patients be evacuated from Zone IV as quickly

and safely as feasible and that the site access be immediately restricted for all individuals until the arrival of MR equipment services or other qualified personnel.

A Level 2 MR Personnel should monitor the quench to determine when it is safe for nonmedical emergency responders to enter Zone IV. It may take more than a minute for the magnetic field to dissipate sufficiently for responders to safely enter Zone IV with ferromagnetic equipment [2].

Quenching a magnet can introduce new hazards. This is especially true in the event of a venting failure in which cryogenic gases are vented partially or completely into the scan room, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. Such circumstances could introduce the risk of cold-related injuries (i.e., frostbite or hypothermia) and asphyxiation due to oxygen displacement from helium, which is less dense than air.

In the case of a quench venting failure, it is important for Level 2 Personnel to remain calm and follow the established standard operating procedures for their area, including the following:

- If a patient is currently in the scanner and is ambulatory, advise the patient to leave Zone IV as soon as possible, walking as low to the floor as possible to maintain their head below the potential accumulation of cryogen gas to minimize the risk of asphyxia.
- Immediately turn on the exhaust fan in the MRI suite to help eliminate the cryogen gas from the room.
- Open the scan room door to ventilate Zone IV.
- Consider opening the door to other zones to help ventilate Zone III.
- If entering Zone IV to rescue the patient or personnel, stay as low to the ground as possible. If a gurney or wheelchair is needed, assume the magnet is still on and at field and use MR Conditional equipment if possible.
- When the rescue is complete, close the door to Zone IV to stop helium flow into Zone III. Evacuate the area to allow helium gas to dissipate. MR vendor personnel would be anticipated to assist in indicating when it is safe to re-enter the site.

There are newer MR systems in which an externally vented quench pipe is unnecessary due to low cryogen volume. While quenching does not lead to a release of high volumes of cryogen in the room with such scanners, the magnetic field in the room remains a risk until it can be verified it is sufficiently dissipated.

For resistive systems (without cryogenic gases), the magnetic field of the MR scanner should be shut down as completely as possible and verified prior to permitting the emergency response personnel access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR Personnel should ideally be available to warn the emergency response personnel that a very powerful magnetic field is still present in Zone IV and secure dangerous ferromagnetic objects, if possible.

Fire

All MR facilities should prospectively educate their local firefighters, fire marshals, and police and security personnel about the potential hazards of responding to emergencies in the MR suite.

It should be assumed that in the event of a fire (or other emergency) in Zone IV, the magnetic field is present, fully operational, and potentially dangerous. Therefore, free access to Zone III or IV by firefighters or other non-MR Personnel with air tanks, axes, crowbars, and other firefighting equipment might prove catastrophic or even lethal to those responding or to others in the vicinity.

As part of the Zone III and IV restrictions, all MR facilities must have clearly marked, readily accessible MR Conditional or MR Safe fire extinguishing equipment physically stored within Zones III or IV. All conventional fire extinguishers and other firefighting equipment not tested and verified as safe in the MR environment should be restricted from Zone III and IV.

RACE can be a useful mnemonic for MR staff response to fire:

- Rescue persons in danger IF SAFE TO DO SO.
- Activate the nearest Alarm, and call, when possible, to provide specific information.
- Contain the fire by closing ALL doors of the room/area, including fire doors. An MR Conditional fire extinguisher may be used to control the fire IF SAFE TO DO SO.
- Evacuate if instructed to do so by the fire department.

When a fire is in the magnet room (Zone IV) and cannot be contained by the in-room sprinkler system or by the safe use of an MR Conditional fire extinguisher and the fire department will require access to the room, the Emergency Magnet Off (quench) should be engaged to avoid potential serious injury to the fire department staff or damage to MRI equipment. Note that for superconducting magnets, this will initiate a "quench," a process that has its own safety considerations (see Emergency Magnet Off).

When a fire is in Zone II or III, restricting access to Zone IV by closing and locking the access doors is recommended to prevent entry of fire personnel or hazardous material.

Medical Code

In case of cardiac or respiratory arrest or other medical emergencies within Zone IV for which emergent medical intervention or resuscitation is required, the patient or research participant must be removed immediately from Zone IV to a predetermined, magnetically safe location, and appropriately trained and certified MR Personnel should immediately initiate basic life support or cardiopulmonary resuscitation as required by the situation. Facilities must have immediate access to an MR Conditional gurney on which to transfer the patient when the MR table cannot be undocked. If transferring the unstable patient outside Zone IV is delayed for more than a few seconds, the MR Personnel should prioritize patient safety and initiate cardiorespiratory resuscitation maneuvers (i.e., chest compressions, rescue breaths), as needed, while still in Zone IV. However, MR Unsafe items such as automated external defibrillators should not be brought into Zone IV. The Emergency Magnet Off (quench) procedure is not routinely recommended for these scenarios. All priorities should be focused on initiating necessary basic life support with cardiac compressions and manual ventilation and evacuating the patient as rapidly and safely as possible. Once the resuscitation is moved to Zone III, it is recommended that the Zone IV door be closed and secured to avoid inadvertent potentially dangerous entry by those responding to the code.

It is recommended that sites implement mock code training exercises and practice opportunities with specific issues that may arise in the MR environment. Engagement of MR Personnel and the related staff that would be involved in a code situation is essential. Mock code team leaders can be helpful to access performance and maintenance of important MR safety measures in what are usually high-stress situations. Debriefing sessions and performance feedback following the mock code can help identify areas for improvement and potential additional needed resources. Facilities should consider the need to perform multiple mock code training sessions when there are substantial intra-practice differences in the MRI suite design and/or MR Personnel (e.g., inpatient, outpatient, intraoperative, etc.).

Entrapment

In the event of patient or personnel entrapment against the bore by a sizable ferromagnetic object, causing injury or potential death without possibility of timely extraction, initiating the Emergency Magnet Off (quench) procedure for the magnet is recommended.

KEY ABBREVIATIONS

AED: automated external defibrillator

RF: radiofrequency

UPS: uninterrupted power supply

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CHAPTER 15:
Special Patient and Personnel Considerations

Pregnancy

Health care practitioner pregnancies. Pregnant health care practitioners are permitted to work in and around the MR environment, including Zone III and IV throughout all stages of their pregnancy [1]. There are no restrictions of activities in Zone III. Physical presence in Zone IV is permissible for all activities when there is no active scanning occurring. Although there is no current evidence that exposure to the MR environment during scanning causes harm to the fetus, it seems prudent that pregnant staff, both MR Personnel and non-MR Personnel, should not be in Zone IV during scanning due to the currently unknown side effects of prolonged interactions with the radiofrequency (RF) field and acoustic noise [2]. For example, the effects of acoustic noise to the fetus in the occupational setting is unknown [3]. There is no data available to date regarding human pregnancy exposures to 7-T and higher static magnetic fields.

Patient pregnancies. The vast majority of data today has failed to show that exposure to MR has deleterious effects on the developing fetus [4-6]. Nevertheless, there are indications that the embryo is potentially more sensitive to thermal events in the first trimester. To this end, if pregnancy is established, the decision to proceed with a noncontrast MR study in the Normal Operating Mode for a whole body–averaged specific absorption rate (SAR; ≤2 W/kg) should be based on the medical benefits weighed against unknown potential risk.

The preponderance of research studies has failed to demonstrate any reproducible harmful effects of exposure of the mother or developing fetus to the 3-T or weaker magnetic fields used in the routine clinical MR practice [7,8]. Theoretical concerns include time-varying gradient and RF magnetic fields, potential acoustic noise–related issues, and heat deposition in tissue, respectively. There is little peer-reviewed literature regarding the acoustic safety of fetal scanning, but the majority of published material on this topic has failed to find deleterious effects on newborn hearing when exposed to MRI in utero [9-14]. The thermal-related theoretical concerns are addressed by results from experiments in pregnant pigs exposed to standard MR sequences commonly used in clinical practice that are associated with relatively high SAR levels (i.e., half-Fourier single-shot spin-echo). Such studies failed to demonstrate substantial heating in fetal tissues or amniotic fluid when imaging at 3 T with the MR system operating in the Normal Operating Mode (whole body–averaged SAR, 2 W/kg) and a maximum scan time of 30 minutes [15,16]. Thus, the ACR Manual on MR Safety supports the clinical use of MR imaging for patients known or suspected to be pregnant under the following conditions: 1) MR system up to 3T in Normal Operating Mode (Whole body-averaged-SAR, 2-W/kg); 2) there is expected benefit to the patient and/or fetus from performing the exam; 3) There is no other practical way to obtain the same information for patient care [7]. The American College of Obstetricians and Gynecologists clinical guidelines acknowledge MR and ultrasound (US) as the 'imaging techniques of choice for the pregnant patient, but they should be used prudently and only when use is expected to answer a relevant clinical question or otherwise provide medical benefit to the patient' [17]. The risks of exposure to MR fields >3T are currently unknown. The ACR Committee on MR Safety also supports the enrollment of pregnant research participants for research studies using MR systems up to 3T to investigate conditions related to

pregnancy if they are willing to consent to participate in the research study. However, the enrollment of pregnant patients for other research studies to investigate conditions not related to pregnancy with MRI is discouraged.

Use of gadolinium-based contrast media. The committee supports the recommendations of the ACR Manual on Contrast Media in relation to the administration of gadolinium-based contrast media to pregnant or potentially pregnant patients: MR contrast agents should not be routinely administered to pregnant patients [18,19].

Also, there is widespread consensus that avoiding gadolinium-based contrast media (GBCM) in pregnancy is prudent [18]. The decision to administer GBCM is typically made according to the institutional contrast policy, on a case-by-case basis, by the responsible Level 2 MR Physician who can assess the risk versus benefit ratio for that particular patient. While additional research is needed, one paper suggested that exposure to GBCM at any time during pregnancy has been associated with an increased risk of a broad set of rheumatological, inflammatory, or infiltrative skin conditions and risk of stillbirth or neonatal death [20]. Thus, the decision should be accompanied by thoughtful risk-benefit analysis and well-documented with written informed consent. This analysis should be able to defend a decision to administer the contrast agent based on the potential benefit to the patient or fetus outweighing the potential risks of exposure of the developing fetus to a GBCM.

A 2019 paper highlighted an increased exposure level of first trimester pregnancies to GBCM, suggesting that increased screening and vigilance may be warranted when administering these contrast agents to potentially pregnant patient populations [21].

Pediatric MR Safety Concerns

Pediatric patients may present with additional MR safety concerns, including potentially increasing projectile risks in Zone IV, as well as body temperature considerations, and obtaining nondiagnostic MR examinations due to the inability to cooperate [22].

Projectile risks and the need for enhanced screening have been discussed in Chapter 5: MR Screening.

For the neonatal and the young pediatric population, special attention is needed in monitoring body temperature for both hypo- and hyperthermia as well as other vital signs [22]. MR Conditional temperature-monitoring equipment that is approved for use in the MR suite is readily available. Commercially available neonatal isolation transport units and other warming devices intended to be used in the MR environment are also available. In addition, as an option for performing MRI exams in neonatal patients at the “point of care,” there is now a head-only scanner specially designed for this patient population [23].

Particular attention should be paid to the body temperature of neonates and infants while in the MRI environment [22]. In a study by Don Paul et al [24], only 43% of infants were normothermic upon return to the neonatal intensive care unit (NICU) following MRI, suggesting that MRI-related unintentional hypothermia is common unless proactively managed. Predictors of a post-MRI decrease in body temperature in neonates and infants include younger age, lower weight, lower pre-MRI temperature, use of propofol as the primary anesthetic, use of an advanced airway device, and being outside the NICU [25]. In the event that the pediatric patient requires

sedation/anesthesia, the ACR MR Safety Committee defers to the American Society of Anesthesiologists on pediatric sedation guidelines [26-29]. Alternative methods to facilitate compliance without sedation/anesthesia should be considered (e.g., fast/accelerated MR sequences, engagement of child life specialists, MR Conditional video entertainment headsets).

Claustrophobia, Anxiety, and Sedation

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR practice parameters [30], American Society of Anesthesiologists [26-29], and The Joint Commission standards [31]. Implementation of SOPs and policies for the management of claustrophobic/anxious patients is recommended. *Similarly, sites should develop policies for the release of patients who receive sedation. For example, the requirement of a responsible person, 18 years of age or older, to accompany and drive the patient after an MR procedure.*

Large Body Habitus

Very large patient/research participant body habitus is an MR safety concern primarily due to inherent risk of RF burns. As noted in earlier sections of this manual (see Chapter 8: RF section), contact or excessive proximity to the bore of the magnet can result in near field RF burns, and appropriate insulating pad thickness and positioning about the patient/subject is essential to prevent burns. Ensuring adequate appropriately placed padding can be difficult with very large patients/subjects, and particularly while under general anesthesia or while sedated, padding must be scrupulously assessed to prevent burns. Another consideration in very large patients/subjects is the possibility of forming closed-loop tissued proximities and contacts, such that skin-to-skin contacts become more likely (e.g., between thighs, between abdominal panniculus and thigh, etc.). Thus, properly applied padding that serves as insulation is vital in this patient population. Strategies to reduce patient heating include using a detachable transmit-receive RF coil as well as choosing lower SAR and reducing scan time to minimize overall energy deposition in the patient.

Prisoners/Detainees

MR scanning presents unique MR safety challenges for patients who are incarcerated. These patients may present wearing metallic or ferromagnetic handcuffs, ankle cuffs, or shackles. Accompanying correctional officers may be carrying ferromagnetic objects including guns or other weapons. Prior to the patient arriving at the MR department, notification to the corrections department for an alternative nonferromagnetic restraining option should be requested. MR screening of the patient and the accompanying correctional officer(s) should take place prior to entering Zone III. The accompanying officer(s) should be educated as to the static magnetic field–related safety issues and, if they agree following screening, should accompany the technologist into Zone IV for patient positioning and removal.

Ferromagnetic weapons should not be permitted into Zone III unless essential for maintenance of security. Firearms with ferromagnetic components pose a potential serious threat in Zone IV and can become dangerous projectiles and may discharge, resulting in a death, as described recently in 2023 [32,33].

Firearms represent potential projectiles and are a hazard to all if brought into Zone IV [32,33].

Parolees

Patients on parole wearing metallic prisoner-monitoring devices such as radiofrequency identification (RFID) tags or tracking bracelets could theoretically lead to adverse events, including the following:

1. Ferromagnetic attractive effects leading to patient injury
2. Ferromagnetic attractive effects leading to device/battery pack damage
3. RF interference with the MRI study and secondary image artifact
4. RF interference with the functionality of the device
5. RF power deposition leading to heating of the bracelet, tagging device, or its circuitry, and secondary patient injury (if the bracelet is in the volume of the RF transmitter coil being used for imaging)

Therefore, in cases in which a patient wearing an RFID tag or tracking bracelet needs an MR examination, a request should be made to the appropriate authorities that the monitoring device be removed prior to the MR examination. At that time, it can also be determined if the appropriate authorities should be in attendance at the time of the scan. Plans for monitoring device replacement following the scan should also be made.

KEY POINTS

- Pregnancy
  - Pregnant health care practitioners are permitted to work in and around the MR environment, including Zone III and IV, except in Zone IV during active scanning.
  - Research studies have failed to demonstrate any reproducible harmful effects of exposure of the mother or developing fetus to 3-T or weaker static magnetic fields used in the routine clinical MRI practice. Nevertheless, the decision to proceed with an MR examination should be based on the medical benefits weighed against unknown potential risks.
  - If an MR examination of a pregnant patient is indicated, the Level 2 MR Technologist should confirm that the Normal Operating Mode is selected.
  - The committee supports the recommendations of the *ACR Manual on Contrast Media* in relation to GBCM administration to pregnant or potentially pregnant patients.
- Pediatric
  - Need enhanced screening for projectile risks.
  - Need special attention to body temperature (particularly neonates and infants).
  - ACR MR Safety Committee defers to the American Society of Anesthesiologists on pediatric sedation guidelines.
- Claustrophobia, anxiety, sedation
  - Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR, American Society of Anesthesiologists, and The Joint Commission standards.
- Large body habitus
  - Inherent increased risk of RF burns.
  - Requires special attention to padding.
- Prisoners/detainees
  - Notification to the corrections department for an alternative nonferromagnetic restraining option should be requested.
  - MR screening of the patient and the accompanying correctional officer(s) should take place prior to entering Zone III.
- Parolees
  - Arrangements should be made with proper authorities to remove and replace RFID tags or tracking bracelets as needed.

KEY ABBREVIATIONS

ACR: American College of Radiology

GBCM: gadolinium-based contrast material

NICU: neonatal intensive care unit

RF: radiofrequency

RFID: radiofrequency identification

SAR: specific absorption rate

SOP: standard operating procedure

T: tesla

TJC: The Joint Commission

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CHAPTER 16:
Alternative MR Environments

MR systems are increasingly being operated in alternative environments outside of conventional diagnostic MR facilities. Examples of such facilities include hybrid PET/MR, intraoperative/interventional MR, MR-guided radiation therapy, and point-of-care scanners [1-4]. Each of these facilities presents unique challenges to implementing MR safety policies and standard operating procedures (SOPs), particularly with regard to unique devices, procedures, personnel, site access restrictions, screening, site contamination and infection control, and adverse event management.

As the type and number of personnel who work in these complex MR settings are often more varied and numerous than in conventional diagnostic MR facilities, the MR Medical Director (MRMD) should ensure specific SOPs are in place that define the roles and responsibilities of these MR Personnel [5].

> *This should include identification of the responsible person to ensure the safety of the patient, MR Personnel, and other personnel who may care for the patient while in these alternative environments.*

Specialized personnel with MR safety training as well as specific training to the workflows and procedures in these more complex, alternative environments are recommended. Personnel working in the MR environment should have a minimum of Level 1 MR training or be supervised by Level 2 MR Personnel. It is crucial to develop a process to educate all other personnel who have the need to access Zone IV in these complex environments (e.g., interventional radiologists, nurses, surgeons, anesthesiologists, respiratory therapists).

As in all MR settings, SOPs should include the process for evaluation and screening of patients and health care personnel, implants or devices, and equipment (e.g., patient support equipment and surgical, radiation, and anesthesia devices) that enter the MR environment. Also, SOPs should be in place for contrast reaction/code situations, transport during emergent events, and cryogen safety in these alternative MR environments.

PET/MR

Hybrid PET/MR systems are currently available for clinical and research imaging. These hybrid systems pose unique safety challenges because each modality requires a different group of personnel with varied training and access [6-8]. Governance can be complicated by the inherent multifaceted challenges of each imaging technique, requiring careful communication and delineation of responsibilities. Often the best option is to form a codirectorship between the MRMD (i.e., responsible for MR safety) and another director such as a physician with specialized training in nuclear medicine and the handling/use of radioactive materials (i.e., authorized user). These codirectors must work together to develop policies and SOPs and ensure that the facility follows current MR and PET safety procedures. All MR safety procedures must be overseen by Level 2 MR Personnel. Similarly, all radiation protection and handling of radioactive material must follow state and federal policies (refer to US Nuclear Regulatory Commission 10 CFR part 20 and part 35) [9]. PET imaging personnel who work in Zone III and IV should additionally be trained as MR Personnel following local standard policies and procedures.

Supplementary to standard MR safety considerations, PET imaging poses several additional challenges in the MR environment. Facilities must be appropriately shielded to avoid radioactive doses to personnel and the public, and facility cleaning must be executed to ensure infection control and to avoid potential radioactivity contamination. Because of the regulations around the use of radioactive materials, uptake rooms and Zone III serving a PET/MR scanner must be adequately isolated following the institution's radiation safety policies and procedures. Additionally, the handling, dissemination, and disposal of radioactive material requires specialized training and knowledge. Specialized equipment used in PET, such as shielded syringes or phantoms, need to be assessed for ferromagnetic properties before entering into Zone IV. Emergency procedures should be developed that incorporate quenches, radioactive spills, and other emergencies. In the event of spillage of radioactive material in Zone IV, a wipe test bringing the sample into Zone III may be required to assess radiation levels if the facility does not have access to an MR Conditional survey meter that allows interrogation of the contaminated site.

Intraoperative/Interventional MR

The physical environment for intraoperative/interventional MR presents substantial challenges [5]. Each entrance to Zone IV (e.g., operative room patient entry, angiography suite, control room entry) requires appropriate controlled access and effective screening practices to prevent the introduction of potentially dangerous objects or equipment. Transient changes in MR Zone labeling can occur in dynamic MR environments. A space that may be Zone IV in one instance may convert to Zone III at another time or configuration. Thus, multiple points of entry and variable room configurations can considerably increase the complexity required to achieve effective MR safety planning and design of these facilities [5].

Attempts to "retrofit" safe practices into intraoperative/interventional MR environments that have already been constructed can be challenging and lead to unintended consequences. Careful planning of the facility prior to construction is highly recommended.

These environments present unique circumstances that require site-specific coordination to manage time-sensitive emergent responses. Policies and procedures for emergency and adverse event management must be developed, reviewed by personnel expected to execute the defined procedures, and approved by the MRMD. In the development of such procedures, each person's role must be clearly identified and documented. Particularly, specific MR Personnel responsible for overseeing MR safety should be clearly identified.

Although the challenges to each intraoperative MR environment vary from site to site, the guiding principles of MR safety remain. MR Personnel must be appropriately educated, be vigilant in their awareness of a dynamic environment, and apply that knowledge to successfully ensure patient and staff safety in the MR environment. Additionally, many devices that are not used in a routine diagnostic suite nor in and around a patient undergoing a diagnostic MR are frequently present in these environments. Rigorous adherence to testing, labeling, appropriate storage, securing, and usage guidelines are paramount to avoiding accidents. Ultimately, the MRMD must facilitate a culture of safety in which adverse events as well as "near misses" (e.g., accidental introduction of MR Unsafe equipment or devices into Zone IV without unintended consequences) are reviewed regularly so that policies and procedures can be updated and personnel education enhanced, as needed, to prevent similar events in the future.

MR Simulator and MR Linear Accelerator

Due to its unique and excellent soft-tissue contrast, MR is a popular tool for planning and delivering radiation therapy through the use of MR simulators to image the patient in treatment position in a manner similar to CT. Additionally, hybrid systems in which a linear accelerator (LINAC) is coupled with an MR are now commercially available [10]. As with prior hybrid PET/MR scanners, unique challenges arise for guaranteeing patient and personnel safety in these environments [11].

From an MR safety standpoint, the MR simulator is a standard MR scanner housed in a nondiagnostic imaging environment such as a radiation oncology department. Since MR safety is generally not a routine part of radiation oncology training and workflow, careful consideration needs to go into personnel access, training, and proficiency in MR safety tasks such as patient and personnel screening, patient positioning, and emergent procedures. Development of training programs and proficiency tests that include MR safety are likely beneficial in orienting staff to the new environment. It is worth noting that patients often receive multiple radiation doses (i.e., fractions) and may visit the MR simulator several times during the course of their therapy. Furthermore, such patients often undergo multidisciplinary care with other procedures being performed concurrently during the radiation therapy. Therefore, as in diagnostic imaging, it is important to screen the patient each time prior to the patient receiving the MR examination and make certain there has been no change in status. Many devices used during treatment simulation, such as immobilization devices, need to be evaluated for patient safety and artifacts. Conducting materials such as metal (both ferromagnetic and nonferromagnetic) and some carbon fiber objects can potentially be a source of heating and can also generate severe artifacts. Alternative materials should be procured in these situations.

The hybrid MR-LINAC system requires additional consideration, since the overall design of the facility must accommodate both radiation and the MR environment. Devices used during the delivery of radiation to immobilize the patient as well as those used to measure radiation should be MR Conditional for the MR environment employed. Since motors and measurements used for the calibration of these systems can be affected by the magnetic field, modified equipment may be needed. All considerations given for the MR simulator also apply to the MR-LINAC, in which the unique environmental concerns of the hybrid system necessitate careful screening, access restriction, and training.

7-T MR Environments

Ultra-high field-strength MRI scanners (i.e., >3 tesla) exist both for clinical and research imaging. Presently, the FDA limits on static magnetic field exposure vary depending on the age of the patient or research participant.

Static Magnetic Field [12]

TABLE 5.

Population	Maximum static magnetic field (tesla)
Adults, children, and infant aged >1 month	8
Neonates (i.e., infants aged ≤1 month)	4

The FDA clearance for clinical use of 7-T MR necessitated the development of specific guidelines for these scanners [13,14].

Transient bioeffects associated with the static magnetic field tend to increase with field strength and/or its associated spatial field gradient and are felt more strongly by some individuals and not at all by others [15]. At 7 T, the sensation of vertigo is the most often reported biologic effect. Other effects observed include dizziness, nausea, nystagmus (involuntary eye movements), magnetophosphenes (perceived visual flashes of light), and electrogustatory effects (metallic taste in the mouth). All effects are considered transient with no permanent cognitive or other health effects observed [16]. These transient effects are not known to have a negative health effect for staff or patients; however, the potential for patient and staff discomfort must be recognized and managed accordingly. Because some of these effects are influenced by the Lenz effect, limiting patient motion during their positioning into the MR scanner (i.e., during MR table motion) has been shown to decrease vertigo. Moving the patient with slow table velocity in and out of the MR scanner may also decrease this effect. Similarly, patient head motion during the MR examination should be minimized [16]. Given these potential side effects, MR Personnel should check with the patient or research participant prior to complete removal from the table. Sitting on the MR table for some time may be helpful. Similarly, access to an MR Conditional wheelchair may be helpful for some patients.

There are several particular considerations that should be taken into account for metallic implants, devices, and foreign bodies in the 7-T environment. Compared with lower field-strength MR environments, 7-T strength is associated with greater transmitted radiofrequency (RF) energy. Devices that can be safely imaged at 3 T may represent a risk at 7 T because of length-dependent RF heating. Thus, RF field–induced heating leading to dangerous temperature elevations of shorter electrically conductive objects is theoretically more likely at 7 T than at 1.5 T or even 3 T.

The MR Conditional status at 7 T cannot be assumed from existing MR Conditional status at 3 T or other field strengths. A major concern for implants and devices in the 7-T environment or in patients undergoing MR is that relatively few objects have undergone standardized testing to determine their level of safety. Because 7-T MR exposes implants and devices to higher static magnetic field strength and RF energy, each item must be evaluated at 7 T, even if the object had been previously deemed safe for a patient undergoing an MR examination at 1.5 T or 3 T. For example, a patient with an aneurysm clip that can be imaged safely at 3 T (i.e., labeled MR Conditional) may not be allowed to undergo an MR exam at 7 T [17,18].

Translational forces on unsaturated ferromagnetic objects are broadly similar in the fringe field region of actively shielded 7-T systems compared to modern lower field-strength MR systems, albeit subject to slightly more extended fringe fields, while rotational forces may scale approximately with the static magnetic field. Also, note that substantially higher Lenz forces associated with conducting material moving through the field may be associated with 7-T environments [19]. Additionally, certain implants such as programmable cerebral spinal fluid shunt valves and active implanted medical devices (AIMDs; e.g., neuromodulation devices, cochlear implants, etc.) that retain functionality at lower field strengths may potentially malfunction or suffer interference, altered settings, or permanent damage at 7 T [20].

As with other complex MR environments, guiding MR safety principles must drive practice decisions in the 7-T setting. A risk versus benefit assessment with the most current information available to determine whether a certain patient diagnostic question, possibly with particular implant or device considerations, warrants undergoing MR at 7 T.

Point-of-Care MRI Systems

A point-of-care portable ultra-low field-strength (<0.1 T) system with FDA clearance exists, permitting bedside head scanning and rapid diagnostic results (e.g., recent infarcts, hemorrhages) and obviating the need to transport patients to fixed-location MR units. For the systems with ultra-low B_0 field strength, projectile incidents are presently considered to be relatively low risk, particularly compared to conventional superconducting 1.5-T and 3-T magnets or low-field MR scanners (e.g., <1 T). No cryogens are used to maintain a superconducting environment, eliminating that safety concern. Although the relatively lower energies utilized in low-field point-of-care MR make these systems lower risk than traditional MR systems, care should still be taken that staff, particularly non-MR Personnel, still follow appropriate safety procedures that specify screening and other safety protocols around point-of-care systems. In particular, noting the portable nature of these systems, they should be safely stored in a dedicated secure storage area and transported to the patient area while preventing unintentional access by unscreened persons when not in use, according to manufacturer's instructions.

This is an evolving field, and evaluation and assessment of safety concerns related to this class of MRs will continue to be of interest to the ACR MR Safety Committee going forward as new information emerges. In situations in which there is not a registered trained MR Technologist, there should be sufficient training for all individuals operating the unit to ensure safety. At present, there is insufficient data to assess safety related to scanning in the presence of AIMDs and other devices such as programmable ventricular shunts, although preliminary reports are emerging [21-22]. The 4-zone model (Chapter 3) is not applicable to ultra-low field-strength magnet systems.

Mobile MR Scanners

Mobile MR scanners are often constructed or sited near facilities with insufficient room but a radiological need for additional MR capabilities. While these scanners may offer imaging services at typical clinical field strengths, their environments generate unique MR safety considerations. Mobile units are often parked near moving vehicles, which can potentially expose external persons to magnetic fringe fields. If the fringe fields extend outside of the mobile unit, there must be appropriate access restriction relative to the 9-gauss line. Stray magnetic field interference and vibrations from outside the mobile unit can also directly affect image quality, and thus, appropriate siting restrictions (e.g., restricted parking around mobile MR unit) should also be in place. While some mobile facilities include a Zone II area outside the Zone III console room, many mobile structures only have an enclosed Zone III console room and a Zone IV scan room. In these situations, Zone II could be a parking lot or other open area outside radiology that can be difficult to manage. Not infrequently, Zone III is relatively small, necessitating strict Zone IV access restrictions.

KEY POINTS

- Alternative MR environments
  - Personnel working in the MR environment should have a minimum of Level 1 MR training or be screened and directly supervised by Level 2 MR Personnel.
- PET/MR
  - MR safety and radiation regulatory requirements often need shared responsibilities between 2 medical directors (MRMD and nuclear medicine authorized user).
- Intraoperative/interventional MR
  - Policies and procedures must clearly indicate which specific Level 2 MR Personnel is responsible for overseeing MR safety.
- 7 T
  - The risk of accidents due to projectiles or complications related to implanted devices is substantially increased.
  - MR Conditional status at 7 T cannot be assumed from existing MR Conditional status at 3 T or other field strengths.
- Point-of-care MRI systems
  - Low risk of missile-effect projectile incidents.
  - Insufficient data to assess safety related to scanning in the presence of AIMDs and other devices.
  - All involved staff, including non-MR Personnel, should follow appropriate safety procedures.
- Mobile MR scanners
  - Siting may be associated with additional challenges around MR Zone restrictions.

KEY ABBREVIATIONS

ACR: American College of Radiology

AIMD: active implanted medical device

B_0: static magnetic field

CT: computed tomography

FDA: Food and Drug Administration

MRMD: Magnetic Resonance Medical Director

PET: positron emission tomography

RF: radiofrequency

RFID: radiofrequency identification

SOP: standard operating procedure

T: tesla

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APPENDIX 1:
MR Safety Policies and Standard Operating Procedures

Facilities should develop written MR safety policies and standard operating procedures (SOPs) to minimize risks to patients, patient families, research participants, visitors, and personnel. Whereas the general approach to MR safety should be documented in institutional MR safety policies, items that require frequent updates and/or include detailed instructions (e.g., MR imaging with implanted devices) may be better documented in SOPs. A checklist such as the one provided below can be of assistance in the development of such policies and SOPs. Note that policies related to the use of contrast in MR should follow the recommendations from the ACR Committee on Drugs and Contrast Media and thus are not included in this checklist.

Designated MR Safety Committee with MR Medical Director (MRMD), MR Safety Officer (MRSO), Designated MR Safety Expert (MRSE) Designation of formal safety roles for the MRMD, MRSO, and MRSE should include specific duties, training, and competencies for each role. The policy should also refer to a document with the current names and contact information for the designated individuals.	
Specific members of a MR Safety Committee	☐
Specific duties for MRMD	☐
Specific duties for MRSO	☐
Specific duties for MRSE	☐
Specific training and competencies	☐
Document with the current names and contact information (i.e., phone tree, expertise contact list)	☐
Supervision These policies should include supervision responsibility and independent access within Zone III and Zone IV and include the process/procedure for the formal transfer of Level 2 responsibility.	
Level 2 MR Personnel access and responsibility	☐
Level 1 MR Personnel access and responsibility	☐
Non-MR Personnel access	☐
Level 2 responsibility transfer process	☐
Reporting of MR-related adverse events and near misses The reporting of MR-related adverse events and near misses should specify reporting procedures and corresponding time intervals.	
Reporting procedures	☐

Time interval	□
Documented MR safety education/training/availability of resources for all MR Personnel The policy should define MR Personnel, required training for each level designation, specific training content and/or competency measures for each level, and the time interval of education training.	
Definition of MR Personnel training levels	□
Specific training content and/or competency measures for each level	□
Training time interval	□
MR Equipment Operator Manual(s)/instructions for use availability as necessary for specific job role	□
Site access privileges (MR zones) and methods of controlled access Areas to be controlled and the methods used to restrict unauthorized access to Zone III and IV should be defined. The policy should clearly associate the MR safety personnel levels and their site access privileges.	
Areas to be controlled	□
Methods to grant access to Zone III and IV	□
MR safety personnel levels and site access privileges	□
Staffing A minimum staffing plan for each MR area in a facility must be established with the aim of ensuring an appropriate number of appropriately trained personnel are staffed to ensure safety.	
Staffing plan	□
MR safety warning signage Signage should include illuminated or reflective sign stating “Magnet is Always On” with a battery backup (if illuminated) at Zone IV entrance(s). Additional signage that describes hazards and access restrictions (at a minimum at entrances to Zone III and IV).	
MR safety warning signage	□

MR safety screening Policies should include the following: Staff/personnel screening: process for documented screening for all MR Personnel that includes initial onboarding MR screening, periodic annual screening, and provisions to update screening upon change in medical status. Patient screening: Process for documented screening of all patients that includes screening practices for conscious, unconscious, unresponsive, altered-level-of-consciousness, communication-restricted, and emergent patients, in addition to companions/family members. The screening policy should also include the appropriate use of physical screening adjuncts (i.e., ferromagnetic detection). Pediatric patients: process for both screening with parents/guardian and private clinical screening.	
Staff/MR Personnel screening	□
Conscious, nonemergent patient screening	□
Unconscious, unresponsive, altered-level-of-consciousness patient screening	□
Emergent patient screening	□
Companion/family member screening	□
Communication-restricted screening (i.e., medical translator, interpreter services)	□
Physical screening adjuncts (i.e., ferromagnetic detectors)	□
Pediatric patient screening	□
Risk identification, assessment, and mitigation Risk management should include processes for identification and safety assessment for any metallic object in or about the patient, including implanted/on-planted devices and other foreign bodies with particular attention to objects that may involve orbital, intracranial, intraspinal, or other critical areas.	
Processes for identification of implanted devices, foreign body, and orbital trauma during the screening process	□
Assessment of risk	
Mitigation of risk	□
Patient preparation The policy should include MR Safe attire (pocketless garments) and means to reliably remove metallic personal belongings and devices and gowning provisions for all patients/research participants to ensure removable metal does not enter Zone IV. Provisions to ensure patient cell phones do not enter Zone III (e.g., dedicated storage locations in Zone II, etc.).	
MR Safe attire	□

Removal of readily removable metallic personal belongings and devices	☐
Ensure that any patient assist/transport devices are MR Conditional	☐
Prevention of patient cell phones entering Zone III	☐
Full stop/final check process — routine	☐
Full stop/final check process — augmented	☐
Acoustic noise protection Hearing protection provisions for all patients/persons in Zone IV during scanning should include instructions on proper "fit and function" of hearing protection and the process and procedure for patients who refuse hearing protection.	
Hearing protection	☐
Fit and function of hearing protection	☐
Process and procedures for patients who refuse hearing protection	☐
MR scanning safety Guidance for patient positioning, coil choice and placement, and padding should be documented. A policy should also include patient communication management to include the use of a technologist notification device (i.e., squeeze ball) and continuous acoustic monitoring (i.e., open 2-way intercom channel) during MR examinations of conscious patients.	
Positioning	☐
Coil choice and placement	☐
Determination of appropriate operating mode	☐
Padding, burn prevention	☐
Patient communication management	☐
Implant/device/object management The process/methodology for examination approval/denial for patients with implants/devices/objects.	
Process/methodology for examination approval for implants/devices/objects that have manufacturer MR safety labeling	☐
Process/methodology for examination approval for implants/devices/objects that have no or incomplete MR safety labeling	☐
Process/methodology for examination approval for MR Conditional labeled implants/devices/objects when the	☐

manufacturer's stated conditions cannot be met	
Portable objects in Zone IV Policies and SOPs to decrease projectile risk from portable equipment/devices.	
Zone IV doorway protection	
Deployment of MR Safe or MR Conditional equipment/devices in Zone IV when possible	☐
Use of tethers for MR Conditional and MR Unsafe items as necessary	☐
MR Safe attire for MR Personnel who routinely work in Zone IV to mitigate projectile risks	☐
MR Personnel cell phone management	☐
Emergency The processes for appropriate use of emergency table stop and emergency power off switch should also include guidance on when to initiate emergency magnet off (versus an emergency power off) by designated authorized personnel. Processes of emergency response for various emergent situations including fire, medical (e.g., code), and other emergencies (e.g., entrapment) should also be included.	
Emergency table stop and emergency power off switches	☐
Emergency Magnet Off (quench)	☐
Fire	☐
Code	☐
Entrapment/other emergencies	☐
Education for first responders such as firefighters who may respond to emergencies in the MR environment	☐
Cryogen safety (as applicable) The frequency and process for documentation of inspection of the MR quench pipe assembly and the education/training required for any person working or managing others working near the quench pipe discharge point (e.g., roofing or air conditioning repair personnel) should be included in a cryogen policy.	
Frequency and documentation of inspection of MR quench pipe assembly	☐
Education/training for any person working near the quench pipe discharge point	☐

Pregnant patients and staff The policy should include the screening process for pregnancy and the management of pregnant patient care within the MR environment. The policy for pregnant health care practitioners should define permitted workplace activities and restrictions.	
Screening process for pregnancy	□
Management of pregnant patient care within the MR environment	□
Permitted workplace activities and restrictions for pregnant health care practitioners	□
Claustrophobia The policy should include the management of patients with claustrophobia, anxiety, or emotional distress in the MR environment.	
Management of patients with claustrophobia, anxiety, or emotional distress in the MR environment	□
Sedation/anesthesia The policy should include the management of patients who have undergone sedation or anesthesia within the MR environment and actions related to the release of such patients.	
Management of patients who have undergone sedation/anesthesia within the MR environment	□
Actions for release of patients who have undergone sedation or anesthesia	□
Infection control and medical waste The policy should include requirements for MR area cleaning, including access for environmental services, normal and terminal (following patient discharge) cleaning, and the use of staff personal protective equipment (PPE) based on potential infection/contamination risk.	
Requirements of MR area cleaning	□
Access for environmental services, normal and terminal cleaning	□
Use of staff PPE based on potential infection/contamination risk	□
Alternative MR environments Policies and SOPs that are site specific for these complex environments must be created adhering to basic MR safety principles used in more routine settings.	

Responsible individuals for each unique alternative MR environment	□
Policy access and review The policy should detail the process for review and update/re-endorsement of MR safety policies and SOPs by the MR Medical Director (MRMD) and relevant institutional responsible person concurrently with the introduction of any substantial changes in safety parameters of the MR system or suite. Policies and SOPs should include citations/references to contemporary standards or best practice documentation and include appendices when applicable. Policies should be present and readily available to facility staff (either physically or electronically).	
Reviewed/updated/re-endorsed at defined interval specific to the policy/SOP	□
Endorsed by current MRMD and relevant institutional responsible person	□
Policies include citations/references to contemporary standards or best practice documentation and appendices when applicable	□
Present and readily available to facility staff (either physically or electronically)	□

APPENDIX 2:
MR Facility Safety Design Guidelines

According to safety and human factors engineering principles, employing multiple and varied safety strategies can enhance a program's effectiveness. This multifaceted approach is sometimes termed *defense in depth*. The safety strategies outlined in the preceding main body of this *MR Safety Manual* can be enhanced by thoughtful safety-oriented architectural and interior design strategies. For example, a facility's physical design can strategically encourage safety and compliance with best practices by facilitating MR Personnel safety-related workflows while enhancing patient flow through the facility. Different design elements may be incorporated depending on the setting (e.g., inpatient versus outpatient, diagnostic versus interventional) within the same institution that aim to optimize the main function of that particular site.

Some examples of designing prospectively in an effort to improve safety follow. For example, having a private area for patient screening interviews will make it more likely that patients will disclose sensitive types of implants. Similarly, dedicated permanent and temporary storage space in Zone III, including lockable space and equipment tether points for MR Unsafe equipment (e.g., ferromagnetic intravenous poles, oximetry monitors, wheelchairs, transport stretchers) is desirable.

For MR suites planning to use MR Conditional equipment in Zone IV (e.g., anesthesia machines), it is recommended that the installation of tethers in their appropriate locations is planned during the design phase. Similarly, marking relevant gauss lines (e.g., 200 gauss) on the floor of Zone IV is recommended to help define the necessary length of such tethers. There may be special circumstances (e.g., hybrid procedural suites) in which the storage of MR Unsafe equipment in Zone IV may be accomplished with wall anchor and tether strap/cable systems that prevent such equipment from becoming a projectile. In certain circumstances, maintaining such equipment in Zone IV is crucial for standard operations (see Chapter 16: Alternative MR Environments). However, the storage of unsafe equipment in Zone IV in routine MR settings is strongly discouraged.

Effective and safe MR suites must balance the technical demands of the MR equipment with local and state building codes, standards of accrediting bodies, clinical and patient population needs, payor requirements, and a collage of civil requirements from the HIPAA to the Americans with Disabilities Act.

Although it could be desirable to provide a universal MR safety design, the variables are too numerous to adequately address in a single template. The following MR Facility Safety Design Guidelines [1] are provided to support the planning, design, and construction of MR facilities, including updates to existing MR facilities, which enhance the safety of patients, visitors, and staff. Sites may be faced with bringing existing facilities into compliance with modern MR safety standards. Until more complete renovation can occur, the primary goal should be safety in the MR suite, including appropriately labeled and secured access to Zone III and IV as well as attention to what devices and types of procedures may be appropriate for the site.

This information is intended to supplement and expand on patient safety guidance provided throughout the *ACR Manual on MR Safety*.

General principles

- Facility location, access, etc.
  - An important consideration is the physical weight of the MR unit and having adequate foundation to support it. The weight of the magnet and associated structural pressures may influence what floors it can be sited on. Magnets sited on the ground floor or lower may need to be protected from flooding.
  - There should be a careful assessment of facility location to avoid potential areas of unintended interaction (e.g., magnetic field, vibrations, etc.) with MRI scanners (e.g., elevator shaft, train rail tracks, etc.).
  - Consider ease of access to Zone IV for deployment of the MR scanner and future upgrades/replacements. A location with a removable panel for Zone IV in the exterior wall of the building is desirable to allow direct access from the outside into Zone IV. Alternatively, a path for delivery of the MR scanner (or extraction and delivery of future replacements) should be available, including doors and hallways that are wide enough (i.e., 8 feet or larger).
- **MR equipment vendor templates**
  - Design templates provided by MR equipment manufacturers are invaluable in developing suites that meet the minimum technical siting requirements for the specific equipment.
  - Vendor design templates, however, typically depict only the control and equipment rooms in addition to the magnet room, Zone IV.
  - Patient/family waiting, interview areas, physical screening/changing areas, access controls, storage, crash carts, induction, medical gas services, post-screened patient holding areas, infection control provisions, and interventional applications, among many other issues, are not addressed in typical vendor-provided drawings. These issues are left to facility owners, operators, and their design professionals to resolve.

Zone II

- **Patient interview/screening**
  - Reviewing the patient Safety Screening Form and MR Hazard Checklist requires discussing confidential personal information.
    - To facilitate full and complete patient disclosure of their medical history, this clinical screening should be conducted in an area that provides auditory and visual privacy for the patient.
    - Facilities should prospectively plan for electronic patient medical records, which are useful in clinical screening, and should provide access to records in the MR suite in support of clinical patient screening.
    - Clinical screening of inpatients may be completed in the patient room for hospital-based MR facilities.
- **Changing areas/gowning**

  - A location should be provided for patients where they may change out of their street clothes and into facility-provided MR Safe pocketless garments.
  - All facilities must provide means of identifying, removing, and temporarily storing items that the patient may have brought with them that might pose threats in the MR environment. It is recommended that keyless lockable storage or nonferromagnetic keys are available for valuable personal belongings.
- **Transfer area/ferromagnetic quarantine storage**
  - An area should be provided to transfer the patient from MR Unsafe transport equipment (e.g., ferromagnetic wheelchair) to equipment appropriate for the MR environment.
  - Unsafe equipment accompanying the patient should be secured in a "ferromagnetic quarantine" storage area outside of Zone III, distinct from storage areas for MR Safe and MR Conditional equipment.

Zone II or III

- **Emergency resuscitation space and equipment**
  - It is recommended that emergency code and emergency resuscitation equipment be stored in a readily accessible area within either Zone II or Zone III, in close proximity to Zone IV. If the equipment is MR Conditional and to be stored in Zone III, providing securing tethers is recommended.
  - A dedicated area to hold a patient in acute distress is recommended in Zone II or III, in close proximity to Zone IV, sufficiently large to allow the conducting of a patient resuscitation (i.e., cardiopulmonary resuscitation maneuvers).
- **MR Conditional fire extinguisher storage**
- **MR Conditional housekeeping equipment storage**
- **MR Conditional patient transport equipment storage (e.g., wheelchairs, stretchers, walkers, lifts)**
- **Patient recovery area**
  - Facilities performing MR examinations in patients undergoing moderate sedation or anesthesia, such as those imaging inpatient and performing MRI-guided procedures, should consider a patient recovery area in Zone II or III that is adequately equipped (e.g., medical gases, crash cart). It is recommended that the recovery area is in close proximity to Zone IV to minimize distance during the transport of intubated patients.
  - Involvement of personnel with expertise in anesthesia procedures is helpful during the design phase of the facility.
- **Ferromagnetic detection devices (FMDS)**
  - Permanently installed FMDS have been demonstrated to be effective as adjuncts to the MR safety screening process. It is recommended that new facility construction anticipates the use of an FMDS for screening and provide for installation of the device in a location that facilitates use and throughput.
  - Several types of FMDS and roles for them exist.

        - Patient screening FMDS, at a distance from entrance to Zone IV (typically Zone II to III).
            - Considered useful for screening of ambulatory patients/subjects who have changed into MR Safe pocketless garments in an effort to identify any concealed/forgotten ferromagnetic object. Peer-reviewed publications report evidence that some implanted and on-planted devices may be detected. Can be useful to verify ferrous-free status of patients prior to passing into Zone III.
        - Entryway FMDS
            - Intent is to provide a final ferromagnetic check immediately before entering Zone IV.
        - Handheld FMDS
            - Can be useful to specifically assess specific body parts, particularly to more precisely determine the location/identity of a potential ferromagnetic object indicated by patient screening FMDS.
            - Can be useful to screen nonambulatory patients if on MR Conditional transport equipment.
        - Permanent magnet (at least 1000 gauss)
    - Depending on the workflow of the facility, FMDS should be optimally sited in Zone II and/or Zone III.
    - Handheld FMDS and permanent magnets, while needing to be accessible, must have provisions/standard operating procedures to prevent their introduction into Zone IV.

Zone III

- **Access control**
    - Means of physically securing and restricting access to Zone III from all adjacent areas must be provided.
    - Access to Zone III should be limited by usage of a personalized electronic badge to those who have been granted access by the MR Medical Director based on local policy.
    - Access to Zone III must be guaranteed in the event of a power outage, either with emergency power or a mechanical release from inside Zone III.
- **Post-screened patient holding/transit**
    - Depending on facility functionality, capacity, and patient volume, it may be advisable to provide a post-screened patient holding area.
    - Zone III holding areas should be equipped and staffed to prevent patient exit and subsequent reentry to avoid the introduction of unscreened objects and personnel.
    - Multimodal radiology facilities combine patient holding and/or induction areas for patients of different modalities.
- This presents safety challenges because patients for a different modality would not typically be screened for MR contraindications or ferromagnetic materials. This poses a risk for a patient or other individual with a contraindicated implant. Those in MR Zone IV

would be subjected to a serious safety threat if an erroneously unscreened or suboptimally screened individual entered Zone IV with a ferromagnetic object.

- A patient holding area in Zone III should be used exclusively for post-screened MR patients.
- A small Zone III may be sufficient in outpatient facilities performing diagnostic MR scans. In this scenario, Zone III serves as a transit zone for the patient being transported from Zone II into Zone IV, with no patient holding occurring in Zone III.
- **Lines of sight/situational awareness**
- Level 2 MR Personnel should have a direct line of sight to the entrance to Zone IV.
- The MR Technologist seated at the MR operator's console should be able to view the patient in the MR scanner.
- Remote video and audio capabilities can be helpful to enhance the communication between personnel in Zone III and Zone II.
- Video recording equipment monitoring the Zone IV door may be helpful in quality improvement efforts to evaluate best practices, near misses, and safety events. Prospective planning for such equipment could be helpful.
- **Appropriate signage**
- Battery backup "Magnet is Always on" sign.
- **Potential harmful unique aspects of the MR environment**
- For many MR system installations, the magnetic field may project beyond the confines of the magnet room (Zone IV) and can superimpose potential hazards on spaces that may be outside the MR suite, even on floors above or below the MR facility and perhaps even outside the building.
- Facilities must identify all areas, including those outside the MR suite (including rooftops, storage areas, mechanical closets, crawling spaces, etc.) that are exposed to potentially hazardous fields related to the MR environment and that may be occupied.
- Areas of potential hazard must be clearly identified, and access to these areas must be restricted and clearly indicated with appropriate signage just as they would be within the MR suite.

Zone IV

- The design of Zone IV (and MR equipment room) is complex and typically requires following the MR vendor recommendations.
- Being the location of the MR magnet itself, many critical issues and items must be considered thoughtfully during the Zone IV design stage. Adjoining building space must be large enough, accessible enough, and with sufficient foundational support to accommodate delivery of the large and heavy MR unit.
- Adequate space must be devoted to adjacent equipment rooms, and access to these rooms must be planned in advance.
- Planning is essential for runs/chases for electrical lines; data management lines; heating, ventilation, and air conditioning (with considerations for unique temperature, humidity control, and airflow requirements); and plumbing lines.
- Quench pipe routing pathways must be considered (see Cryogen vent pathway).

- Various shielding elements must be built into Zone IV walls to contain and/or limit the fringe field, radiofrequency (RF) field, and acoustic noise.
- Depending on whether the RF door opens inwardly or outwardly, discuss with the vendor the need for a pressure release mechanism during a quench venting failure. If the RF door opens outward, the line of site and ferromagnetic detector placement should be considered.
- Planning for the contents of Zone IV is essential, and the overall room size must be sufficient to accommodate all the planned elements. These elements must be thoughtfully sited to maintain practice efficiency as well as safety. Please refer to Figure 21 for a depiction of a typical contemporary Zone IV room and its contents of a facility performing both inpatient and outpatient MR examinations, understanding that this is not intended to be absolutely all inclusive of room contents and that individual practices need to tailor their facilities to best serve their unique needs. Common elements are included in the following table:

TABLE 6. Common Elements for Zone IV

Visual in/on floor 9 and 200 gauss and other device-specific gauss line markers	Emergency call/assistance button (either Zone IV or close proximity in Zone III)
Power injector	Safety strap/access control barrier at Zone IV door
Data ports	Waveguide and other cable management
Anesthesia machine	Temperature/humidity control
Emergency backup power	Ambient and procedural lighting and controls
Wall anchor and fixed length tethers	In-room storage, cabinets, shelves, or others permitting access to coils/phantoms, RF insulating pad, contrast media, linen, and entertainment/fMRI systems
Medical gases	Sink
Suction	Sharps container
Physiologic monitoring equipment	Glove dispenser
Patient monitoring camera and intercom system and patient squeeze ball	Hand antiseptic dispenser
Emergency Magnet Off button	Waste receptacle

- **Cryogen safety**
    - For most MR systems, if the magnet quenches (i.e., loss of superconductivity/magnetic field), the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area. Accommodation for such an area and plans for appropriate access restriction and signage must be included in the design phase.
    - Superconductive MR scanners with very small volumes of cryogen do not require a quench pipe in the room. Permanent magnet MR scanners do not use cryogens.
    - The following recommended MRI suite design and construction elements reduce patient and staff risks in the unlikely event of a quench in which the cryogen vent pathway (quench pipe) ruptures or leaks into Zone IV:
        - All magnet rooms/Zone IV regions for superconducting magnets should be provided with an emergency exhaust pathway (unless the vendor specifically indicates that the magnet does not require one). The emergency exhaust grille is to be located in the ceiling opposite the entrance to the magnet room (Zone IV) door. At this location, when activated in the unlikely event of a quench breach (inadvertent venting of cryogenic gases into Zone IV), the exhaust fan is positioned to draw the cryogenic cloud away from the magnet room exit.
        - Many MR manufacturers now require that magnet rooms for superconducting magnets also be provided with an additional form of passive pressure relief/pressure equalization to minimize the risks of positive-pressure entrapment. Designs for passive pressure relief mechanisms should follow design criteria similar to that of the cryogen vent pathway and active exhaust, including discharge to a protected area.
    - Even with an exhaust fan, designing the door to Zone IV to swing outward is not, by itself, an appropriate means of pressure relief.
    - Once provided with appropriate pressure equalization and emergency exhaust, magnet room door-swing direction and design should be left to the discretion of a facility and their design professionals.
- **Cryogen vent pathway**
    - Obstructions, inappropriate pipe materials, insufficient pipe caliber and/or length, or faulty connections in the length of the cryogen vent pathway can cause failure between the magnet and point of discharge.
    - Because minimum design requirements for some cryogen vent systems have been revised by magnet system vendors, facilities should obtain current standards from the original equipment manufacturers to use in evaluating their cryogen vent assembly and not rely on original siting requirements.
    - Because obstructions/occlusions of the cryogen vent can increase the likelihood of rupture in a quench event, facilities should ensure the following:
        - The discharge point has an appropriate weather head that prevents horizontal, wind-driven precipitation from entering, collecting, or freezing in the quench exhaust pipe.
        - The discharge point is positioned so that snow or debris cannot enter or occlude the pipe.

        - The discharge is covered by a material of sufficiently small openings to prevent birds, other animals, or other material from entering the quench pipe, while not occluding cryogenic gaseous egress in a quench situation.
    - To protect persons from cryogen exposure at the point of discharge during a quench, facilities should ensure the following:
        - At the point of cryogen discharge, a quench safety exclusion zone should be established and clearly marked with surface warnings and signage. Note that the quench pathway discharge point must be surrounded by physical restrictions for non-MR Personnel.
        - The quench safety exclusion zone should be devoid of serviceable equipment, air intakes, operable windows, or unsecured doors that either require servicing or offer a pathway for cryogenic gases to re-enter the building.
- **MR Conditional, external, non-implanted equipment and devices**
    - Examples of such equipment/devices include anesthesia machines and power injectors for use in Zone IV. The specific MR conditions for use should be carefully assessed, and permissible distances/proximity to the magnet should be identified. It is recommended that these allowable proximity lines be delineated on the floor and walls of the magnet to aid in safe positioning and effective use of the equipment.
    - The use of tethering hooks in the wall of the MR suite (Zone IV) and tethers with specific lengths to prevent the MR Conditional device from moving closer to the MR scanner beyond the conditions specified by the vendor are strongly recommended in those facilities using such devices routinely.
    - Tether anchor points should be prospectively planned in the design and construction of the Zone IV enclosure, as penetrations into existing RF-shielded walls or floors could damage the function of an RF-shielded enclosure.
- **Infection control**
    - The magnet system room finishes, and construction details should be designed to facilitate cleaning by appropriately trained staff with nonmotorized equipment.
    - For interventional and MR-guided procedures, basic infection control protocols such as seamless floorings, scrubbable surfaces, and hand-washing stations should be considered.

Disclaimers and recommendations. The facility design issues identified in this appendix only address general safety design issues for MRI suites. There are a multitude of site-specific and magnet-specific operational and technical design considerations relevant to MR facility design and construction that are not addressed in this appendix. These issues include, but are not limited to, patient acuity, staff access, modality conflicts, vibration sensitivity, throughput/efficiency, HIPAA considerations, magnetic contamination, sound transmission, magnet shim tolerances, shielding design, moving metal interferences, MR equipment upgrades, and electromagnetic interference.

In addition to incorporating the guidance from this appendix, a facility would be well advised to seek expert assistance in the planning and design of MRI and multimodal radiology suites.

Reference

1. The Facility Guidelines Institute. Guidelines for Design and Construction of Hospitals. 2018 ed.

APPENDIX 3:
MR Facility Maintenance and Emergency Preparedness Guidelines

Health care facilities have a unique obligation to minimize the disruption from maintenance issues as well as disasters and hasten their ability to restore critical patient care services when interrupted.

Those charged with the operation of MR facilities have the added complexities of protecting not only the staff and structure but also the equipment, which may be extraordinarily sensitive to changes in its environment, including vibration, interrupted power supply, and water damage.

Depending on location, facilities may have to contend with earthquakes, tornadoes, fires, ice storms, snowstorms, or blackouts. Prospective disaster planning may prove beneficial to such sites.

1. **Maintenance**
   Maintenance in Zone IV brings many unique challenges. Maintenance efforts should be well planned and monitored, and an MR Safety Officer should be available to supervise contractors and maintenance personnel. Appropriate role-specific MR safety training for these individuals is recommended. Every effort should be made to have nonferrous tools, and if ferromagnetic material must be brought into Zone IV, there must be a well-designed plan of action to ensure safety (i.e., tethering, potentially ramping the magnet down prior to the maintenance work). Maintenance should be performed in accordance with manufacturer's recommendations and schedules.

2. **Water damage**
   Whether from roof failure, burst pipes, storm surges, or rising water levels, every facility has the potential for water damage to equipment and facilities. It takes only a small quantity of water in contact with an MRI scanner to incapacitate or destroy the equipment.

   In the event of impending water damage, facilities may decide to prepare by covering gantries and equipment with sturdy plastic taped in place. Where possible, electronic components should be raised from the ground. Radiofrequency (RF) shields, particularly the floor assembly, may be significantly damaged and may need to be replaced following a flood if not designed to be protected against water damage.

   Temporary electrical power may be provided either through on-site or portable emergency generators. Facilities should evaluate risks from water damage and assess their preparations for failure of the building enclosure and be especially sensitive to emergency generators that may be located in basements or other low-lying areas.

3. **Structural damage**
   MRI presents a particular challenge with structural failure. Although unlikely with current MR systems, vibrations from seismic events have the potential to initiate a

quench of the MR system. Structural damage or motion may also damage the RF shield enclosure, potentially degrading image quality.

4. **Power outage**

   Without electrical power to the vacuum pump/cold head to reliquefy the cryogen within a superconducting MR system, the cryogens will begin to boil off at an accelerated rate. Depending on cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water or water vapor in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench.

   At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gases. This poses a safety risk to anyone near the discharge and runs a risk of potentially permanently damaging the magnet's coils.

   However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption.

5. **Quench**

   Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in nonemergent situations only after verifying the function of emergency exhaust systems and verifying or providing means of pressure relief. The facility should check for water leaking from fittings or condensation forming on vent pipe sections as possible signs for water or ice inside the pipe. If/when feasible, a discussion with the device manufacturer regarding an intentional, controlled static magnetic field ramp down may be advisable.

6. **Prevention**

   Although it is the nature of emergencies to be surprises, we can anticipate the types of incidents that have higher likelihoods given our facilities, practices, and locations. Every facility should anticipate the potential for flooding and fire.

   State and federal offices of emergency preparedness are dedicated to anticipating and preparing for the specific threats of a given region. These can serve as an excellent resource regarding risks and strategies for preparation.

   Once a disaster has struck, it is important to assess what the immediate needs of a community are and to restore those critical patient care services first.

   Damage to MRI equipment and facilities may not be repaired as quickly. For seriously incapacitated facilities, the use of mobile MR system units may be the only means of quickly restoring radiology capacity.

All health care facilities should have emergency preparedness plans. The health care plans for MRI facilities should specifically address the unique aspects of MRI equipment. These plans should define who has the authority to authorize nonemergent quenches, procedures for emergency or backup power for the vacuum pump/cold head, and instructions on how to protect gantries and sensitive electronics. Facilities should have the necessary supplies prepositioned and checklists for preparatory and responsive actions. Emergency preparedness plans should also include information necessary for restoring clinical services, including contacts for the MR system vendor, RF shield vendor, cryogen contractor, MR suite architect and construction contractor, local and state officials, and affiliated hospital and professional organizations.

Below are a few questions that may facilitate the development of an emergency preparedness plan specific to the needs of a facility.

- What are the likely/possible natural disasters to affect the area?
- What are the likely/possible manmade disasters to affect the area?
- Is electrical power likely to be interrupted?
- Would other utilities (natural gas, telecommunications, etc.) likely be interrupted?
- What equipment would be inoperative during the emergency?
- What equipment could be damaged by the emergency?
- What equipment should be provided with critical or backup power?
- If the utility service is not quickly restored, what other risks may arise?
- Would patients and staff be able to get to the facility?
- Would patients or staff be trapped at the facility?
- How critical is each patient care service provided at the facility?
- How does the facility protect the equipment needed to support each service?
- How does the facility protect the patient data (including such options as off-site storage) from each service?
- If the facility does not have the resources for the above on-site, who can provide them?

APPENDIX 4:
Implanted Device MR Risk/Safety Assessment

In clinical practice, medically necessary MR examinations in the presence of implanted devices with potential safety concerns have become increasingly common [1]. MR Conditional implanted devices may require specific conditions for safe scanning that may be difficult to meet or limit the ability to acquire MR images of sufficient quality to address the specific clinical question. Similarly, implanted devices may lack documentation in the medical record (e.g., implanted at a different medical center or several years prior) and thus challenge the ability to determine the risk level. Moreover, a patient with the need for MR imaging may have an implanted device labeled as MR Unsafe, potentially precluding MR imaging.

Here, we provide a general approach to evaluating the potential risks of performing an MR examination when patients have implanted devices that, for example, may not meet all MR conditions for safe scanning. A similar discussion is included in the Medicines and Healthcare products Regulatory Agency document for reference [2]. It should be noted that itemizing the complex, multifactorial decision tree in all clinical scenarios is not only beyond the scope of this manual but also virtually impossible. Nevertheless, the guiding principle in this decision process should be to adequately address the risk versus benefit ratio of undergoing an MR examination for the patient. This often requires a discussion between the treating physician(s) and MR Personnel with expertise in MR safety (i.e., Level 2 MR Physician, MR Medical Director (MRMD), MR Safety Officer (MRSO), and/or MR Safety Expert (MRSE)). Alternative imaging modalities (e.g., computed tomography, ultrasound) and the medical risk of not receiving an MR examination should be considered. Lastly, research participants generally do not benefit from a research MR examination, and therefore, the threshold for accepting an unknown or higher-risk scenario should be much higher than that of a clinically indicated MR examination.

The following considerations, among potential others, should be addressed during the initial assessment, preparation, scanning, and post-examination follow-up phases of the MRI exam.

Initial assessment

1. Implanted device(s)
    a. Type of device(s).
    b. Manufacturer(s) and model(s).
    c. Anatomic location(s).
    d. Available information on MR conditions.
        i. Device eligibility for MR.
        ii. Vendor MR Conditional instructions for use (IFU).
            1. Exposure of object/device to
                a. static magnetic field
                b. time-varying gradient magnetic field
                c. radiofrequency (RF) magnetic field
        iii. Published recommendations from appropriate professional bodies.
        iv. Published evidence of scanning device under similar conditions.

e. Current device status (operational, abandoned, damaged, implanted outside of vendor MR conditions, etc.).

Note: addressing the above may require consulting the device manufacturer or local representative, a device specialist, relevant documentation, prior imaging, and/or operative reports and could lead to the need to acquire x-rays or CT prior to making a decision.

2. MR scanner
    a. Availability of a scanner to meet MR conditions.
        i. Field strength and orientation, spatial field gradient, gradient performance, RF coil (e.g., detachable transmit-receive coils).
        ii. Sequences and options for obtaining needed information within specific absorption rate (SAR)/$B_1^+{}_{rms}$ and/or dB/dt exposure limits with appropriate image quality.
        iii. MR Equipment Output Conditioning (MROC) options to manage RF and gradient outputs [3].
        iv. Availability of appropriate ancillary equipment, expert personnel, and emergent response team for monitoring and managing patient and device in the MR environment.
3. Patient
    a. Clinical question and/or requested examination.
        i. Patient positioning permitting compliance with MR conditions as well as consideration of location of implant(s) within the scanner to assess impact of static, RF, and gradient field conditions.
    b. Patient eligibility for MRI with device(s) via vendor IFU.
    c. Patient status (routine, emergency, under anesthesia, compromised thermoregulatory system, etc.).
    d. Potential impact of device artifacts and/or MR protocol and parameter limitations on examination image quality/diagnostic capacity.
    e. Further risk/benefit considerations.
        i. Potential injury to the patient.
        ii. Potential damage to the device and associated impact on the patient.
        iii. Clinical impact of performing a procedure to remove a device prior to examination.
        iv. Clinical impact of not performing or delaying the MR examination.
        v. Identification of alternative imaging approaches.
    f. Document risk versus benefit decision, and plan for managing risk during MR examination.

Preparation and scanning

1. Implanted device(s) (as appropriate).
    a. Appropriate device expert, including MRSE and/or clinician present if needed.
    b. Device battery level.
    c. Patient/clinician implanted device programmer electrically charged and available

        i. Interrogate device to establish/verify eligibility (i.e., impedance check/lead damage).
        ii. Record/save settings (i.e., cardiac implantable devices, deep brain stimulator, vagal nerve stimulator, programmable shunt).
        iii. Program device for MR environment (e.g., MR Conditional mode).
    d. Secure and immobilize on patient (i.e., cochlear magnet, tissue expander with magnetic port).
    e. Plan for device damage or inability to recover normal function.
2. MR scanner and environment.
    a. Patient scheduled to appropriate MR resource at an appropriate time.
    b. MR safety screening and training of team members possibly to include non-MR Personnel that may need to be present during examination.
    c. Consultation or direct supervision (MRMD, MRSO, or MRSE) as needed/required
    d. Modified MR protocol available to meet planned conditions.
    e. Scanner in appropriate operating mode or MROC setting for SAR/$B_1{}^+{}_{rms}$ and dB/dt.
        i. Active monitoring of scanner output and timing during examination by appropriately trained personnel to meet MR conditions.
3. Patient
    a. Verification of patient eligibility for MR.
    b. Informed consent when appropriate.
    c. Educated on device preparation for examination.
    d. Proper positioning of patient and device within bore and RF coil.
        i. Management of external leads or cables.
        ii. Distancing device from bore wall.
        iii. Placement of sealed ice packs for external object cooling.
    e. Communication plan (with the team and with the patient).
        i. Audible, visual, and squeeze ball.
        ii. Clear instructions to patient (and team) on what sensations to expect and when/how to stop examination or communicate with the team.
    f. Patient monitoring and management plan.
        i. Appropriate physiological monitoring.
        ii. Sedation or anesthesia.
        iii. Planned periods of nonscanning for cooling off if necessary.

Post-examination follow-up

1. Patient: assess for pain or injury.
2. Device: assess and/or reprogram device to normal function.

Sites are encouraged to objectively assess their capability of safely performing an MR examination under challenging/unusual conditions. Thoughtful consideration of referring the patient to an alternate imaging facility with the necessary expertise is encouraged when appropriate.

References

1. Shellock FG. Chapter 18: MRI issues for implants and devices. In: Shellock FG, Crues JV III, eds. *MRI Biological Effects, Safety, and Patient Management*. Biomedical Research Publishing Group; 2022:462-497.
2. Medicines and Healthcare products Regulatory Agency. Safety guidelines for magnetic resonance imaging equipment in clinical use. Published November 7, 2014. Accessed April 22, 2024. https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use#full-publication-update-history
3. International Electrotechnical Commission. Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. 4th ed. Published August 4, 2022. Accessed April 22, 2024. https://webstore.iec.ch/publication/67211

APPENDIX 5:
Spatial Field Gradient Evaluation

The translational force on an object in the MR environment is proportional to the product of the induced field in the object by the magnetic field and the spatial field gradient (SFG). Therefore, the SFG plays an important role in the forces experienced by an object in addition to the magnitude of the magnetic field itself. The SFG characterizes the static spatial gradient of the magnetic field surrounding an MR system. It is the spatial rate of change (Δ) in the magnetic field at any given position in space around the MR scanner. The SFG increases substantially as one approaches either end, or "face," of an MR scanner.

A map of the SFG is necessary to characterize or predict forces on ferromagnetic objects in the vicinity of the MR system and so is required to be disclosed for each specific magnet configuration in the MR vendor operating manual [1]. Note that this information is most often applied to assess the MR safety conditions on implanted medical devices.

MR Conditional labeling of implants and devices typically provide 2 numbers relevant to translational and rotational forces, the maximum static field (B_0) and the maximum SFG (DB/Dz), to which the device/implant has been tested and shown to be safe when exposed [2,3]. The SFG varies as a function of the proximity to the bore wall, increasing with increased bore wall proximity. Based on the physical location of the implant in the patient's body, the use of specific SFG plots provided by manufacturers for the specific MRI unit permits predicting the maximum SFG to which an implant would be subjected based on its physical location in the body and its location relative to the bore wall. Implanted device vendors provide the maximum SFG value that should not be exceeded with the device's MR Conditional labeling in its instructions for use. Note the maximum allowable SFG may be quoted as a function of maximal static B_0 value or may be stated to be independent of this value [1,3].

The relevant question to be answered is the following: What is the maximum SFG a device in the patient will be exposed to for a specific anatomic scan during movement into and out of the MR scanner bore?

Currently, MR system vendors provide SFG maps specific to their magnets. The suggested visual layout, advocated by the current International Electrotechnical Commission standard, is via manufacturer-provided SFG maps that depict a transaxial view of the bore of the magnet and include the patient couch, with equidistant concentric circles around the scanner isocenter (Figure 30) [4]. Each concentric circle represents the cross-section of a cylindrical volume within the scanner bore and the maximum estimated or measured SFG value within this volume, which is listed in a legend for reference. Limitations of such axial SFG maps include ambiguity of the exact location of the maximum SFG value along the cylindrical volume associated with each circle. Another common representation of SFG values are maps that depict either sagittal (Figure 31) or coronal planes passing through the center of the magnet bore, with contours tracing out the regions of constant SFG values (isogradient contours). If provided in only 1/4 view, the operator should understand that these representations of SFG are typically both horizontally (about both the central *y* and central *x* axes) and radially (about the central *z* axis) symmetric. Quarter SFG maps may be mirrored to yield a map that covers the entire MR bore.

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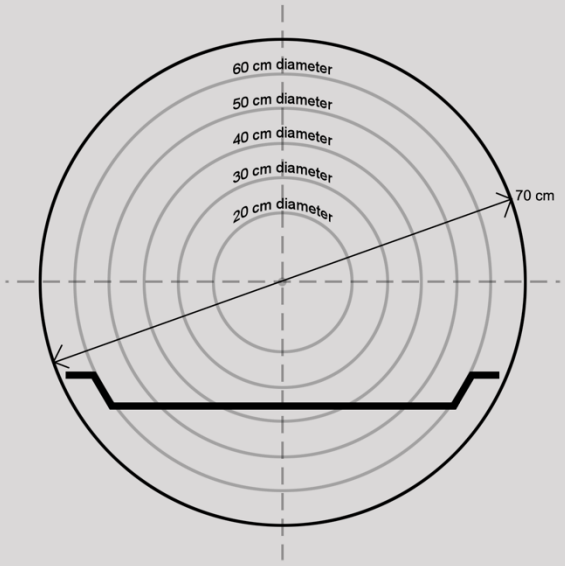

		Spatial Field Gradient
On central Z-axis	35 cm from bore wall	190 G/cm
20 cm diameter	25 cm from bore wall	230 G/cm
30 cm diameter	20 cm from bore wall	280 G/cm
40 cm diameter	15 cm from bore wall	320 G/cm
50 cm diameter	10 cm from bore wall	490 G/cm
60 cm diameter	5 cm from bore wall	520 G/cm
70 cm diamter	On bore wall	770 G/cm

FIGURE 30. Transaxial view SFG map of an MR system indicating maximum SFG values that may be encountered within each of the cylindrical volumes within the diameter of the bore (image courtesy of Tobias Gilk of Gilk Radiology Consultants).

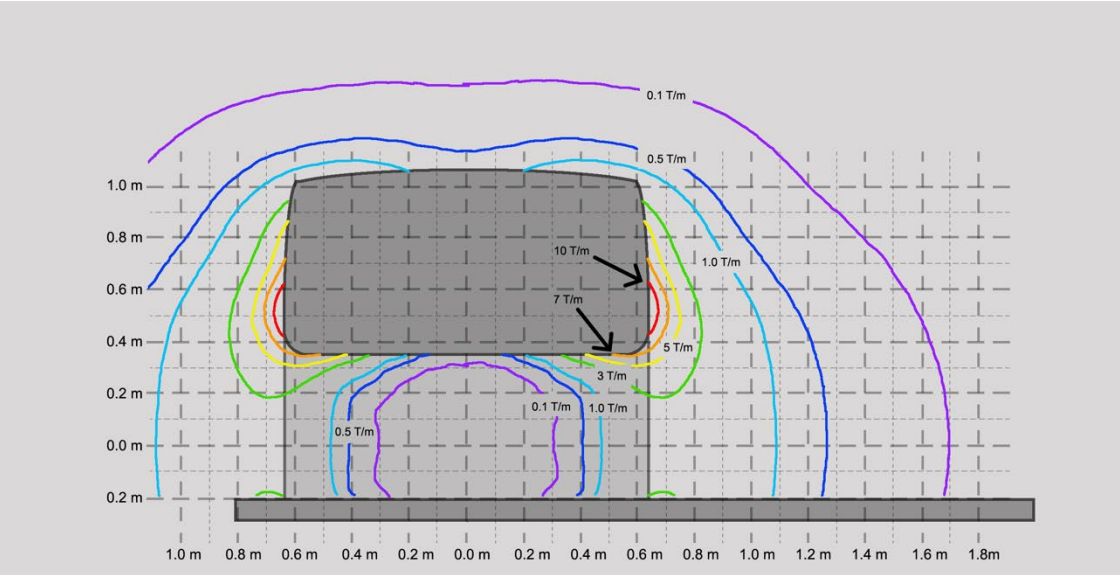

FIGURE 31. Sagittal view spatial field gradient map of an MR system. The solid gray line just above the horizontal x-axis is the tabletop. Each dotted line represents spatial increments of 10 cm (image courtesy of Tobias Gilk of Radiology Consultants).

It is essential that the physician responsible for MR safety, or the physician's designee(s) (i.e., often the MR Safety Expert), be able to apply the manufacturer-provided SFG values and maps to each scanning event as a means of safe scanning in the presence of a medical device, taking into consideration the anatomy scanned and the route the device will take during its course in Zone IV [1].

References

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