Radiology

REVIEWS AND COMMENTARY • STATEMENTS AND GUIDELINES

American College of Radiology Manual on MR Safety: 2024 Update and Revisions

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Conflicts of interest are listed at the end of this article.

See also the editorial by Kanal in this issue.

Radiology 2025; 315(1):e241405 • https://doi.org/10.1148/radiol.241405 • Content codes: SQ MR

Since the introduction of the American College of Radiology (ACR) MRI safety guidelines in 2002, the indications for use of MRI in clinical care and research have continued to expand. Similarly, MRI technologies have evolved, with multiple field strengths now available for human imaging. While several publications have updated the ACR recommendations since the first guidelines, a single source in a structured format was lacking. Accordingly, the ACR Committee on MR Safety recently updated the online ACR Manual on MR Safety that compiles ACR recommendations for safe use of MRI equipment in humans into a single document. This review describes the new structure of the ACR Manual on MR Safety, discusses new content, indicates gaps in knowledge that require further research, and explains the rationale for the Committee on MR Safety recommendations on certain topics, such as remote operation of MRI systems.

The utilization of MR technologies in patient care and research continues to expand, with increasing complexity of MR environments becoming the standard. Further, the complexity of patients and research participants undergoing MR examinations continues to increase, paralleling the development and dissemination of an increasing number of new implanted devices. The American College of Radiology (ACR) Committee on MR Safety has published guidelines for the safe use of MR in humans for over 20 years (1–5). In 2020, the guidance manuscript was posted online as the ACR Manual on MR Safety (hereafter, ACR Manual). In 2022, the committee was charged with updating the MR safety guidelines and redesigning the online manual in a chapter-based format. The rationale for transitioning from regularly published manuscripts to a comprehensive online manual include *(a)* timely updates should be provided in the fast-evolving field of MRI; *(b)* MR safety information should be available worldwide to all involved in the care of patients and research participants in MR environments; *(c)* current guidelines include far more content than can be collated in a typical manuscript; and *(d)* it is difficult to maintain the overall organization of the content, especially as new sections or revisions of the guidelines emerge and are subsequently published separately in manuscript format.

Accordingly, the goals for the new ACR Manual are to *(a)* provide comprehensive and up-to-date safety practices in a single and searchable location to facilitate the safe use of MR in clinical practice and human research; *(b)* enable timely updating of the MR safety guidelines as new data and evidence emerge; and *(c)* indicate areas where data are lacking to support definitive expert recommendation. The ACR Manual provides general guidelines and recommendations for best practices that are based on the consensus expert opinion of the committee members and available literature, with the goal of minimizing the risk of adverse events in real-world MR clinical and research settings, noting pressures related to throughput, financial considerations, and potential personnel shortages, among others. This review provides an overview of the organization of the online manual and highlights the rationale and approach taken by the committee members to develop content that is new from previous versions of the ACR guidelines on MR safety. However, this review does not encompass a comprehensive overview of the manual content, and the reader is directed to the ACR Manual for detailed information (6).

General Considerations and New Structure of the ACR Manual on MR Safety

The updated ACR Manual is intended to serve as an educational tool to increase understanding of core MR principles and how they affect MR safety. These 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.

The new organization of the ACR Manual follows a stepwise framework that includes initial considerations for facility design, guidelines for safety policies and standard operating procedures (SOPs), suggested leadership and expert supervision, and current recommendations for procedures before, during, and after completing an MRI examination. The ACR Manual is enriched by several appendices that provide additional information about the design and operation of an MR facility.

Abbreviations

ACR = American College of Radiology, IEC = International Electrotechnical Commission, MRMD = MR Medical Director, RF = radiofrequency, SAR = specific absorption ratio, SOP = standard operating procedure

Summary

The 2024 updated American College of Radiology Manual on MR Safety provides a comprehensive source of information and recommendations for topics related to the safe operation of an MRI facility.

Essentials

- The online edition of the American College of Radiology (ACR) Manual on MR Safety represents a new resource that can be updated in a timely fashion to address the rapidly evolving field of MRI.
- The ACR Manual on MR Safety provides new guidelines for MR personnel training levels and responsibilities.
- Staffing models should address emerging complexities of MR environments, including hybrid systems, intraoperative or interventional MR suites, MRI facilities outside radiology departments (eg, radiation oncology), and remote scanning.
- The remote operation of MR systems is an innovative solution to image patients but also poses new challenges for the safe operation of MRI facilities.
- A comprehensive list of policies and standard operating procedures is offered as a guide to assist MRI facilities in maintaining adequate safety standards for MR use in humans.

The ACR Manual refers to other available documents for topics that are either beyond the scope of the manual or covered in detail by other expert panels. For example, the manual refers to the ACR Manual on Contrast Media (7) for recommendations regarding the use of contrast media for MRI. Similarly, the manual refers to the current recommendations from the Heart Rhythm Society (8) for MR examinations in patients with cardiovascular implantable electronic devices.

MR Safety, Policies, and SOPs

Death and serious injury have occurred in MR facilities. MR safety events are often linked to unsafe practices, failure to follow MR safety policies and SOPs, or gaps in safety policies and SOPs. Equipment failures are rarely the primary cause of MR safety events. The risks of MR are related to the static field (B_0) and the two time-varying fields, the gradient field (dB_0/dt) and the radiofrequency (RF) field (B_1). The risks associated with B_1 and dB_0/dt are managed in part with the different scanner operating modes (eg, normal and first-level controlled). These fields can interact with implanted and on-planted (ie, worn or located largely external to the body, such as insulin pumps) medical devices in potentially deleterious ways.

All clinical and research MR facilities, irrespective of magnet design or field strength, including installations for diagnostic, research, interventional, and/or intra- or perioperative applications, should maintain MR safety policies. A recommended management structure of the facility includes an MR Medical Director (MRMD), an MR Safety Officer, and an MR Safety Expert, with the roles and responsibilities of such individuals clearly defined (9). In addition, an MR Safety Committee including those in the management structure and, when feasible, other pertinent stakeholders (eg, radiologists, physicists, technologists, advanced practice providers, nurses, anesthesia personnel, MR technical maintenance personnel), is encouraged. The committee should regularly meet, review, and report (when appropriate) MR-related adverse events, safety incidents, "near misses," and other MR safety issues so that policies and SOPs can be updated as needed in an effort to prevent future incidents. The ACR Manual now provides, for the first time, a comprehensive list of suggested policies and SOPs for MRI facilities in Appendix 1 (6).

The MR Environment: MRI Site Planning and MR Zones

Plans for the design of a new MRI facility should be reviewed by experienced personnel familiar with patient safety and patient flow considerations. Appendix 2 in the ACR Manual now provides a comprehensive bulleted list of items, broken down into applicable MR safety zones that should be considered. Appropriately placed magnetic hazard signage remains one of the pillars of MRI safety (Fig 1). Emphasis is now made on three key definitions adapted from several sources to better describe MR safety risks in relation to physical location within the facility (10–12).

MR Environment

The MR Environment is the three-dimensional volume surrounding the MR system that contains both the Faraday-shielded volume and the 9-G line. In this region, 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 essential for risk mitigation.

MR Controlled Access Area

The MR Controlled Access Area is the locally defined area around the MR system that contains the MR Environment (including its static magnetic field) to which access is limited to authorized personnel. Additional areas outside the MR Environment may be within the controlled access area.

Areas where a magnetic field greater than 9 G extends into spaces above, below, and around the suite—even if not directly contiguous with Zone IV—are considered part of the B_0 hazard risk area and within the MR Controlled Access Area. Because of the additional projectile risks, any entrance to Zone III providing direct access to Zone IV should be restricted by access control cards, badges, or other technology to ensure access for designated personnel only. A new safety recommendation is made for tethers in Zone III to secure MR Unsafe equipment temporarily stored in this zone (Fig 2).

MR Projectile Area

The MR Projectile Area is the area within Zone IV surrounding the MRI system in which ferromagnetic objects are at risk for becoming projectiles.

While the four MR safety zones remain largely unchanged, the reader is directed to the ACR Manual for detailed definitions, as a few updates are worth special attention.

With regard to the 9-G line, Zone III includes primarily the MR Controlled Access Area. Historically, the 5-G line has been a standard threshold for risk. A magnetic fringe field of 5 G (0.5 mT) was considered synonymous with the "pacemaker line" for MRI safety (ie, a conservative threshold based on fringe field requirements for cardiovascular implantable electronic devices

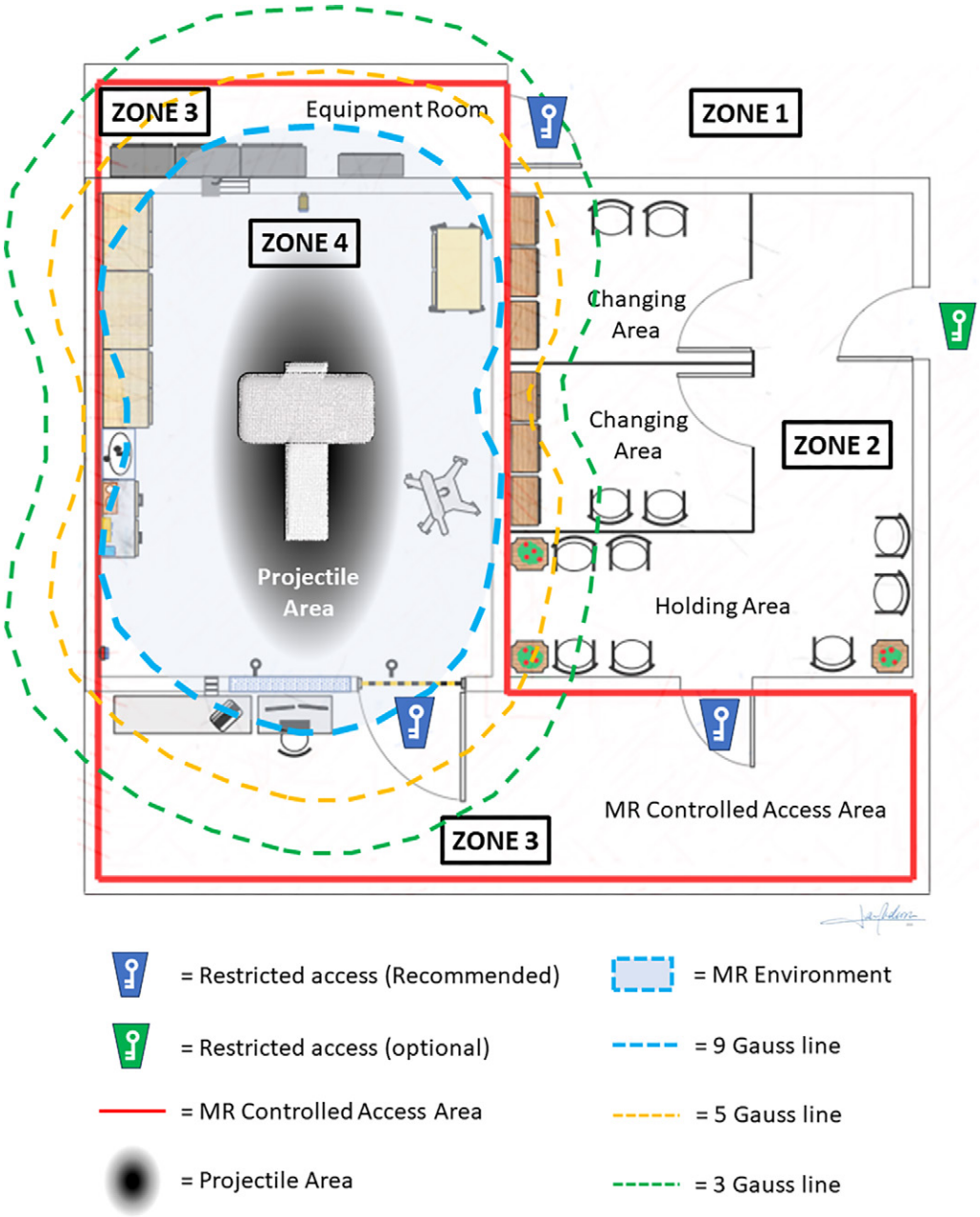

Figure 1: Diagram illustrates example layout of an MRI facility. Note depictions of "MR Controlled Access Area," "MR Environment," and "Projectile Area" as they relate to the American College of Radiology four-zone model.

[13,14]). A recent update to the International Electrotechnical Commission (IEC) standard (IEC 60601–2-33:2022) has revised the fringe field limit to 9 G (0.9 mT) (15). The ACR Manual endorses the new IEC standard. Because the 9-G line is located within the 5-G line (ie, it is closer to the magnet), facilities following prior recommendations to use the 5-G line as the B_0 hazard zone do not require adjustments to maintain the safety of the MR Environment.

Cryogen Venting Zone

The area designated for cryogen venting (typically on the roof of the facility), previously considered part of Zone III, now receives separate consideration. Typically, it is not contiguous with the MR Controlled Access Areas containing Zones III and IV, and it is virtually impossible for MR Personnel to control access. However, the need for facilities to control access to this area and maintain safety signage remains.

MR Personnel and Staffing

MR Personnel (those routinely working in the MRI facility) remain differentiated from non–MR Personnel (patients, visitors, or staff not meeting the criteria of MR Personnel). MR Personnel are classified as *(a)* Level 1, having passed the MR safety education defined by the MRMD to ensure they do not constitute a danger to themselves or others in the MR Environment, and *(b)* Level 2, more extensively trained in the broader aspects of MR safety issues. The ACR Manual now provides guidelines about common safety elements expected for the training of Level 1 and Level 2 MR Personnel (Table 1).

Additional education to further stratify Level 1 and Level 2 MR Personnel may be necessary in certain circumstances (eg, alternative MR Environments) to ensure safety and operational efficiency. Although the staffing model of a specific MRI facility is influenced by many factors, including its design and function (eg, outpatients, inpatients, emergency department, research), general recommendations that apply broadly should be considered. Each facility should establish a minimum staffing plan for each MR area to ensure adequate numbers of appropriately trained personnel on-site to guarantee safety. MR Technologists are health care professionals who have received specific training and satisfy the local requirements to operate MRI systems for human scanning. A minimum of one Level 2–trained MR Technologist per scanner is needed during routine hours. The Level 2 MR Personnel operating the MRI scanner for human scanning are trained and certified Level 2 MR Technologists. There must also be a minimum of one additional MR Personnel (Level 1 or Level 2) in Zone III, with a temporary exception made for patient interviewing or retrieving from Zone II.

Figure 2: Photograph shows the use of tethers in Zone III. Example of temporary storage of an MR Unsafe stretcher in Zone III. While temporary storage of such equipment may be necessary in certain situations to facilitate patient care, tethering minimizes the risk of inadvertently introducing MR Unsafe equipment into Zone IV. Note the clear signage on the wall indicating that this equipment cannot be taken into the magnet room.

Remote Operation

The recent development of remote operation capabilities (also known as *remote scanning*, where the MRI console is controlled by an operator at a location remote to the contiguous Zone III) offers potential benefits to patients (eg, improved access to expert MR Technologists); however, this also brings new complexities to the staffing models of MRI facilities. Recognizing that this is an evolving technology, the ACR Manual indicates that the overriding principle in situations where 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 with the MR Technologist on-site.

The MRMD of the facility is responsible for the development and implementation of policy regarding staffing and training required for the safety of those being scanned at their facility. It should be noted that recent publications have proposed that within remote scanning environments, nonscanning duties typically performed by MR Technologists can be performed by non-technologists specially trained in their place. This new role has been variably referred to as an "MRI tech aide" (16) or "patient manager" (17). However, national and state standards and licensures for these new positions, including necessary training and accreditation, do not exist at this time.

Details of multiple potential scenarios are beyond the scope of this review (Fig 3). However, certain essential elements of the staffing model should be recognized: *(a)* a Level 2 MR Technologist must be in full control of the MRI system in either Zone III or remotely; *(b)* direct, in-person patient monitoring should be continuous when scanning is performed remotely; *(c)* dedicated on-site Level 2 MR Personnel with the sole responsibility for monitoring and communicating with both the patient and the remote MR Technologist must be assigned to each patient when the patient is in Zone IV. Due to patient monitoring and safety concerns, the ACR Manual currently discourages situations where a remote MR Technologist scans more than one patient simultaneously.

The ACR Committee on MR Safety recognizes the merits of remote scanning and the potential to address staffing challenges. However, it also recognizes that the function of the MR console operator extends well beyond the technical aspects related to MR system operation. Even when they are using assistive technology, an essential role of the MR operator is to identify situations that may compromise patient safety. This includes review of images for artifacts (eg, related to an unexpected foreign body), motion as a sign of patient distress, and acute medical findings requiring urgent communication with the supervising physician. These cognitive tasks cannot be replaced by current software or by an assistant in Zone III, and safety may be compromised if a single operator is concurrently scanning more than one patient.

Remote scanning requires an adequate staffing model with predefined roles (Table 2). The ACR Committee on MR Safety acknowledges that the MR safety guidelines for remote scanning will likely evolve with changes in the technology, experience, and training standards.

MR Screening

Thorough screening of any person (eg, patients, research participants, companions, staff) before entering Zone III and IV remains one of the most important steps to ensure safety during MRI. Ultimately, the final determination of whether or not to scan a patient is to be made by the MRMD or designated 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. Importantly, the supervising physician must balance the benefit of the MRI examination (eg, diagnosis, care plan), including the risks that may arise if the study is not performed, against the risks of proceeding. These complex decisions often involve patients with implanted devices and may require input from multiple health care professionals (eg, physicians, MR Safety Officer, MR Safety Expert, device manufacturer representative).

An approach to risk identification, assessment, and mitigation before MRI is now described in the ACR Manual, including for patients with implanted devices for which all MRI conditions for safe scanning may not have been met. It is essential to identify the type, location, make, and model of implanted devices accurately and consider the availability of an MRI scanner that meets the device-specific conditions for imaging. It is also important to evaluate patient-related characteristics such as medical conditions and the potential effect of the device on the diagnostic quality of the MRI examination (eg, artifacts in the anatomic area

Table 1: Common Key Elements of MRI Safety Training Expected for Level 1 and Level 2 MR Personnel

Topic	Level 1 MR Personnel	Level 2 MR Personnel
Ferromagnetic projectile risks	✓	✓
General magnetic field safety: "Magnet Is Always On" signage	✓	✓
Importance of maintaining Zone III and IV doorway security and vigilance	✓	✓
Emergency procedures and responsibilities in the MR Environment, including Emergency Magnet Off procedures (quench)	✓	✓
Importance of MR safety screening before entering Zone III and Zone IV	✓	✓
Understanding the roles of MRMD, MRSO, and MRSE and how to contact these personnel	✓	✓
Understanding the importance of safety events and near-miss reporting, and the site-specific mechanisms of doing this	✓	✓
Procedures to secure potentially MR Unsafe equipment in Zone III (tether, locked storage, etc)	✓	✓
Appropriate precautions and procedures for operation in alternative MR Environments (eg, PET/MRI, intraoperative or interventional, 7 T)	✓	✓
Elements of MR safety screening before entering Zone III and Zone IV, including proper use of ferromagnetic detection equipment		✓
Radiofrequency-related safety		✓
Time-varying magnetic fields: PNS and acoustic noise		✓
Cryogen and quench safety		✓
Implanted device safety		✓
Contrast agent safety		✓
Proper use and function of all safety switches		✓
Static magnetic field safety: spatial gradients and Lenz-related forces		✓
Thermal burn prevention		✓
Procedures to ensure ability to communicate with the patient or research participant when scanning		✓
Factors related to scanning of unique patients (eg, pregnant, pediatric, claustrophobic, large body habitus, and imprisoned, detained, or paroled patients)		✓

Note.—The expected content of Level 1 and 2 training may change, at the direction of the MR Medical Director (MRMD), between different MRI facilities based on specific local needs. MRSE = MR Safety Expert, MRSO = MR Safety Officer, PNS = peripheral nerve stimulation.

of interest). Moreover, the MRI facility should have appropriate SOPs for patient preparation before the examination (eg, device set to a specific MRI scan mode), MRI system operations during the examination (eg, modified acquisition protocol and technologist training), and postexamination care (eg, device reprogramming to normal operating mode).

Full Stop and Final Check, Examination Preparation and Completion

The importance of a "full stop and final check," performed by the MR Technologist, has been emphasized in the ACR Manual. A tiered approach is now suggested that addresses the different levels of MR safety risks: *(a)* routine, typical ambulatory setting with satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately before entering Zone IV and *(b)* augmented, more complex settings (eg, hospitalized or interventional patients) including items from the routine process plus thorough screening of any support staff and transport or support equipment entering Zone III or IV (eg, MRI safety conditions, tethering equipment to the wall). The augmented full stop and final check process includes a verbal review by the supervising Level 2 MR Technologist and an acknowledgment by a second MR Personnel team member, modeled on elements of Universal Protocol Final operating room/preprocedure check (Table 3). In more complex scenarios, such as intraoperative MRI suites, it is important to implement specific SOPs for the facility design and functionality. One example is to confirm the absence of a change in patient condition from an MRI safety perspective (eg, a new device implanted in the operating room) as part of the full stop and final check process.

MR Fields and Safety Concerns

The primary sources of safety concern associated with the use of MR technology include the following.

Static Magnetic Field (B_0)

The strong, unchanging field that always remains on for most human MR systems plays a fundamental role in potential forces on metallic implants, devices, and objects. B_0 is generally constant within the magnet bore and tapers quickly outside the magnet. The U.S. Food and Drug Administration, or FDA, recognizes the new IEC standard of the 9-G line as the B_0 hazard area.

The rapid spatial change in the magnetic field from the center of the magnet bore to the fringes of the static magnetic field region is referred to as the spatial field gradient, which describes the rate of change in B_0 as a function of position around the MR system (measured in tesla per meter or gauss per centimeter). In terms of risk, rotational torque forces on objects are determined primarily by B_0 field strength and are greatest within the bore of the magnet, while translational displacement forces tend to be greatest near the edge of the magnet, where the spatial field

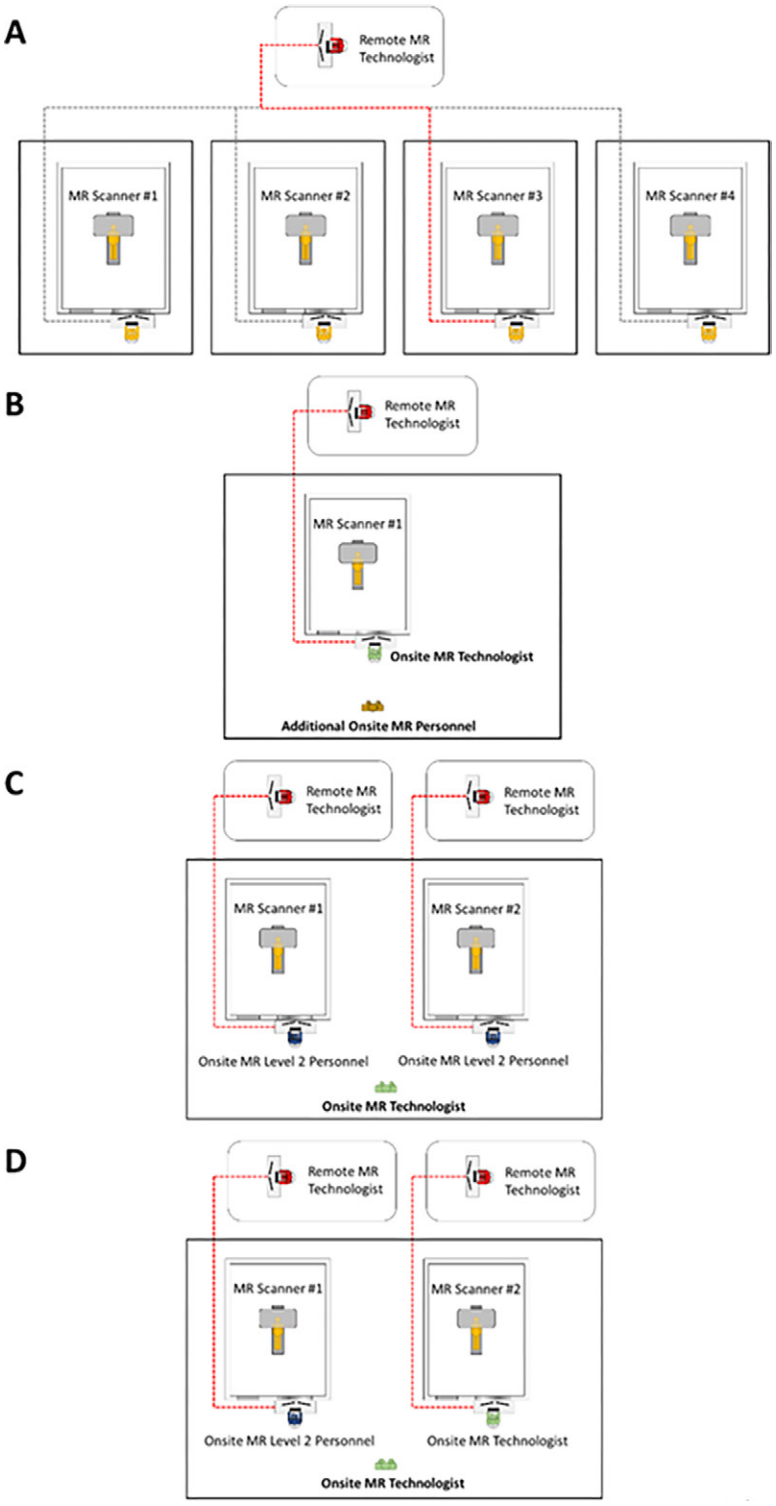

Figure 3: Diagram shows examples of possible staffing scenarios in remote MR scanning. Other possible situations may exist and should be addressed by the MR Medical Director at each specific site. **(A)** A remote console may be connected to a single or multiple MR scanners. However, simultaneous remote monitoring and/or scanning (ie, active connection) with more than one scanner at a given time by a single remote technologist is currently not recommended. In this example, the remote console is connected to four different MR scanners, although the remote MR Technologist has established an active connection only with scanner no. 3 (red dashed line). **(B)** Single scanner per Zone III. 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 MRI 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 MRI 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 MRI 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 MRI 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 MR scanner 2 cannot assist the MR Level 2 Personnel at MR scanner 1.

gradient is largest. As a ferromagnetic object is carried toward the face of a cylindrical bore magnet, it experiences rapidly escalating translational forces, potentially resulting in a dangerous projectile. The ACR Manual incorporates new schematics that depict differences between the static magnetic field (B_0) and the spatial field gradient (Fig 4).

Time-Varying RF Magnetic Field (B_1)

A primary source for thermal burns in MR is the generation of electric fields by the transmitted B_1 field, which can lead to localized heating, particularly in areas of high local impedance (18). New schematics are provided to illustrate potential differences in RF deposition and regions of tissue heating when using the built-in body coil versus a transmit-receive coil (Fig 5). Understanding such differences is crucial in selecting the best RF coil for a patient. Common potential sources of tissue heating and risk mitigation approaches are discussed, including particular issues frequently encountered in recent years (eg, electrically conductive clothing, piercings, drug delivery patches and pads).

Certain important parameters are clarified regarding how MR manufacturers estimate the risk of tissue and total body heating. The specific absorption ratio (SAR) (in watts per kilogram) estimates the rate of absorption of RF energy by human tissue in MRI, which is the mass-normalized rate at which RF power is coupled to biologic tissue (19). SAR is an estimation of the energy absorption rate in a patient, not the total dose of energy. In contrast, the total energy absorbed by the patient over the course of an MRI examination is referred to as the specific energy dose, the specific absorbed energy, or the specific absorption (in joules per kilogram or kilojoules per kilogram). SAR limits are designed to avoid short-term RF-related whole-body and local tissue heating, while specific energy dose limits were developed to provide guidance on the safety of the net energy delivered over the course of the examination (ie, possibly causing core temperature elevations, discomfort, or physiologic stress) (20). A discussion on the potential risks associated with SAR and specific energy dose measures is included in the ACR Manual.

Time-Varying Magnetic Field Gradient (dB_0/dt)

MR systems use magnetic field gradients to modulate the B_0 field. Gradients are rapidly alternated and varied over time for spatial localization of the MR signal; these are described by their

Table 2: Common Responsibilities/Duties When Remote MR Scanning Technology is Employed

A	B	C	D
Onsite MR Technologist with Level 2 training	Onsite Monitoring Level 2 MR Personnel (MR Technologist or specially trained non-MR Technologist)	Additional onsite Level 1 or Level 2 Personnel	Remote MR Technologist
1. Complete the patient/research participant MR safety screening process. 2. Position the patient/research participant in the MR scanner, including appropriate elements to include, but not limited to: a. Setup of physiologic monitoring equipment and other equipment with proper safe placement of wires/cables. b. Placement of insulating padding, etc. c. Provide proper hearing protection and ensure that it is used appropriately by the patient/research participant. d. Provide emergency squeeze alarm. 3. Be present in Zone III to IV whenever a patient/research participant is in Zone IV or supervise a non-technologist with Level 2 MR safety training. 4. 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	1. 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 and during the examination. 2. Continuously monitor each specifically assigned patient/research participant while they are in Zone IV to include, but not limited to: a. Respond immediately to patient/research participant emergency notification (eg, squeeze ball) and other verbal communication in which onsite response is appropriate. b. Respond to possible contrast agent reactions, contrast agent extravasation, concern for possible excessive heating and/or burns, and other related issues. c. Serve as the point of contact for the remote MR scanning Technologist and assist with conveying any necessary patient/research participant instructions (eg, issues related to patient motion etc).	1. Assist in maintaining site safety. 2. Assist in event of emergencies (eg, calling and providing access to Zone III for a code team).	1. Perform MR scan, assess/monitor images, and effectively coordinate with patient site personnel regarding all aspects of acquiring MRI and maintaining patient safety.

Note.—These may vary among facilities based on needs, policies, and procedures as established by the MR Medical Director. Onsite MR Personnel must continuously monitor and communicate with the patient before, during, and after the scan. The personnel for column B may be the same person as column A. Adapted, with permission, from the American College of Radiology Manual on MR Safety (6).

Table 3: Elements of Verification during the Full Stop and Final Check Process

Element	Routine	Augmented
Patient identification and visual inspection	✓	✓
The examination to be performed includes potential use of contrast material and completion of associated contrast material risk assessment	✓	✓
Appropriately performed screening	✓	✓
Proper preparation, programming, or removal of implanted or on-planted devices	✓	✓
Lack of change in patient status while in Zone III	✓	✓
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		✓
Careful visual inspection of the patient as well as the transport or support equipment that will enter Zone IV for presence of concealed or previously unrecognized potentially dangerous items that could pose projectile risk (eg, steel oxygen cylinders), burn risk (eg, unconnected ECG electrodes and lead), or other safety issues (eg, RFID tags in hospital linens)		✓
Identify appropriate port or line to be accessed for potential gadolinium-based contrast agent injection		✓
Ensure equipment needing to be tethered in Zone IV is properly secured before allowing patient to enter MR system room		✓
Ensure no change in equipment status while in Zone III		✓

Note.—ECG = electrocardiogram, RFID = radiofrequency identification. Adapted, with permission, from the American College of Radiology Manual on MR Safety (6).

temporal rate of change (ie, in dB_0/dt). The rapid switching of gradients requires the use of strong switching electric currents, which, in the presence of a strong B_0 field, leads to strong mechanical forces described by Faraday's law. As a result, MR systems can produce sound pressures exceeding 99 A-weighted decibels, which are considered a significant risk by the FDA and require hearing protection (21). Nerve and muscle cells can be stimulated by currents induced by rapidly switching gradient

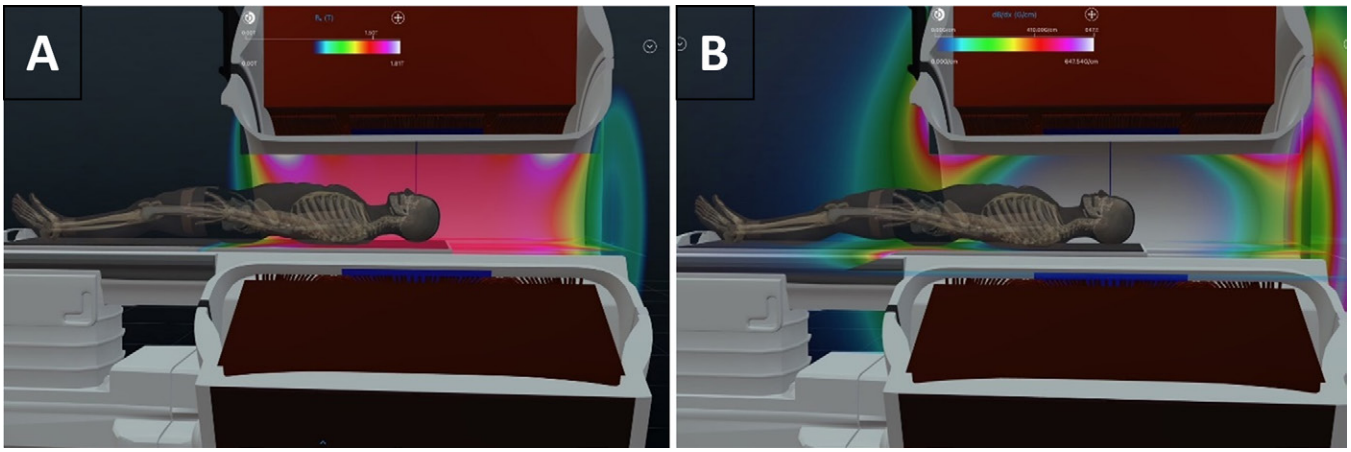

Figure 4: Three-dimensional depiction of **(A)** the static B_0 magnetic field and **(B)** spatial field gradient in a 1.5-T MRI scanner for unloaded MRI scanners or coils. The near side of the scanner has been rendered transparent so that the energies/fields can be depicted three-dimensionally throughout the MRI scanner bore and room. The strength and spatial distribution of the static magnetic field B_0 and spatial field gradient are depicted. Notice that, in the homogeneous static magnetic field at the center of the MRI scanner, the strength of the spatial field gradient and, therefore, potential translational forces on ferromagnetic materials and objects are minimal. The greatest translational forces scale with the spatial field gradient of this magnet, which maximizes near the radial extremes or borders at the entrance (and exits) to the MRI scanner bore. Images courtesy of Emanuel Kanal, MD, Presbyterian University Hospital, University of Pittsburgh Medical Center, created using MagnetVision (Advanced Magnetic Analytics).

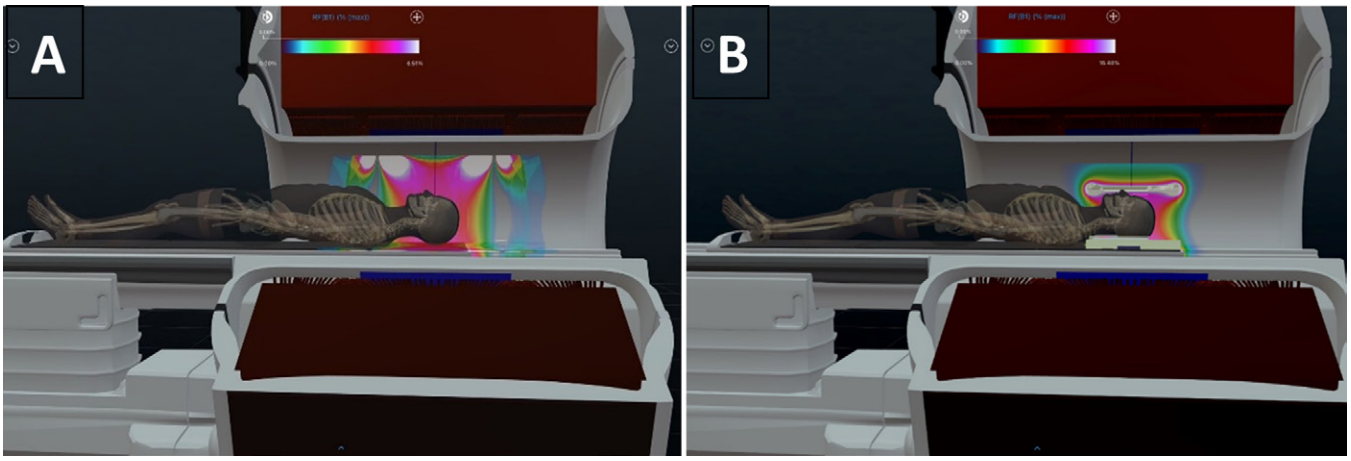

Figure 5: Three-dimensional depiction of the transmitted radiofrequency (RF) (B_1) oscillating magnetic fields in a 1.5-T MRI scanner for unloaded MRI scanners or coils. The near side of the scanner has been rendered transparent so that the energies/fields can be depicted three-dimensionally throughout the MRI scanner bore. **(A)** The spatial distribution of the transmitted RF (B_1) oscillating magnetic fields with the body RF coil of the 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 the same scanner. Images courtesy of Emanuel Kanal, MD, Presbyterian University Hospital, University of Pittsburgh Medical Center, created using MagnetVision (Advanced Magnetic Analytics).

magnetic field variation. In the context of increasingly available higher performance gradient systems in commercial human MRI systems, these concerns were recently addressed in IEC standard 60601–2-33 (15), which defines different scanning modes. Clinical systems are usually restricted to the normal and first-level modes, within which devices and implants may experience induced voltages, vibration, potentially permanent damage, or further heating. MR operators should be able to understand and apply recommended dB_0/dt limits for devices using information provided by the MR system vendor.

Objects and Medical Devices in the MR Environment

Patients or research participants should remove all clothing, including undergarments, when contained within the range of RF transmission (eg, within the scanner bore when the built-in body coil is used for RF transmission) and wear site-supplied MR Safe pocketless garments. Garments and objects that may interact with the MR Environment continue to grow in number and broadly fall into two major categories: *(a)* equipment, objects, and other portable items peripheral to the patient (eg, intravenous poles, anesthesia machines, injection pumps); and *(b)* medical devices within the patient (eg, cardiovascular implantable electronic devices, aneurysm clips) and on-planted devices external to their body, at least in part (eg, insulin pumps, continuous glucose monitors, hearing aids). The ACR Manual continues to apply the standard MRI labeling terms (*MR Safe*, *MR Conditional*, *MR Unsafe*) designated by the American Society for Testing Materials (ie, ASTM International) (12) for both categories.

Portable Metallic Objects and Equipment

Portable metallic or partially metallic objects intended to be stored or located in Zone III and/or IV should be properly labeled,

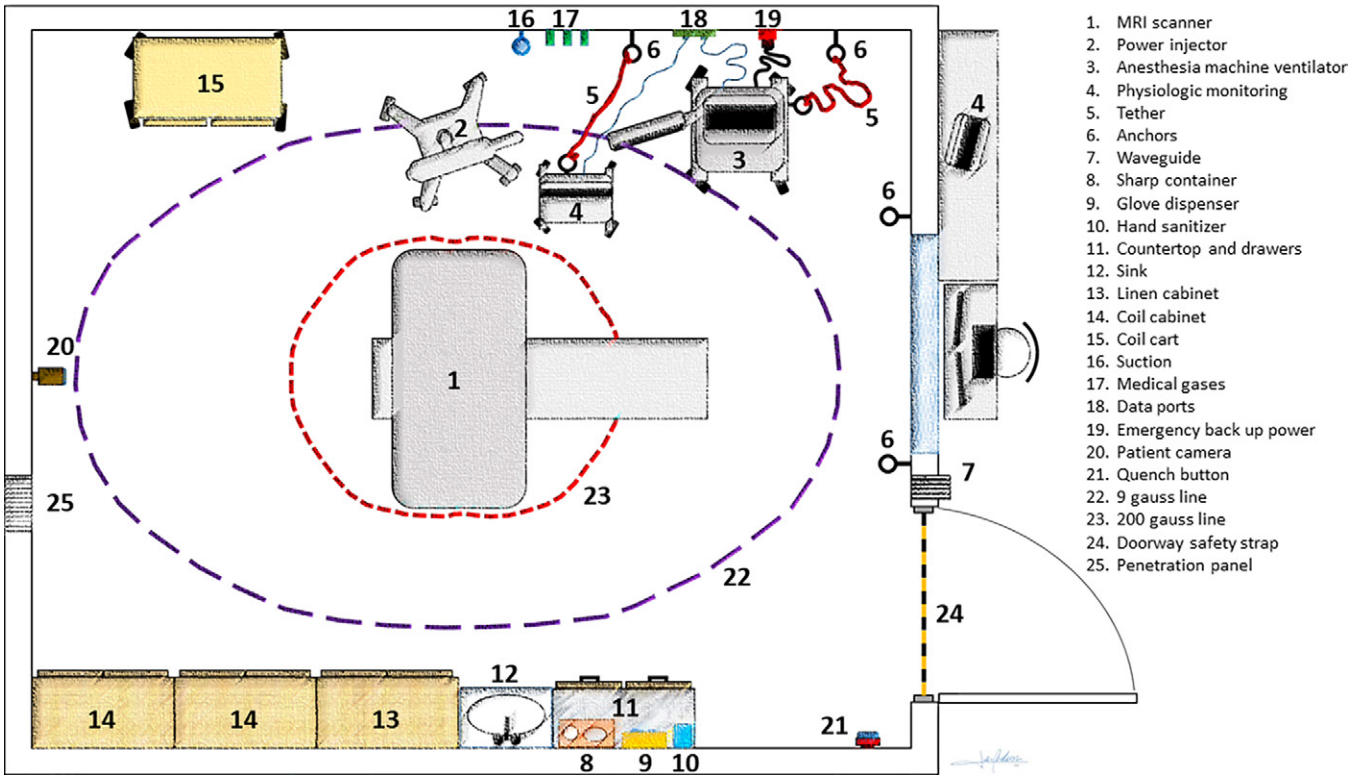

Figure 6: Diagram shows typical configuration of an MR system in an inpatient facility. The design of Zone IV should consider the optimal workflow during more complex MR examinations, such as those requiring anesthesia. It is recommended that dedicated space is devoted to the anesthesia ventilator and 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 staff 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-G line marking on the floor, a 200-G 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-G line. This is an example configuration, and appropriate physics testing may be required for specific devices at any given facility.

when practical, as MR Unsafe or MR Conditional before permitting them into Zone III. If MR Unsafe transport equipment (eg, wheelchairs, gurneys) is brought into Zone III temporarily to facilitate patient care, it should be directly supervised by designated MR Personnel, physically secured, tethered, and monitored at all times within Zone III to prevent equipment crossing the Zone IV threshold.

Cellphones represent a particular challenge. Although commonly present in Zone III, they may become projectiles if brought into Zone IV. Facilities should develop policies and SOPs to ensure cellphone safety. Use of pocketless scrubs for staff and secured Zone III storage can assist with this and other potential hazards (eg, keys, dressing scissors).

Objects not immediately required for patient care should not enter Zone IV if a patient is occupying the room (ie, seek to introduce these objects before patient occupancy). The introduction of MR Conditional equipment should follow manufacturer recommendations, with clear documentation of the conditions and communication among personnel involved. Notably, some MR Conditional and all MR Unsafe equipment entering Zone IV require tethering to a wall. The use of tethers is critical, the intent being to prevent equipment from getting close enough to the MRI scanner to become a projectile. The tether should be treated as a location reminder; it should not be assumed that the tether will be sufficiently strong to keep objects in place and prevent projectiles. Therefore, it is important to consider the position of the tethers during the design of Zone IV (Figs 6, 7).

Patients and Research Participants with Medical Devices

Medical devices (implanted and on-planted) can be classified as *(a)* active devices (ie, containing an energy source such as a battery or having the ability to be inductively coupled [22,23]) or *(b)* passive devices (ie, not containing an intrinsic electrical power source). While some rules have been proposed for specific categories of devices, the increasing number and complexity of active and passive medical devices (each inherently different) makes it virtually impossible to develop universal rules. MR Personnel must thoroughly review the manufacturer information and scanning conditions before MRI. All passive implants that contain metal are, by definition, either MR Conditional or MR Unsafe. Considerations for some common devices are presented in Table 4.

Emergency Situations

MRI facilities should develop policies and SOPs to address emergent situations specific to their equipment and environment. These include adequate training of MR Personnel about the functionality and location in the MRI suite of the different emergency switches: *(a)* emergency stop, designed to immediately stop MRI scanning and table motion; *(b)* emergency power off, used to cut electrical power to the entire suite and computer room, including an uninterrupted power supply if present; and *(c)* emergency magnet off (quench), used to quickly shut down the magnetic field. Policies and SOPs should also address the response to fire emergencies and rapid clinical deterioration (ie,

"code" situation) of patients and/or research participants, including a designated area for patient care outside Zone IV.

Special Patient and Personnel Considerations

Special considerations exist for certain personnel, patients, or research participants in the MR Environment. Examples include pregnant health care providers, patients, or research participants, as well as individuals experiencing claustrophobia or anxiety or requiring sedation, those with a large body habitus, and prisoners or detainees. Currently available research has failed to demonstrate any harmful effects to the pregnant person or developing fetus from exposure to magnetic fields used in routine clinical MRI practice, including 3 T or less. If pregnancy is known or suspected, the ACR Manual supports the clinical use of MRI up to 3 T in Normal Operating Mode (whole-body averaged SAR, 2 W/kg) when there is expected benefit to the patient and/or fetus from performing the examination and no other practical way to obtain the same information for patient care (25). Current guidelines from the American College of Obstetricians and Gynecologists consider MRI, together with US, 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" (26). The risks of exposure to MRI fields greater than 3 T are unknown. Similarly, the ACR Manual supports the enrollment of pregnant research participants (ie, consenting to participate in the research) for research studies using MRI systems up to 3 T to investigate conditions related to pregnancy. However, it discourages the enrollment of pregnant patients for other research studies using MRI to investigate conditions not related to pregnancy.

Figure 7: Photograph shows the use of tethers in Zone IV. Example of tethering of an MR Conditional ventilator in Zone IV to keep the equipment outside of the 200-G line (manufacturer guidelines indicate the need to operate this equipment outside the 300-G line). This facility uses marks on the floor for the 200-G line (black arrows). Note that the function of the tether (white arrow) is not to prevent the equipment from becoming a projectile when attracted by the static magnetic field. Instead, tethers must have the appropriate length to prevent equipment from getting close enough to become a projectile. The location of tethers in Zone IV must be carefully planned during the design of Zone IV, keeping in mind the facility's plan for the functionality of the MRI suite (eg, use of anesthesia). Note an MR Conditional intravenous pole on the side; intravenous poles at this facility are colored in yellow and tagged (arrowhead) with MRI conditions. This model is safe for use up to 10000 G. The side door in Zone IV in this facility is used for transporting patients from and to an adjacent angiography suite. Courtesy of Manuel J. Rojas Jr, BSRS, R.T.(R), (MR), MRSO, University of Texas Southwestern.

Alternative MR Environments

In the past 2 decades, the increasing number of nonconventional MRI suite designs and alternative MR Environments has added complexity to the operations of many facilities. Many reside outside radiology departments (eg, MRI simulators in radiation oncology, perioperative MRI, mobile MRI systems), while others in radiology departments require additional expertise (eg, interventional MRI suites, PET/MRI). Additionally, new systems have been approved by the FDA for clinical use beyond the traditional 1.5- and 3-T systems, including ultra-high-field-strength (5-T, 7-T), low-field-strength (0.55-T), and ultralow-field-strength point-of-care (<0.1-T) MRI systems. Hence, institutional policies should include identification of responsible personnel to ensure the safety of the patient, MR Personnel, and others who may care for the patient while in these alternative environments. Importantly, such policies need to consider potential dynamic changes in the designation of MR safety zones that can occur in different clinical scenarios. For example, in an operating room plus MRI setting, areas normally designated as Zone II may temporarily become a functional, but nontraditional, Zone III when there is need to access Zone IV through a specialized entry door (Fig 8). Level 2 personnel must carefully control patient, personnel, and equipment access to Zone IV in these alternative scenarios.

Personnel working in alternative MR Environments should have a minimum of Level 1 MR training or be screened and directly supervised by Level 2 MR Personnel. Ultralow-field-strength MR systems are presently considered to have relatively low risk (27). Given the emergence and variability of new ultralow-field-strength MR systems, facilities should develop SOPs for storage and use of these devices, with consideration for involvement of Level 2–trained MR Personnel as needed. Specific considerations for such alternative environments are discussed in the ACR Manual and summarized in Table 5.

Conclusion

Careful planning and implementation of policies and standard operating procedures (SOPs) for the expected functionality of an MRI facility are crucial to ensure the safety of personnel,

Table 4: Common Implanted and On-planted Devices in Patients Undergoing MRI

Device Type	Comments
Active devices	
CIEDs	Follow recommendations from the Heart Rhythm Society (8) for CIEDs that have not been labeled MR Conditional; further information related to MRI scanning of patients with CIEDs has been provided by the International Society for Magnetic Resonance in Medicine (24)
Epicardial pacing wires or leads	
Temporary epicardial pacing wires and remnants	No adverse outcomes associated with retained temporary epicardial wire fragment reported to date; postsurgical temporary epicardial wires that have been partially removed are not considered to be abandoned pacing leads (8)
Permanently implanted epicardial leads or CIEDs	Often implanted in children or infants with congenital heart defects; insufficient data about the safety of MRI
Retained or abandoned endovascular and intracardiac leads	Insufficient data about the safety of MRI
Neuromodulation systems	Extensive and increasing number of devices Careful attention to accurate identification of the precise make, model, manufacturer, and 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 implanted can markedly change the scanning conditions, including an MR Conditional device becoming MR Unsafe and posing a serious risk to the patient Programming device before and after MR examination frequently required
Implantable infusion pumps	Potential for patient injury or death that can be related to drug overdosage or potentially from interrupted drug infusion; adherence to MR conditions for safe scanning is crucial; evaluate pump to ensure proper operation following MR scanning
Implantable and external insulin pumps	Increasingly widespread use; presently are considered MR Unsafe; if the device is exposed to the MR Environment, malfunction may lead to life-threatening hypo- or hyperglycemia
Passive devices	
Intracranial aneurysm clips	MR examination should typically not be performed until the specific manufacturer, model, and type of aneurysm clip is identified; see ACR Manual on MR Safety (6) for further discussion

Note.—ACR = American College of Radiology, AIMD = active implanted medical device, CIED = cardiac implantable electronic device, IPG = implantable pulse generator.

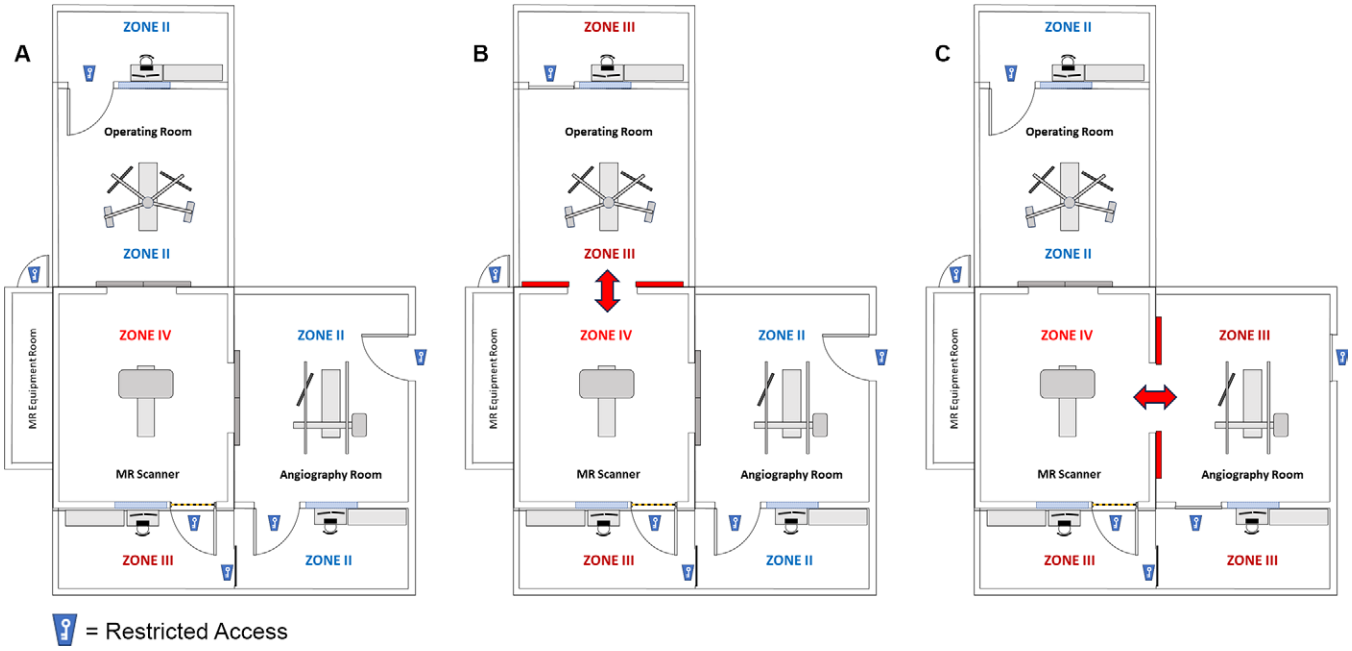

Figure 8: Dynamic changes in safety zones in alternative MR Environments. Diagram shows representative example of an MR suite with direct access to Zone IV from adjacent operating and angiography rooms. **(A)** Zone IV is contained to the MR suite. When the connecting doors to the operating room and the angiography room remain closed, Zone III is limited to the adjacent MR control room, similar to a traditional MRI suite design. In this instance, the operating room and the angiography room (ie, not connected directly with Zone IV in the MRI suite) are both defined as Zone II. **(B)** When the doors between the operating room and the MRI suite are opened to facilitate movement of a patient from one to the other, the operating room becomes de facto part of Zone III and its adjacent control area (if available) becomes an additional extension of Zone III. **(C)** When the doors between the angiography room and the MRI suite are opened to facilitate movement of a patient from one to the other, the angiography room becomes de facto part of Zone III and its adjacent control area becomes an additional extension of Zone III. It is necessary to restrict access to MR Personnel and establish standard operating procedures for the use of such facilities that are specific to their design.

Table 5: Specific Considerations for Alternative MR Environments

Alternative Environment	Specific Needs
PET/MRI	MR safety and radiation regulatory requirements often need shared responsibilities between two medical directors (MR Medical Director and nuclear medicine authorized user) MR safety procedures should be overseen by Level 2 MR Personnel, and PET personnel should receive MR safety training Radiation protection and handling of radioactive material should follow state and federal policies (refer to U.S. Nuclear Regulatory Commission 10 CFR part 20 and part 35)
Intraoperative or interventional MR	Policies and SOPs should clearly indicate which specific Level 2 MR Personnel is responsible for overseeing MR safety Each entrance to Zone IV (eg, from operating room, angiography suite, and control room) requires appropriate controlled access and effective screening Transient changes in MR Zone labeling can occur in dynamic MR Environments (eg, Zone II becomes a functional yet nontraditional Zone III when opening access between the MR scanner and adjacent space) MR Personnel should be appropriately educated on and vigilant of unique safety risks in a dynamic environment Rigorous adherence to testing, labeling, appropriate storage, securing, and usage guidelines of devices is crucial to avoiding accidents
MRI simulator and MR LINAC	Training of MR Personnel in the Department of Radiation Oncology should parallel the training received by MR Personnel in the Department of Radiology Patients undergoing multiple MRI examinations in the course of their treatment should be screened each time before MRI to assess potential changes related to MR safety Equipment used for the delivery of radiation therapy within Zone IV of hybrid MR LINAC units should be labeled MR Conditional
7-T MR Environments	Consequences of accidents due to projectiles or complications related to implanted devices is substantially increased Contraindicated in neonates (ie, infants ≤1 month of age) Transient bioeffects associated with the static magnetic field tend to increase with field strength (eg, vertigo more often reported at 7 T) Special considerations should be taken into account for metallic implants, devices, and foreign bodies (MR Conditional status should not be assumed for devices that are MR Conditional at 3 T)
Point-of-care ultralow-field-strength MR systems	Low risk of missile-effect projectile incidents (27) Evolving data for assessing safety related to scanning in the presence of AIMDs and other devices All involved staff, including non–MR Personnel, should follow appropriate safety procedures MR systems 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
Mobile MRI systems	May require additional consideration for appropriate site-specific MR Zones and access control

Note.—AIMD = active implanted medical device, CFR = Code of Federal Regulations, LINAC = linear accelerator, SOP = standard operating procedure.

patients, and research participants. The rapidly evolving field of MR requires a dynamic process where such policies and procedures are regularly reviewed and updated. Importantly, an operational structure including the MR Medical Director, MR Safety Officer, and MR Safety Expert should be established to ensure the facility always operates under these existing policies and SOPs. Similarly, an MR Safety Committee should review adverse events and near misses so that such policies and procedures can be promptly updated, with ongoing education to prevent future incidents. The updated American College of Radiology Manual on MR Safety represents a comprehensive source of information about contemporary best practices and current guidelines in MR safety. Its online availability enables timely updates as new information emerges in the field of MR safety.

Deputy Editor: Kathryn Fowler

Author contributions: Guarantors of integrity of entire study, **I.P., R.E.W.**; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; agrees to ensure any questions related to the work are appropriately resolved, all authors; literature research, **I.P., D.A.A., J.R.D., M.N.H., A.M.M., S.B.R., J.M.R., R.J.S., D.L.H., R.E.W.**; clinical studies, **J.M.R., R.E.W.**; and manuscript editing, all authors

Disclosures of conflicts of interest: I.P. Warrants for consulting from Health Tech International; board of directors member for the Society for Advanced Body Imaging (unpaid). **D.A.A.** Vice chair of the American Board of Magnetic Resonance Safety (unpaid). **J.R.D.** Grants from Perspectum, Motilent, Philips Healthcare, GE HealthCare, Bracco, and Guerbet; support for attending meetings or travel from Philips Healthcare and GE HealthCare. **M.N.H.** No relevant relationships. **A.M.M.** No relevant relationships. **S.B.R.** Research support to institution from GE HealthCare, Bracco Diagnostics, Bayer Healthcare, and Pfizer; ownership interests in Calimetrix, Reveal Pharmaceuticals, Cellectar Biosciences, Elucent Medical, Vista.ai, and RevOps; consulting fees from Bracco Diagnostics, Protara, Bayer Healthcare, and Marea Therapeutics. **J.M.R.** Member of the American Board of Magnetic Resonance Safety. **R.J.S.** Member of the board of directors of the American Board of Magnetic Resonance Safety (unpaid). **J.A.W.** Leadership or fiduciary role in the American Board of Magnetic Resonance Safety (unpaid). **D.L.H.** No relevant relationships. **R.E.W.** Past chair of the American College of Radiology Committee on MR Safety.

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