Regulating MR Safety Standards

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Magnetic resonance (MR) imaging uses magnetic fields and radio waves to generate an image of the body. Though it is considered safe because it does not emit ionizing radiation, the strong magnetic fields produced by the MR scanner require unique safety considerations. The American College of Radiology (ACR) has provided guidance documents on MR safety since 2002 and recently updated and reorganized these documents into the ACR Manual on MR Safety. This article discusses the physics of MR imaging, the evolution of MR safety recommendations, and MR safety procedures.

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After completing this article, the reader should be able to:

- Summarize the physics of magnetic resonance (MR) imaging.
- Recognize potential hazards of the MR environment.
- Discuss the evolution of recommended safety guidelines.
- Describe MR safety procedures.
- Explain the importance of MR safety regulations.

Magnetic resonance (MR) imaging uses strong magnetic fields and radio waves to create images of the body and has become one of the most important diagnostic modalities in medical imaging. Advantages of MR imaging include imaging flexibility (eg, acquire images in multiple planes without repositioning), high patient acceptance, the capability to evaluate anatomic and physiologic parameters, and the ability to acquire unique clinical information such as an elastogram.[1] In addition, MR imaging does not expose patients to ionizing radiation; however, the strong magnetic field of the MR scanner does require safety considerations. Cases of injuries and fatalities caused by a lack of knowledge or failure to follow recommended MR safety guidelines in and near the magnetic field have been reported. The American College of Radiology (ACR) provides MR safety recommendations, but no regulatory organization currently requires specific safety standards to protect patients and staff in the MR imaging environment.[2,3]

Tobias Gilk is an expert on MR safety operations and accreditation standards.[4] He served as coauthor for the ACR guidance documents on MR safety and is a board member for the American Board of Magnetic Resonance Safety.[4] During an interview with Fox News in 2015, Gilk explained that the number of reported MR imaging accidents has risen every year and estimated that more than 7000 MR imaging accidents occur in the United States each year, an increase of 500% since 2000, according to federal data.[4] Although this represents a fraction of the estimated 30 million MR examinations performed each year, Gilk said a greater focus on safety is needed in the profession because 85% of the MR imaging injury accidents might have been prevented if existing best practice guidance had been followed.[4]

MR Imaging Physics

MR imaging is based on nuclear MR, in which magnetic fields and radio waves cause atoms to emit tiny radio signals.[5] These radio signals are processed by a computer system

to generate a detailed image of the body part being scanned.[5] All matter, including humans, is composed of atoms.[5] The nucleus is at the center of each atom; it consists of positively charged protons, neutrons that have no net charge (ie, neutral), and negatively charged electrons that orbit the nucleus. The nuclear mass of an atom is the sum of the protons and neutrons in the nucleus.[5] Atoms with an odd number of neutrons and protons have angular momentum or spin.

Nuclei with spin are important to MR imaging and are referred to as *MR active nuclei*.[5] MR active nuclei that have a net charge and are spinning (ie, in motion) automatically acquire a magnetic moment and can align with an external magnetic field (B_0).[5] Hydrogen is the MR active nucleus used in clinical MR imaging because it is abundant in the body, randomly oriented, and contains a single spinning proton, which gives it a large magnetic moment.[5] When in the magnetic field, the proton's spin induces an additional magnetic field around the hydrogen atom, which causes the hydrogen atom to behave like a small magnet.[5]

When a patient enters the bore of the MR imaging system, their hydrogen molecules align parallel and antiparallel to the magnetic field, and the patient becomes the net magnetization vector; essentially, the patient is a magnet with a magnetic vector aligned with the external magnetic field.[5,6] The lower-energy hydrogen molecules align parallel to the external field and are called *spin-up nuclei*.[5] The higher-energy ones align antiparallel to the field and are referred to as *spin-down nuclei*.[5] Each hydrogen nucleus spins on its own axis. The magnetic field causes a secondary spin, or wobble, called *precession*. Precession causes the magnetic moments to follow a circular path around the external magnetic field.[5] The rate of precession is called the *Larmor* or *precessional frequency*.[5,6] The frequency of precession is related to the strength of the magnetic field. The gyromagnetic ratio represents the relationship between the angular momentum and the magnetic moment of each MR active nucleus.[5] Each nucleus precesses at a different frequency and, therefore, has a unique gyromagnetic ratio. This allows for imaging of hydrogen specifically.[5]

A radiofrequency (RF) pulse at the Larmor frequency of hydrogen is applied to initiate resonance.[5,6] Resonance occurs when an object is exposed to an oscillating motion with a frequency close to its own.[5] This also causes the nucleus to gain energy, referred to as *excitation*.[5] The occurrence of resonance and excitation produces 2 results.[5,6] One, some lower-energy nuclei receive sufficient energy to become higher-energy nuclei. Because of this energy transfer, the net magnetization vector rotates from its parallel alignment with the external magnetic field (ie, its longitudinal plane) to its traverse plane.[5,6] The amount of rotation that the net magnetization vector experiences is called the *flip angle* and depends on the duration of the RF pulse; usually it is 90°.[5]

The second result from resonance is that the magnetic moments of hydrogen move into phase with one another.[5] Phase is the position around the precessional path of the external magnetic field.[5] Magnetic moments that are in phase, or coherent, are in the same place on the path; those that are not in the same place on the path are out of phase, or incoherent.[5] When resonance occurs, the hydrogen atoms move to the same position, in phase, and precess at the Larmor frequency in the transverse plane.[5]

The Faraday law of electromagnetic induction states that if a receiver coil or any conductive loop is placed in a moving magnetic field, with the magnetization precessing in the transverse plane, a voltage will be induced in that coil.[5] The coherent magnetization produces fluctuations of the magnetic field inside the coil, and this induces an electrical voltage in the coil.[5] Thus, the MR signal is produced.[5,6] The frequency of this signal is equal to the Larmor frequency.[5]

When the RF pulse is switched off, the net magnetization vector tries to realign with the external magnetic field.[5,6] The hydrogen nuclei releases the energy it gained from the RF pulse (relaxation), and the amount of magnetization in the longitudinal plane increases (recovery).[5] At the same time, but independently, the transverse plane experiences a decrease in the amount of magnetization (decay).[5] As the transverse magnetization decreases, the voltage magnitude in the receiver coil also decreases. This is called *free induction decay*.[5]

During relaxation, the hydrogen nuclei release RF energy, and the net magnetization vector returns to alignment with the external magnetic field.[5] At the

same time, the hydrogen magnetic moments lose coherency because of dephasing.[5] The magnitude and timing of RF pulses form the pulse sequences, which are the basis of image contrast generation in MR imaging.[5] A simplified pulse sequence in MR imaging is a combination of RF pulses, signals, and periods of recovery.[5]

Potential Safety Hazards and Risks of MR Imaging

There are potential safety hazards and risks associated with the MR environment, not only for the patient but also for attending health care professionals, accompanying family members, and others, including security officers, housekeeping personnel, firefighters, and police who might encounter the magnetic fields and other energy sources associated with MR scanners.[2,7,8] MR safety hazards and risks include[2,7,8]:

- adverse reactions to contrast agent
- auditory effects
- burn risks associated with RF
- electrical stimulation of muscles and nerves
- interference with electromagnetically active devices
- missile effect incidents from ferromagnetic devices
- rotation or torque of implants or devices on or in a person's body
- superconducting cryogen risks

Risks Associated with Static Magnetic Fields

The static magnetic field of the MR imaging system is exceptionally strong. For example, a 1.5 T magnetic field is approximately 21 000 times that of the earth's natural field.[9] This can generate a missile effect in which loose ferromagnetic objects become airborne and move suddenly toward the magnet as projectiles. The magnetic field also can cause rotation or torque of ferromagnetic implants and devices.

The maximum static magnetic field gradient is the strongest area of the static magnetic field, usually located at the outermost portion of the magnet bore, at the entry of the scanner, under the cover, and inaccessible by the patient.[2] As the patient moves from the outer portion of the bore entrance to the center of the bore, known as *isocenter*, the field force drops to 0. There is no translational force or torque on an object at isocenter. Therefore, when an object becomes a projectile at or near the outer portion of the magnet bore, it will stop once it reaches the isocenter and remain there. The spatial field gradient also is important in determining magnetic strength on an object. The spatial field gradient refers to the rate at which the static magnetic field strength changes with distance.[2] As you walk toward the magnet, the field strength increases. How quickly it does so, is the spatial field gradient.

There are 2 important laws of electromagnetism related to static magnetic field effects.[2] The Faraday law suggests that a changing magnetic field will induce a current into a perpendicularly oriented conductor. If we place a ferromagnetic object into the magnet, a voltage (current) will be induced. The Lenz law compliments the Faraday law and states that the induced current will generate a secondary magnetic field that opposes the original field, effectively stopping the motion of the object.[2] For example, as a nonferrous metallic device (eg, oxygen tank) is moved toward the bore, Lenz's forces might be sufficient to stop forward progress of the device. In addition, the faster an object moves toward the magnet or into the bore, the greater the opposing force that is created to stop the motion.[2] Even large implanted devices that do not pose as projectile hazards might be tugged or pulled on by the opposing Lenz force if the patient and implant are moved rapidly in a direction perpendicular to the static magnetic field. Nonferrous metallic devices should be moved into and out of the bore slowly.

Risks Associated with Time-Varying Gradient Magnetic Fields

In MR imaging, the time-varying gradient magnetic field increases and decreases rapidly during imaging acquisition. The rapid switching of the gradients can cause auditory effects and possible stimulation of nerves or muscle. The International Commission on Non-Ionizing Radiation Protection has noted temporary effects from higher field strength MR imaging such as vertigo, tinnitus, and hearing loss.[2] Patients and volunteers should be given ear protection.[2] The U.S. Food and Drug Administration (FDA) considers MR systems capable of producing sound pressures that exceed 99 dBA (A-weighted decibels).[2] The

International Electrotechnical Commission states that ear protection is required when equipment produces sound levels of 99 dBA or greater; the type of ear protection must be able to reduce the sound pressure to a level below 99 dBA.[2] Facilities should provide proper instructions on how to properly place ear plugs and verify fit.[2]

The time-varying gradient field also can stimulate nerves or muscles by introducing electric fields into the patient potentially causing mild cutaneous sensations, involuntary muscle contractions, or cardiac arrythmias. Protecting the patient from potential life-threatening heart and ventricular stimulations is a priority, particularly if they have an implanted device or wire.[2] Patients with implanted or retained wires should be considered at higher risk, especially for faster MR imaging sequences such as echo-planar imaging (eg, diffusion-weighted imaging and functional MR imaging).[2] This risk is dependent on the wire being exposed directly to the time-varying gradient.[2]

Risks Associated with Radiofrequency Field

MR images are acquired by using a strong magnetic field and then applying RF pulses, produced by RF coils. Radiofrequency is a frequency within the electromagnetic spectrum and is a source of heat production. Before imaging, unused or unnecessary electrically conductive devices or materials external to the patient should be removed from the MR system to help eliminate possible injuries associated with RF fields (eg, burns).[2] To prevent tissue injury, padding materials that meet the manufacturer's recommended standards can be placed between the patient's skin and the transmitting coils.[2] Padding ensures sufficient spacing between the patient's tissue and the coil to prevent proximity thermal injury from coil contact.[2] A patient also can create a large conducting loop while laying inside the magnet bore.[2] These loops include skin to skin contact such as the patient's upper thighs touching each other or their arms being crossed during imaging. Therefore, possible areas of skin-to-skin contact should have padding or sponging placed between the tissue and the contact object, and the patient should be prevented from laying in a position that can create a loop (eg, crossing their arms or legs).[2]

Electrically conductive implants, wires, or leads pose the greatest potential for thermal risks in MR imaging because they serve as an efficient antenna.[2] Resonant circuitry can be established between the transmitted RF energy and the lead or wire, causing rapid heating. The potential for substantial heating is dependent on multiple factors, including the static magnetic field strength and the length, shape, orientation, position, and inductance of the electrical conductor in the RF-irradiated volume being studied.[2] If the length of the wire matches the half wavelength of the transmitted RF, then heating could occur. Patients should be considered at risk if the body coil is to be used for RF transmission over a region of their body that contains an electrically conductive lead or electrically active implant, such as[2]:

- cochlear implants
- Foley catheters with electrically conductive leads
- implantable cardioverter defibrillator
- neurostimulators
- pacemakers
- Swan-Ganz catheters

Adverse Reaction to Contrast Agent

Several adverse reactions are possible with the use of gadolinium-based contrast agents. Therefore, intravenous injection of a gadolinium-based contrast agent should be performed by qualified MR personnel at the order of a licensed physician. Common adverse effects of gadolinium-based contrast agents are nausea, itching, rash, or injection site pain.[2] Known adverse effects of gadolinium-based contrast agents are nephrogenic systemic fibrosis and retained or residual gadolinium.[2] The most recent ACR Manual on Contrast Media, published in 2021, provides a guide to support the safe and effective use of contrast media, including a section on the treatment of contrast reactions.[2]

To read the ACR Manual on Contrast Media, visit asrt.org/as.rt?sYie3T

Superconducting Cryogen Risks

Contemporary high-field MR imaging systems with superconducting magnets contain cryogens.[2,8] These are super-cooled liquids with temperatures hundreds

of degrees below 0 °C.[8] The physical properties of cryogenic liquids present serious safety hazards.[2] If exposed to room air, cryogenic liquids rapidly boil off and expand into a gaseous state. MR imaging units can suddenly release tens of thousands of liters of gaseous cryogens, known as a *quench*.[8] This produces several safety hazards including asphyxiation, frostbite, fire, and pressure considerations.[2] During a magnet quench, the patient and personnel should evacuate the magnet room immediately.

The cryogenic gas replaces oxygen; therefore, asphyxiation will occur to anyone in the immediate room.[2] Cryogenic liquids are at exceedingly low temperatures capable of causing immediate frostbite. Fire is possible if the gases from the quench fail to escape properly through the escape pipe.[2] There also is a possibility of pressure build up. The thermal expansion of the cryogens can positively pressurize the magnet room and trap persons inside the room until the pressure equalizes.[2] Increased pressure also can damage the building's infrastructure (eg, cracked walls).

For most MR imaging systems, when the magnet quenches, the cryogen gas escapes properly through the vent duct to outside of the building.[2] However, there have been documented failures in cryogen vent or quench pipe assembly that have led to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room (zone IV).[2] The ACR Manual on MR Safety provides facility design guidelines to minimize cryogenic risks. Magnets should have an emergency exhaust pathway that enables the cryogens to vent out of the room by activating the exhaust fan switch, and rooms should have an additional form of pressure relief to prevent expansion damages. For safety, it is recommended that cryogen pathways and vents be checked annually for obstructions and faulty connections.[2] At a minimum, building structure should be inspected annually for damages or design flaws.[2] The point of cryogen discharge should be properly marked with warning signs that designate that area as zone III.[2]

Evolution of MR Safety Standards

MR imaging-related injuries and fatalities that result from a lack of knowledge or a failure to follow safety guidelines in and near the magnetic field have been reported.[10,11] One notable fatal accident occurred in 2001. Michael Colombini, a 6-year-old boy, was being released from Westchester Medical Center in Valhalla, New York, after having a benign brain tumor removed.[10,11] Before leaving the hospital that day, Michael's physicians requested an MR scan.[10,11] Michael was sedated and placed in the MR scanner. As the procedure began, Michael's oxygen saturation level decreased.[10,11] The oxygen system in the MR scanning room malfunctioned, and the anesthesiologist called for oxygen assistance. A nurse who was not part of the usual MR imaging team quickly responded to the physician's request and handed him a steel oxygen tank. When the oxygen tank got close to the scanner, it was pulled from the physician's arms by the scanner's strong magnetic field and flew into the MR imaging unit, striking Michael. He died 2 days later from blunt force trauma caused by the oxygen tank striking his head.[10,11] The oxygen tank was traveling at approximately 45 mph.[10]

Michael Colombini's death initiated the creation of MR safety recommendations. The ACR formed a blue-ribbon panel to address critical safety issues in the MR imaging environment. Emanuel Kanal, MD, a practicing radiologist and MR safety director at the University of Pittsburgh Medical Center, chaired the committee.[12] In 2002, the panel published The ACR's White Paper on MR Safety. The guidance document discussed potential risks in the MR environment and recommended safe practice guidelines that could be used as a template by MR imaging departments developing their own MR safety programs.[10,13] The recommendations were meant for health care personnel, patients, and research subjects in MR settings, including diagnostic, research, interventional, and intraoperative MR suites.[13] This guidance document has been updated continually to address changes in the MR imaging profession and feedback from the medical profession.

In 2020, the ACR created the more in-depth manual ACR Manual on MR Safety, which was based on updates and reorganization of the ACR Guidance Document on MR Safe Practices, previously published in 2013 (see **Box 1**).[2,13] This manual replaces previous versions published by the ACR and is in a web-based

format that can be updated easily. The following topics are addressed in the manual[2]:

- contrast agents
- full stop and final check
- gowning
- implants, devices, and objects
- MR environment
- personnel
- physiologic monitoring during MR studies
- screening and patient risk assessment
- special patient population considerations
- static magnetic field–related issues
- time-varying gradient and RF magnetic field–related issues

In the United States, the ACR's recommendations have been used as best-practice and have infiltrated regulatory agencies as recommended safety procedures; however, they have not been adopted as required regulations.[14] For ACR accreditation, facilities must have written safety policies and practices that are enforced, reviewed, and documented at least annually by an MR supervising physician, and ACR recommends but does not require facilities to follow their guidance in the manual on MR safety.[3]

In addition to his work with the ACR, Dr Kanal created the American Board of Magnetic Resonance Safety in 2014.[12] The board consists of MR experts who specialize in MR safety.[12] The American Board of Magnetic Resonance Safety is an independent, not-for-profit organization that works to improve the safety of medical and research MR environments by promoting simple knowledge of the underlying safety principles of MR imaging and the ability to apply them to ensure safety in MR environments.[12] The American Board of Magnetic Resonance Safety provides 3 certification types: MR medical director, MR safety officer, and MR safety expert.[12] To date, approximately 2500 individuals have earned safety certifications.[12]

MR imaging safety has become the center of attention since the tragic death of Michael Colombini. MR imaging safety committees, formed by organizations such as the ACR, create and document many MR imaging safety recommendations for health care organizations. The American Society of Radiologic Technologists, The Society for MR Radiographers and Technologists, and

Box 1

Revisions in American College of Radiology (ACR) Manual on Magnetic Resonance (MR) Safety[2]

- added Full Stop/Final Check section
- deference to the Heart Rhythm Society on guidance regarding performing MR examinations in patients with non-MR-conditional cardiac devices
- expanded staffing guidance for MR personnel to align with the 2018 Veterans Health Administration directive on MR safety
- expectation of formal safety roles for MR personnel
- removed screening form and made it available for download
- updated MR environments (eg, 7 T and complex intraoperative)
- updated MR imaging contrast agents
- updated special patient population considerations (eg, pregnancy, prisoner or detainee, and parolee)

The Joint Commission provide education programs and advocate for regulated MR safety standards, and their efforts have increased safety awareness and standards in the MR imaging profession. However, to date, only the ACR has attempted to create required standards that protect patients and staff in the MR environment. Delays in implementing these standards likely are the result of the high cost to train staff appropriately, access to training, and quality training that increases the effectiveness of the safety standards.[15] These delays affect the health and safety of the patients and staff.

In 2002, the ACR published the paper on MR safety recommendations, however, MR accidents continue to rise markedly each year in comparison to procedure volume (see **Figure 1**). Though the ACR has provided recommendations, no compliance organization has made these recommendations a requirement or regulation standard for MR facilities. Therefore, MR accidents likely will rise.

MR Safety Labeling of Items

The U.S. Food and Drug Administration, in partnership with the Society for MR Radiographers and Technologists, provides safety labeling criteria for objects being taken into the magnet room

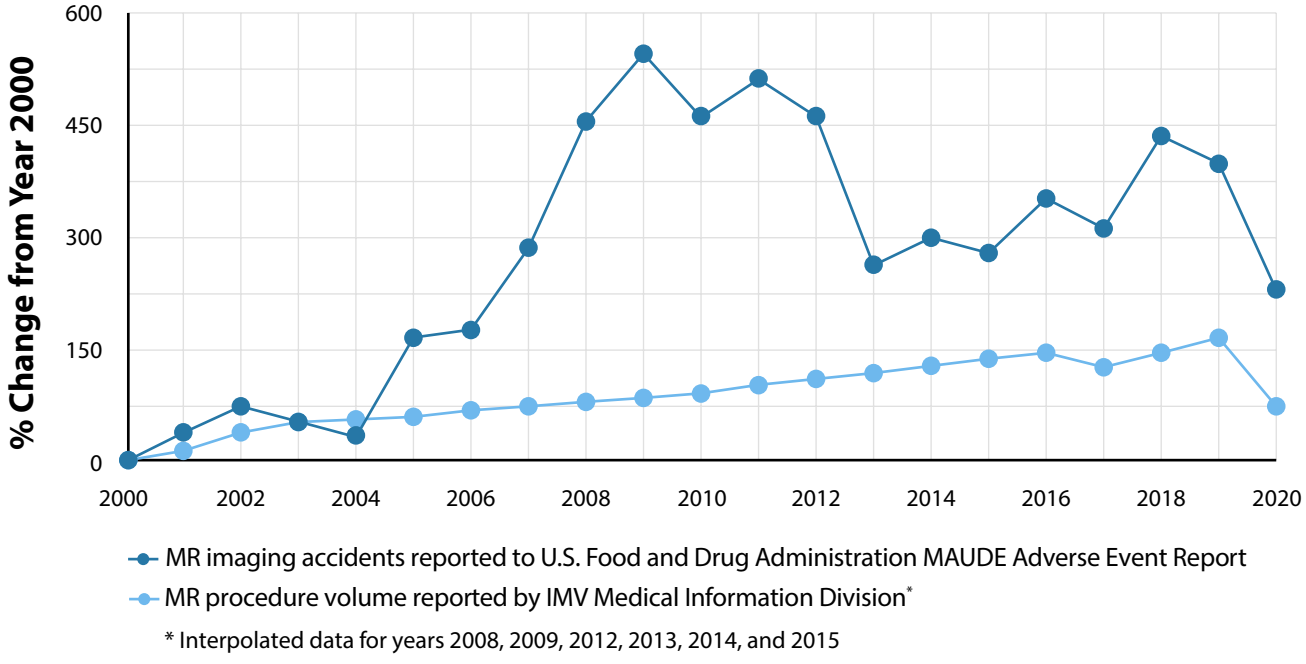

Figure 1. *Changes to magnetic resonance (MR) imaging adverse events vs procedure volume. Abbreviation: MAUDE, Manufacturer and User Facility Device Experience. Graph courtesy of Tobias Gilk.*

(see **Figure 2**).[16] Implants, medical devices, and other equipment used in or near the MR environment should be labeled as MR safe, MR conditional, or MR unsafe. The MR safe label (square) indicates that the object or implant is safe in all MR environments. The item has no metallic components and does not present a deflection hazard when exposed to the magnetic field. The MR conditional label (triangle) indicates that the object, implant or device can be safely used in the MR environment; however, there are specific conditions that must be met to make this item acceptable for exposure to the magnet. The MR conditional safety label includes the strength of the MR system's static magnetic field (B_0) and the maximum static magnetic field gradient (dB/dx).[2] The MR unsafe label (circle) indicates that an item poses a significant safety hazard and should not be exposed to the MR environment. This classification is usually for ferromagnetic objects.[16]

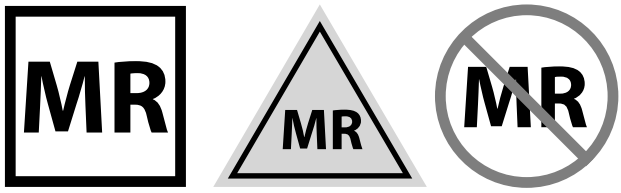

Figure 2. *MR imaging safety labeling. Image adapted from the U.S. Food and Drug Administration MR imaging safety poster. fda.gov/media/101205/download*

MR Safety Procedures

After approval by the FDA in 1984, MR scanners were embraced quickly by the medical community and have become a common imaging tool used in radiology.[7] Because of their strong magnetic fields and use of RF, the MR environment produces unique safety hazards.[7] Safety is a shared responsibility among clinical staff, MR personnel, and facility designers.[8]

Clinical and operational safety procedures are critical components of minimizing risks in the MR department. The ACR Manual on MR Safety recommends that MR departments have specific policies and procedures to reduce risk, including restricted zoning of MR environment, safety training levels for staff working in the MR environment, and thorough screening

processes.[2,13] The manual suggests that policies be reviewed and updated as needed and recommends that MR imaging facilities have an MR medical director who ensures that safety policies are established, understood, and followed by staff.[2,13] For adverse events or MR imaging accidents associated with FDA-regulated products, facilities should document the event and report it to the MedWatch program.[2,13] MedWatch is an FDA safety information and reporting program for health professionals, patients, and consumers.[17] The FDA investigates these reports and, if necessary, publishes safety alerts.[17]

MR Zones

Restricted zoning divides the MR department in to 4 zones or regions (see **Figure 3**).[2,13,18,19] Zone I is the general region where patients and visitors freely move about.[2,8,13] Patients, MR personnel, and other health care employees access the MR imaging environment from zone I.[2,13,19]

Zone II is a restricted area for screening and preparing patients for their MR imaging examination. It is the interface between zone I and strictly controlled zones III and IV. Patients are free to move in zone II unassisted when supervised by MR personnel.[2,13,19] The screening process includes physical and medical screening. Review of the patient's history includes identifying implants, devices, and materials the patient has on or in them.[2,8,13] Zone II should allow for private screening and use of the recommended ferromagnetic detectors. It also should provide comfortable waiting rooms, restrooms, and holding areas for patients.[2,8,13]

Zone III is a more restricted area. Only screened non-MR personnel and trained MR personnel have access.[2,8,13] It usually includes the control room or technologist area.[8,13] The technologist work area should allow for storage cabinets, computer stations, and workstations near each magnet system.[2,8,13] People not trained in MR safety could be severely injured if they are roaming unsupervised in this area.[2,13] Non-MR personnel, patients, and visitors must be accompanied by MR personnel with level 2 training. Zone III should be physically restricted from public access by key locks, passkey locking systems, or other reliable, physically restricting method.[2,13,19]

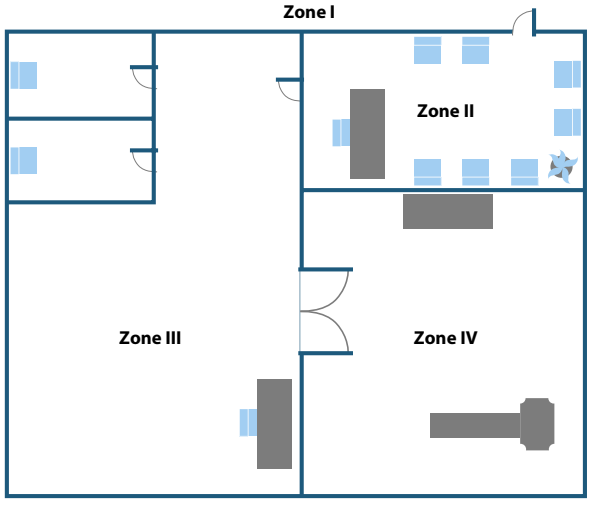

Figure 3. *Example of a 4-zone model system for MR suites.*

Zone IV is the MR scanner room and is the most restricted area.[2,8,13] This area is accessible only by MR-trained personnel, and all persons entering zone IV should be screened appropriately.[2,13,19] Non-MR personnel, patients, and visitors should be under constant immediate supervision of level 2–trained MR personnel while in the area of the magnet.[2,13] Direct visual observation by level 2–trained MR safety personnel, typically through a video monitoring system, should be provided to control the entrance to zone IV.[2,13,19] Zone IV should be marked clearly with a lighted sign stating that the magnet is always on.[2,13,18,19] This sign should be connected to hospital auxiliary power so that it is illuminated continuously.[2,13] No exceptions should be made to the zoning restrictions.[2,13,18,19]

Because the magnetic field penetrates the ceiling, walls, and floors of zone IV, facilities should consider additional restrictions above and below the magnet room.[2,8,13] This might include limiting occupancy on floors above or below the MR department.[2,8,13] The potential effect on neighboring facilities should be considered before construction.[2,8]

Staff and Patient Safety

Along with MR safety zones, the ACR recommendations describe safety policies for staff, patients, and

visitors.[2,13] Individuals entering the MR environment must understand the risks involved. Constant attention and due diligence are required from MR imaging personnel. Screening individuals before permitting entry into the MR imaging environment is a vital part of a facility's MR safety program, and when conducted properly, screening can prevent problems, accidents, and injuries.[2,20,21] Everyone entering zone III must pass a screening process.[2,13] This process includes reviewing history of trauma, medical procedures, or surgeries that might have involved ferromagnetic objects or devices.[2,13,21] The screening process and forms for patients, visitors, and MR personnel should be almost identical.

An example of ACR's Safety Screening Form for MR Procedures can be found at asrt.org/as.rt?bP2t5F

There are 2 levels of MR personnel.[2,13] Level 1 personnel are those who have passed basic MR safety education to secure their own safety as they work in the MR environment.[2,13] They are not allowed to admit or be responsible for non-MR personnel in zones III and IV. Level 2 personnel are those who have been extensively trained in MR safety issues, such as thermal loading or burns from the changing gradient fields produced in MR imaging. Level 2 personnel typically perform MR imaging.[2,13] Individuals working in zone III or IV should successfully complete at least 1 live or prerecorded MR safety presentation approved by the facility's MR medical director.[2,13] For MR personnel, attendance at these safety presentations should be completed annually, and documentation should be kept to verify personnel education.[2,13]

Facility Design

Clinical and operational safety are critical components of minimizing risks in the MR department.[8] Along with people-oriented policies and education, organizations also must adopt safety-oriented architectural and interior design strategies.[2] The design of the MR imaging facility often is overlooked.[2,8]

A well-designed facility can decrease the risk of accidents (eg, projectiles) and prevent patients with hazardous implanted devices from entering zone IV; it also can encourage safety and best practices by improving patient flow, health care personnel processes, and equipment and device use.[2,8] These design elements can support safety procedures by making them easier to follow.[2] The ACR provides guidelines for facility safety design in the ACR Manual of MR Safety (see **Box 2**).[2]

Cryogen use also requires strategic facility design. A quench pipe must be designed to withstand increased pressure and ventilate cryogen gas to an unoccupied area outside the building.[2,8] If the system is designed properly, gas will exit through this vent pipe to the outdoors.[8] If there is a quench pipe leak, however, the pressure will increase in the room, and the door will seal, trapping the patient or staff member inside the magnet room.[8] In the event of a quench pipe failure, the ACR recommends that an additional emergency ventilation system with a transfer grill be installed to permit air flow to the outside through the RF-shielded walls, and many MR vendors require passive pressure-relief mechanisms in magnet rooms to reduce risk of entrapment.[2,8]

Certified MR Safety Personnel

MR facilities should have certified safety personnel, including an MR medical director, an MR safety officer and an MR safety expert.[22] The MR medical director is legally responsible for the MR facility, oversees MR imaging examinations, and ensures that MR-specific policies and procedures are current, appropriate, and followed by staff.[22] They also are responsible for implementing safety and quality assurance programs.[22] The MR medical director should always be accessible during operation of the MR system.[22] The MR medical director is responsible for appropriate investigation into safety adverse events that occur at the facility and ensuring systems are in place for proper recordkeeping of these events, including ongoing risk assessments of the facility and its operations.[22]

The MR safety officer must be readily available to staff at the MR facility.[22] The MR safety officer ensures policies regarding safety-related issues are followed and provides safety advice on equipment, personnel, and protocols.[22] The MR safety officer is responsible for educating facility staff on MR safety procedures and instructing them on current safe patient practices.[22] They ensure that medical, technical, nursing, and other relevant staffing groups who might be exposed

Box 2

Facility Safety Design Guidelines from ACR Manual on MR Safety[2]

- control access (zones III and IV)
- direct line of sight for level 2 MR personnel to entrances and exits (zone III or IV)
- emergency resuscitation equipment available (zones II or III)
- restricted access to areas outside the MR suite that are exposed to potential hazards of the MR scanner
- patient holding area for after screening to prevent patient exit and subsequent reentry (zone III)
- patient interview and clinical screening areas that provide visual and auditory privacy (zone II)
- physical screening and patient changing rooms (zone II)
- reference design templates provided by MR equipment manufacturers when developing MR suite
- transfer area and ferrous quarantine storage (zone II)

to the MR environment are educated appropriately on a regular basis about safety requirements and updated as necessary.[22] The MR safety officer also manages hazards posed by the MR equipment and monitors the measures taken to protect against such hazards. The MR safety officer consults the MR medical director on safety matters when necessary.[22]

The MR safety expert is a resource for the MR medical director and MR safety officer.[22] The MR safety expert often is an MR physicist but might be someone else with an equivalent level of technical expertise.[22] They provide high-level advice on the engineering, scientific, and administrative aspects of the safe use of MR equipment.[22] The MR safety expert advises staff regarding nonroutine MR procedures, the choice of MR safety programs, and quality assurance programs for the facility.[22]

Management's Role

A focus on safety in MR imaging is essential in the overall safety program of hospitals and medical care facilities, and implementing an MR imaging safety program is a necessity for any health care organization.[13,19] The goal of implementing an MR safety program is protecting patients, staff, and others from MR-related accidents or injuries.[19] A strong MR safety program has collaboration among radiology, patient safety and risk management, facilities management, and biomedical engineering.[19]

When driving change in an organization, solid change management education is essential so that staff is comfortable with the changes and not intimidated by them. Management should support frontline staff and help eliminate any fear of change.[13] Management must be aware of safety standards, support education programs for staff, and approve funds to purchase equipment needed to provide a safe imaging environment. Providing staff with solid safety education helps employees take ownership of their jobs, achieve their full potential, and be more productive in the workplace, while providing excellent patient care.[23]

Gaining support from an entire organization for a substantial change initiative is difficult but not impossible.[23] Buy-in is critical during the change process; without it, the safety initiative will fail.[23] Changes should be communicated clearly and repeatedly; keep the plan simple and talk about it often with staff.[23] Two-way communication in this situation is pertinent.[23] Listen to the staff and consider their feedback by allowing them to express their concerns, anxieties, or confusion.[23]

The most efficient way to initiate change is to bring together a group of important leaders to assist with implementing the change.[23] The MR safety committee should hold meetings, send emails, and create videos or catch phrases that focus on the positive outcomes of having a solid, working MR safety program.[23] Communicating a change effort takes consistency, discipline, and 2-way communication, but it will bring the vision of safety to life in the organization, thus completing the buy-in process.[23] The entire staff will buy-in when they realize how these changes will make their work processes more useful and satisfying.[23]

Challenges in MR Safety: Closing the Gaps

Although debate on specific solutions might continue, there is widespread consensus for changes in health care in the United States to address inconsistencies in quality and efficiency.[24] The scope of MR safety is to provide information and guidance to improve the processes needed in clinical and research areas and to

prevent adverse outcomes in relation to MR imaging. However, a lack of standard regulations, underreporting of adverse events, and cost of educating staff places limitations on the scope of MR safety.

Lack of Regulated Standards

Most workers are held to certain health and safety regulations.[25] Health care is the same, with standards and strict regulations; however, there are gaps in regulations and guidelines for MR departments.[25] MR imaging began in the 1980s and was hailed as a safe imaging modality because it does not emit ionizing radiation.[25] Because of the perceived safe nature of MR imaging, few guidelines were put in place to govern this new imaging modality and not enough questions were asked to determine how safety regulations should be designed.[25]

The FDA regulates the manufacturing and marketing of drugs and medical devices and maintains a list of reported adverse events associated with these products (MedWatch). However, the FDA has no authority for operational aspects of MR imaging departments. Individual states regulate exposure to ionizing radiation, yet there are no formal regulations addressing the safety risks associated with the strong magnetic field of MR imaging units. This lack of regulation is causing a safety gap in health care systems.[25] To close the safety gap, MR personnel must continue to be cautious in the MR environment and educate themselves and others, and other health care professionals must be willing to learn about the MR environment and the safety risks associated with it.[25]

Variations in safety practices recommended by compliance agencies do not provide regulated standards and leave room for individual interpretation.[25] The ACR added its most recent MR safety recommendations to its accreditation requirement standards for MR.[14] However, the ACR remains the only group to do so, and although the ACR's guidelines are clear, there is no real enforcement of its recommendations. MR imaging facilities are strongly recommended to follow and implement these safety guidelines; however, they are not standard practice, and it is up to individual health care providers and facilities to implement them.[25]

Underreporting of MR Imaging Adverse Events

Although safety is slightly better since the ACR formed a blue-ribbon panel on MR safety in 2001, accidents have not ceased. Accidents in MR imaging departments worldwide demonstrate these gaps in education and practice. MR safety recommendations or organizations in other countries, such as the Royal Australian and New Zealand College of Radiologists or the Medicines and Healthcare products Regulatory Agency in the United Kingdom, are based on the ACR guidelines. Though recommendations are in place to prevent ferrous objects from entering the magnetic field, accidents still occur.[25]

In April 2019 in Varberg, Sweden, an MR staff member was accompanying a patient into the MR room who was wearing a metallic ankle band with steel balls and the patient's leg reportedly got stuck to the scanner.[26,27] In October 2019 an MR nurse at Sunderby Hospital in Luleå, Sweden sustained injuries from wearing a metal weighted exercise vest while working in a mobile MR imaging unit.[26,27] In January 2018 in Mumbai, India, a man died after bringing an oxygen tank into an MR room.[28] The accident in Mumbai was 1 of many accidents in that country in the past few years.[27] Sweden had 2 nearly fatal MR imaging accidents during the same year, just months apart.[26,27] There are no regulations in MR safety in India or Sweden, nor anywhere else in the world.[25]

Accidents are uncommon.[25] It might take years before a projectile accident happens in a busy MR department.[25] As a result, these accidents are not on the minds of health care professionals every day.[25] In addition, there is a certain professional reproach attached to MR imaging accidents.[25] If an accident occurs, the facility feels isolated because they have not heard of accidents at other hospitals, and this leads to underreporting incidents or suppressing details.[25]

This underreporting creates an information and education gap.[25] Without sharing information and details concerning an accident, the MR community has no opportunity to learn from mistakes and no opportunity to develop processes that will minimize the chance that a facility will have the same accident.[25] Therefore, the same errors are repeated, and no lesson is learned.[25] The FDA speculates its adverse event reporting database

captures just a small percentage of actual incidents, which means many facilities are unaware that these incidents occur and do not take necessary steps to prevent them.[25]

Limitations on Education and Knowledge

MR imaging's expanding applications, such as those in radiation oncology, have added another layer of difficulty in ensuring that safety practices are consistently maintained.[11] Creating a culture of safety requires a complete and thorough knowledge of current MR imaging equipment and principles, contrast media use, adherence to safe practices, and written guidelines and protocols.[11] Educating staff is costly for health care organizations; however, proper education leads to improved safety and a more efficient and safer atmosphere for the staff and patients.[24] Mr Gilk, an MR safety operations expert, said:

> *With the proper training, there is enormous potential to improve safety and do so in a more cost-effective manner…For example, without training regarding the effect of the latest implanted medical devices in patients who need MR imaging, imaging personnel can spend 8 to 8 1/2 hours per magnet per week researching MR imaging best practices for those patients. Training provides personnel with the knowledge to reconcile the impact of each medical device in less time, reducing weekly research time to as little as 2 hours. With understanding come efficiencies.*[29]

Conclusion

Since the death of a 6-year-old patient in 2001, attention has focused on MR safety in health care. The health care profession has standards and regulations in place, but gaps in standards can have serious effects on safety in areas such as MR imaging. Guidelines recommended by compliance agencies are clear; however, there is no real enforcement of MR safety recommendations, and it is up to individual health care organizations to implement these recommendations. It is time to close these gaps by developing standard regulations in MR imaging to better protect patients and staff in health care facilities.

Continual quality management must be encouraged in MR safety practices by creating regulated standards in the MR imaging profession. MR imaging safety cannot be taken lightly. A thorough education on MR imaging equipment, imaging principles, safe practices, and written guidelines is needed. The cost of an MR safety program outweighs the risk of injuring a patient or staff member as a result of a lack of education and policy inefficiencies. We need to overcome these barriers. Health care professionals must understand that implementing these best practices can minimize the chance of MR accidents.

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References

1. Coskun O. Magnetic resonance imaging and safety aspects. *Toxicol Ind Health*. 2011;27(4):307-313. doi:10.1177/0748233710386413
2. Kanal E, Greenberg T, Hoff MN, et al. ACR Manual on MR Safety. American College of Radiology. Published 2020. Accessed May 2020. https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf
3. Quality control: MRI/breast MRI. American College of Radiology. Updated Oct 21, 2020. Accessed August 22, 2020. https://accreditationsupport.acr.org/support/solutions/articles/11000061043-quality-control-mri
4. 2 investigates: girl injured during MRI; experts say accidents rising. KTVU. Published April 28, 2015. Accessed February 2020. http://www.ktvu.com/news/2-investigates-girl-injured-during-mri-experts-say-accidents-rising
5. Westbrook C, Roth CK, Talbot J. *MRI In Practice*. 4th ed. Wiley-Blackwell; 2011.
6. Currie S, Hoggard N, Craven IJ, Hadjivassiliou M, Wilkinson ID. Understanding MRI: basic MR physics for physicians. *Postgrad Med J*. 2013;89(1050):209-223. doi:10.1136/postgradmedj-2012-131342
7. Woods TO. Standards for medical devices in MRI: present and future. *J Magn Reson Imaging*. 2007;26(5):1186-1189. doi:10.1002/jmri.21140

8. Gilk T, Kanal E. Integrating MRI facility design and risk management. *J Healthc Risk Manag.* 2009;26(3):29-37. doi:10.1002/jhrm.5600260307
9. Pai A, Shetty R. Magnetic resonance imaging physics. StatPearls. Updated December 11, 2020. Accessed February 2020. https://www.statpearls.com/ArticleLibrary/viewarticle/34549
10. Gilk T, Latino RJ. MRI Safety 10 years later: what did we learn from the accident that killed Michael Colombini. PSQH Patient Safety and Quality Healthcare. Published October 14, 2011. Accessed January 2020. https://www.psqh.com/analysis/mri-safety-10-years-later/#
11. Crisp S, Dawdy K. Building a magnetic resonance imaging safety culture from the ground up. *J Med Imaging Radiat Sci.* 2018;49(1):18-22. doi:10.1016/j.jmir.2017.10.005
12. Home. American Board of Magnetic Resonance Safety. Accessed January 2020. https://abmrs.org/
13. Kanal E, Barkovich AJ, Bell C, et al; Expert Panel on MR Safety. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging.* 2013;37(3):501-530. doi:10.1002/jmri.24011
14. The Accreditation Process. American College of Radiology. Updated February 4, 2021. Accessed June 11, 2021. https://accreditationsupport.acr.org/support/solutions/articles/11000045691-the-accreditation-process
15. Delaronde S. The iron triangle of health care: access, cost, and quality. 3M Inside Angle. Published February 6, 2019. Accessed January 2020. https://www.3mhisinsideangle.com/blog-post/the-iron-triangle-of-health-care-access-cost-and-quality/
16. MRI Safety Posters. U.S. Food and Drug Administration. Updated November 23, 2020. Accessed June 11, 2021. https://www.fda.gov/radiation-emitting-products/mri-magnetic-resonance-imaging/mri-safety-posters
17. MRI (magnetic resonance imaging). U.S. Food and Drug Administration. Updated August 29, 2018. Accessed January 2020. https://www.fda.gov/radiation-emitting-products/medical-imaging/mri-magnetic-resonance-imaging
18. Tsai LL, Grant AK, Mortele KJ, Kung JW, Smith MP. A practical guide to MR imaging safety: what radiologists need to know. *Radiogr.* 2015;35(6):1722-1737.
19. Joint Commission. Strong MRI safety programs prevent safety events. *Quick Saf.* 2017;31:1-3. https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-31-strong-mri-safety-programs-prevent-safety-events/strong-mri-safety-programs-prevent-safety-events
20. Shellock FG. *Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2020 Edition.* Biomedical Research Publishing Group; 2020.
21. Shellock FG, Spinazzi A. MRI safety update 2008: part 2, screening patients for MRI. *AJR Am J Roentgenol.* 2008;191(4):1140-1149. doi:10.2214/AJR.08.1038.2
22. Harmonay V. MRI system safety, roles and responsibilities. Atlantis Worldwide. Published June 28, 2016. Accessed January 2020. https://info.atlantisworldwide.com/blog/mri-safety-roles-responsibilities
23. Kotter step 4: communication buy-in. Speaking Gump. Accessed January 2020. http://speakinggump.com/blog/kotter-step-4-communication-buy/
24. Pexton C. Overcoming the barriers to change in healthcare system. iSixSigma. Accessed January 2020. https://www.isixsigma.com/implementation/change-management-implementation/overcoming-barriers-change-healthcare-system/
25. Gilk T. Closing the loopholes in MRI safety. Imaging Technology News. Published July 3, 2018. Accessed January 2020. https://www.itnonline.com/article/closing-loopholes-mri-safety
26. Ward P. Details emerge on MRI accident in Sweden. Aunt Minnie. Published October 31, 2019. Accessed January 2020. https://www.auntminnie.com/index.aspx?sec=sup&sub=mri&pag=dis&ItemID=126979
27. Ward P. New details emerge of a 2nd MRI accident in Sweden. Aunt Minnie. Published November 7, 2019. Accessed January 2020. https://www.auntminnie.com/index.aspx?sec=sup&sub=mri&pag=dis&ItemID=127140
28. Hafeez M. Man dies in freak accident in MRI room; 2 arrested. Times of India. Updated January 28, 2018. Accessed January 2020. https://timesofindia.indiatimes.com/city/mumbai/man-gets-sucked-into-mri-machine-at-mumbai-hospital-fir-filed/articleshow/62681341.cms
29. Hardy K. Training staff in MRI safety. *Radiol Today.* 2015;16(12):20.