



An advisory on safety & quality issues

Issue 31

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Strong MRI safety programs prevent safety events

Issue:

Magnetic resonance imaging (MRI) is a widely used diagnostic modality with millions of scans being performed in the U.S. annually, according to the U.S. Food and Drug Administration (FDA).¹ The magnetic resonance (MR) environment poses potential risks to patients, as well as accompanying family members, attending health care professionals and others – such as security or housekeeping personnel, firefighters and local police – who find themselves only occasionally or rarely in the magnetic fields of MRI scanners.² Hospitals and imaging centers that offer the MRI diagnostic modality must maintain a comprehensive MRI safety program in order to mitigate the potential risks to patients, staff and visitors.

According to the FDA, while there are no known health hazards from temporary exposure to the MR environment, the MR environment involves a strong, static magnetic field that has specific safety concerns, including:¹

- Attracting magnetic objects of all sizes that may become projectiles and cause damage to the scanner or injury to the patient or medical professionals.
- Creating loud knocking noises which may harm hearing or may cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.
- Heating of the body, especially during long MRI examinations.

Thermal events (59%) were the most commonly reported serious injury received by the FDA over a 9-year period (2008-2017) of 1,568 adverse event reports for MR systems. Other reports were for mechanical events – defined as slips, falls, crush injuries, broken bones, cuts, and musculoskeletal injuries from lifting or movement of the device – (11%), projectile events (9%), and acoustic events (6%).³

Additional electromagnetic field interactions that may contribute to harm include but are not limited to dislodging or heating medical or other implants; induced electrical currents; and potentially interrupting patient monitoring equipment.^{2,4} Also, the Institute for Medication Safe Practices reported an incident involving an unopened Dilaudid (hydromorphone) prefilled syringe that was brought into a room housing a MRI scanner and was drawn to the magnet. The syringe package contains a canister that holds iron oxide, which prevents oxidation of the drug. Iron oxide is ferromagnetic. No one was harmed in the incident, but the enclosed glass syringe shattered. Both Dilaudid and morphine syringes in Simplist packaging have this iron oxide canister.⁵

Potential contraindications for MRI include but are not limited to cardiac pacemakers, aneurysm clips, neurostimulators and implants, but also tattoos, permanent makeup, hair extensions, tissue expanders, and clothing that may contain metal.^{2,4} See the ACR Safety Screening Form for Magnetic Resonance (MR) Procedures for a detailed list.⁶ Patients must be screened for possible contraindications prior to MRI scanning. Published test results and/or on-site testing of an identical device or foreign body may be helpful in determining whether a patient with a particular medical device or foreign body may be safely scanned.

The development of a complete and efficient screening procedure with multiple check steps for all individuals in the MR setting is one of the most critical components of a comprehensive safety program. The screening process involves maintaining current knowledge and awareness of the risks related to implants, devices, materials and equipment that may have an impact on safety in the MR environment.⁴

(Cont.)



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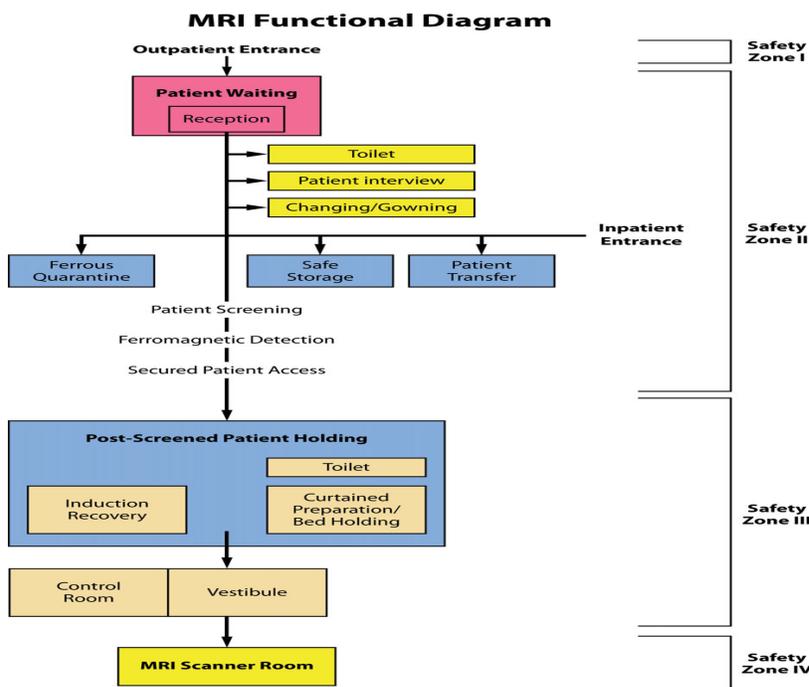
Making the MR environment safe

Due to the powerful magnetic field created by MRI scanners, many hospitals and medical centers do two things to make the physical environment safe:

- 1) Test and label items planned for use in the MR environment using ASTM International standard F2503 [14] so that potentially dangerous items are not brought near the MRI scanner. Only items that are proven to be safe near the MR environment are allowed inside the MR Suite. Once an item is tested, it is classified as: MR Safe, MR Conditional or MR Unsafe. (See Table 1: Definitions from ASTM international standard F2503-13 of the MHRA's [Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use.](#))²

It is essential to safety that all items used have passed rigorous inspection and clearance to be utilized in the various safety zones (described in the MRI Functional Diagram).⁷ Labeling items helps prevent dangerous situations. This includes knowledge of the limitations for MR Conditional items and devices. Assumptions about items should be avoided since items that contain ferrous magnetic materials may surprise both experienced staff and the public and can contribute to safety events, as in the incident mentioned earlier in this newsletter of the prefilled syringe with an iron oxide canister.⁵

- 2) Restrict access to the MR facility or space by establishing four conceptual zones around the MRI scanner. Each boundary zone in this four-zone safety system is defined by its purpose and distance from the MRI scanner. Since the magnetic field extends in three dimensions, some zones may extend into other areas or floors of the facility. (See MRI Functional Diagram.)⁷



Safety Actions to Consider:

A comprehensive MRI safety focus is essential in the overall safety program in hospitals and medical care facilities. The goal of an MRI safety program is: *Protecting patients and individuals from MR system-related accidents and injuries.* A strong program requires the collaboration of imaging, patient safety, facilities management, and biomedical engineering.

Some Joint Commission standards that cover the MR setting include:

- Performance Improvement (PI) Standard PI.01.01.01, Elements of Performance (EPs) 34 and 35 require hospitals, critical access hospitals, and ambulatory care organizations to collect data on thermal injuries that occur during MRI exams and incidents where ferromagnetic objects unintentionally enter the MRI scanner room.
- Environment of Care (EC) Standard EC.02.01.01 EP 14 and 16 require hospitals to manage MRI safety risks.



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- Human Resources (HR) Standard HR.01.05.03 EP 25 requires the hospital to verify and document that MRI technologists participate in ongoing education.

Conducting regular reviews on all safety incidents that occur in the MR environment, including near misses, will help prevent harm to patients, staff and visitors. The FDA asks that MR facilities report adverse events to its MedWatch program.²

MRI safety program essentials should include:

- Establishing, implementing and maintaining safety policies and procedures.²
- Reporting of all MR adverse events, safety incidents or near miss incidents.²
- Restricting site access (see the MRI Functional Diagram).²
- Screening of devices and rating of hazardous materials/equipment.²
- Screening staff and patients to identify any potential risks such as implants (including passive implants) or metallic objects.²
- Managing cardiac or respiratory arrest.²
- Managing patient claustrophobia, anxiety, sedation, anesthesia and violent behavior.²
- Managing contrast agent safety.²
- Performing a “full stop and final check” (performed by the MRI technologist) to confirm the satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately prior to crossing from Zone III to Zone IV. The purpose of this final check is to confirm the patient’s identification, ensure that all screening has been appropriately performed, and ensure that there has been no change in patient and/or equipment status while in Zone III.²
- Monitoring patients in the MR environment.^{2,4}
- Planning for emergencies, including but not limited to fire, flood or water damage, power failure, police action, and magnet quenching.^{2,4}
- Conducting MR safety education (initially and repeated annually) for all staff who are responsible for safety in Zones III or IV of the MR environment.²
- Ensuring effective communication and understanding of risks to patients of diverse cultures, and to those patients who cannot share medical information related to possible contraindications due to disabilities.⁸⁻¹¹
- Conduct failure mode effect analysis (FMEA) whenever changes are being made to the MR environment.

Resources:

1. U.S. Food & Drug Administration. MRI – Benefits and Risks web page. Current as of Dec. 9, 2017. <https://www.fda.gov/radiation-emitting-products/mri-magnetic-resonance-imaging/benefits-and-risks>
2. American College of Radiology (ACR). ACR Committee on MRI Safety. ACR Manual on MR Safety. 2020. ACR, Reston, Virginia. <https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf>
3. JG Delfino, et al. MRI-related FDA adverse event report: A 10-yr review. Medical Physics; 2019;46(12):5562-5571. <https://aapm.onlinelibrary.wiley.com/doi/10.1002/mp.13768>.
4. MRIsafety.com: The List and Safety Topics, Screening forms
5. Institute for Safe Medication Practices. Prefilled opioid syringe attracted by MRI magnet. *ISMP Medication Safety Alert*, Feb. 22, 2018;23(4).
6. American College of Radiology. Safety Screening Form for Magnetic Resonance (MR) Procedures. May 2020. <https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/MR-Safety-Screening-Form.pdf>
7. U.S. Food & Drug Administration. Medicines and Healthcare Products Regulatory Agency (MHRA). Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. February 2021.
8. The Joint Commission. [Overcoming the challenges of providing care to LEP patients](#). Quick Safety, Issue 13, May 2015.
9. The Joint Commission. [Informed consent: More than getting a signature](#). Quick Safety, Issue 21, February 2016.
10. The Joint Commission. [Implicit bias in health care](#). Quick Safety, Issue 23, April 2016.
11. MRIsafety.com. Safety Information Article: [Monitoring Patients in the MR Environment](#).



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Additional resources:

- U.S. Department of Health and Human Services, Food and Drug Administration. Center for Devices and Radiological Health. [Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance \(MR\) Environment](#). Dec. 11, 2014.
- L Clausen, et al. Radiologic Technologist Best Practices for MR Safety (White Paper). American Society of Radiologic Technologists. 2018.
- The Joint Commission. [Safe patient use of insulin pumps & CGM devices during hospitalization](#). Quick Safety, Issue 59, June 2021.

Note: This is not an all-inclusive list.



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