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# Strong MRI safety programs prevent safety events

### Issue:

Magnetic resonance imaging (MRI) is a widely used diagnostic modality with 30 million scans being performed in the U.S annually, according to the U.S. Food and Drug Administration (FDA).<sup>1</sup> 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. Hospitals and imaging centers that offer the MRI diagnostic modality should maintain a comprehensive MRI safety program in order to mitigate the potential risks to patients, staff and visitors.<sup>2</sup>

According to the FDA, while MRI is considered a safe modality, "there is an underlying potential for injury to patients due to the strong electromagnetic (EM) fields used in MR scanning."<sup>1</sup>

EM field interactions that may contribute to hazards include, but are not limited to: dislodging medical or other implants; tissue heating; induced electrical currents; equipment or materials becoming dangerous missiles or projectiles; and potentially interrupting patient monitoring equipment.<sup>2,3</sup>

Potential contraindications for MRI include: cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, implants, and certain other ferromagnetic foreign bodies or electronic devices, tattoos, or permanent makeup.<sup>2</sup> 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.<sup>2</sup>

The development of a complete and efficient screening procedure 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.<sup>3</sup>

# Classification/ratings of items in the MR environment and physical plant

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

 Use an MR Item Classification System 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 text box.)<sup>2</sup>

What is essential to safety is that all items used should have passed rigorous inspection and clearance to be utilized in the various MR Item Classification System ratings

**MR Safe:** Items pose no known hazards in all MR environments and are indicated by a green and white icon.

**MR Conditional:** Items do not pose any known hazards in a specific MR environment with specific conditions of use. The icon consists of "MR" inside of a yellow triangle.

**MR Unsafe:** Items such as any magnetic item, are unsafe in all MR environments. Unsafe icon features a "MR" inside of a red circle with a bar through it.

(Cont.)



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> safety zones (described below). Labeling items and following the MR Item Classification System helps prevent dangerous situations. 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.<sup>2</sup>

 Restrict access to the MR Suite by establishing four conceptual zones around the MRI scanner. Each boundary zone in this fourzone 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.)<sup>2</sup>

# 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 radiology, patient safety, facilities management and biomedical engineering. 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.<sup>2</sup>

#### MRI safety program essentials should include:

- Policies and procedures that are written, enforced and reviewed annually<sup>2</sup>
- Reporting of all MR adverse events, or near miss incidents<sup>2</sup>
- Restricted site access<sup>2</sup>
- Managing MR personnel (including educating and screening personnel)<sup>2</sup>
- Device screening and rating of hazardous materials/equipment<sup>2</sup>
- Patient screening guidelines<sup>2</sup>
- Managing cardiac or respiratory arrest<sup>2</sup>
- Managing patient claustrophobia, anxiety, sedation, anesthesia, violent behavior<sup>2</sup>
- Contrast agent safety<sup>2</sup>
- Monitoring patients in the MR environment<sup>2,8</sup>
- Emergency preparedness (planning for fire, flood or water damage, power failure, police action, and magnet quenching)<sup>2,8</sup>
- Compatibility of passive implants<sup>2</sup>
- Education for all staff who may be operating in one of the MR safety zones, including the facility code teams, hospital security and housekeeping staff<sup>2</sup>
- 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<sup>2,5-8</sup>



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## **Resources:**

- 1. U.S. Department of Health and Human Services. Food and Drug Administration. <u>Magnetic</u> <u>Resonance Imaging (MRI) Safety</u>. Aug. 1, 2016 (accessed Feb. 17, 2017).
- American College of Radiology (ACR) <u>Guidance Document on MR Safety Practices: 2013</u>. Journal of Magnetic Resonance Imaging, 37:501-530 (2013) (accessed Feb. 22, 2017).
- 3. MRIsafety.com. Safety Information Article: <u>Guidelines for Screening Patients For MRI Procedures</u> and Individuals for the MRI Environment (accessed Feb. 21, 2017).
- 4. The Joint Commission. Overcoming the challenges of providing care to LEP patients. Quick Safety, Issue 13, May 2015 (accessed Feb. 21, 2017).
- 5. The Joint Commission. <u>Transitions of Care: Engaging patients and families</u>. Quick Safety, Issue 18, November 2015 (accessed Feb. 21, 2017).
- 6. The Joint Commission. Informed consent: More than getting a signature. Quick Safety, Issue 21, February 2016 (accessed Feb. 21, 2017).
- 7. The Joint Commission. Implicit bias in health care. Quick Safety, Issue 23, April 2016 (accessed Feb. 21, 2017).
- 8. MRIsafety.com. Safety Information Article: <u>Monitoring Patients in the MR Environment</u> (accessed Feb. 21, 2017).

#### Additional resource:

U.S. Department of Health and Human Services, Food and Drug Administration. Center for Devices and Radiological Health. <u>Establishing Safety and Compatibility of Passive Implants in the Magnetic</u> <u>Resonance (MR) Environment</u>. Dec. 11, 2014 (accessed Feb. 22, 2017). *Note: This is not an all-inclusive list.* 



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