

## MRI Safety Still a Concern, But National Guidance Lacking

By Whitney L.J. Howell | July 27, 2012



Last October, the U.S. Food and Drug Administration (FDA) held a meeting to examine the biggest MRI safety concerns and outline best practices to reduce injuries associated with the scans. So far, however, the industry has received no national guidance on how to accomplish this goal.

But the lack of official instruction at the federal level doesn't mean the push toward greater MRI safety — being recognized this week during MRI Safety Week — has stalled. Advancements are underway at the state level and in the accreditation process to prevent another tragedy, such as the 2001 Colombini case when a 6-year-old boy died when an oxygen tank flew across the room and struck him during the imaging process.

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“Any protection that is implemented will benefit the 30 million Americans who get MRIs on an annual basis,” said Tobias Gilk, president and MRI safety director at Mednovus and senior vice president at the design and architecture firm Rad-Planning. “People are beginning to look harder at MRI risk factors as the power of our magnets continue to increase.”

### State Regulations

Many states and the Joint Commission have implemented new regulations that strictly govern the design and construction of new MRI suites. These requirements do not mandate retrofitting existing installations.

“There are a growing number of states that are adopting this building code,” Gilk said. “Anyone who does MRI suite work — renovation, upgrade, equipment replacements, anything with a building permit — in virtually every jurisdiction must follow these state standards.”

To conform to the building regulations, health care engineers must meet eight standards, Gilk said. They must follow the American College of Radiology's (ACR) 4-Zone Principles that address integrated access controls and screening practices. There must also be a clear line-of-sight between the operator's console and patient inside the MRI machine, and designers must include demarcation lines to keep individuals with implantable medical devices far enough away. The presence of ferromagnetic-only detectors is required, and new MRI suites must also have exhaust fans and other protective measures to eliminate any cryogen that escapes into the imaging area. They must include an always-illuminated sign to remind staff that the MRI magnetic field is always active even without a patient.

These new design codes also require a clearly marked safe zone in which staff can use MR conditional equipment. Most importantly, Gilk said, designers and engineers must remember there is no cookie-cutter model for MRI suites. Each site is different and requires individual planning.

### Accreditation

In a switch from years past, Gilk said, the Joint Commission is requiring far more documentation to prove you are making your MRI suite as safe as possible for patients. As part of the ACR's 4-Zone Principles, the Commission now requires proof that you

have established access control and provide proper staff supervision. You must also produce documentation that you have adequately trained your MRI personnel in safety procedures and protocols, he said.

“The Joint Commission wants to see evidence of screening protocols for implants and devices, clinical contraindications, and physical screenings,” Gilk said. “They want to see what you’re doing to make sure visitors aren’t carrying objects that will become dangers in the magnet room and what processes or tools are in place that accidents don’t occur.”

Requiring these measures — from an accreditation standpoint — is a giant step forward, he said.

#### Proactive Planning

Some practices and facilities aren’t waiting for official, mandated guidance, however. St. Luke’s Hospital at The Vintage LLC in Houston has lessened the danger MRI poses to individuals with pacemakers. In April, the hospital launched the FDA-approved, Revo MRI SureScan pacing system for cardiology patients who needed MRI scans.

SureScan has a variety of safety features that protect it inside the MRI suite, including more robust circuitry and a sensor that is immune to strong magnetic fields.

“Compatibility of pacemakers with MRI scans is an important technologic advance,” Maged Amine, MD, St. Luke’s head of cardiology, said in a statement. “We’re proud to provide safer access to MRI for our patients.”

In addition to St. Luke’s, the University of Wisconsin (UW) Hospital and Clinics has also conducted a full review of its MRI policies. Their analysis led to many changes, said Lisa Brunette, UW’s director of media relations. Now, any patient who doesn’t arrive in MRI-safe clothing — those without cell phones or anything metal — is required to change into a hospital gown for imaging.

Staff must also complete a “time-In” protocol on all sedated patients to confirm the patient’s identity, the body part to be imaged, and ensure all metal objects have been removed. Based on UW’s data analysis, this procedure prevented safety hazards in 31 percent of all high-risk, inpatient MRIs.

#### Continuing Concerns

Even with all these moves toward improved safety, there is still much work to be done, Gilk said. As Americans get heavier, MRI vendors must make more powerful machines that can provide proper images. This equates to more powerful magnets, and with more strength comes an increased risk for burns. In addition, stronger machines are also louder, boosting the likelihood of a patient sustaining hearing damage.

These continued problems clearly point to the need for federal guidance, he said.

“All these risk factors are continuing to increase, meaning we will injure more patients for no reason,” he said. “We can mitigate more than 90 percent of all injuries today if we only had mandated best practice guidelines to follow.”

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