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MRI safety

By Loren Bonner

This year, Geoff West, president and chief medical physicist at West Physics Consulting, noticed that several clients were calling in with requests for guidance on MRI safety. The Atlanta, Ga.-based company provides advanced imaging testing services and consulting to hospitals and imaging facilities, but they didn't have a third party assessment and training service for MRI safety in place that could fulfill recommendations from the various U.S. regulatory and accrediting bodies. In fact, they found that no other company offered this service to MRI facilities. So after some careful planning, West Physics launched a multi-element MRI safety service in July.

“Most of the services we introduce are based on demand,” says West.

In essence, the report that West Physics generates is something facilities can hand inspectors to show that they have policies and procedures in place for MRI safety. As West points out, MRI safety has been getting more attention from regulators and accrediting bodies. For one, he says, the American College of Radiology will begin performing unannounced site surveys under the Medicare Improvements for Patients and Providers Act, checking if a facility is compliant with accreditation criteria, which includes safety for MRI and CT programs. In addition to the ACR, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Joint Commission have all shown interest in stepping up efforts to ensure MRI safety. And at the state level, there are even more tangible signs of change.

The Wild West

While West Physics’ new MRI safety service is a step in the right direction, the fact that educational courses for safety exist in the first place highlights a missing component for what should have been a top priority for MRI environments all along.





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“From a regulatory standpoint, MRI is the Wild West,” says Tobias Gilk, president and MRI safety director at Mednovus, Inc. and senior vice president of RAD-Planning. “You would be hard-pressed to find a single regulatory requirement for physical safety in the MRI environment. They don’t exist on the federal level, they exist somewhat at the state level, and they hardly exist from accrediting bodies, even the ones who publish MRI best practice safety data.”

But there may be some valid reasons for the lapse in oversight. MRI safety expert Dr. Emanuel Kanal, director of magnetic resonance services and professor of radiology and neuroradiology at the University of Pittsburgh Medical Center, explains that the infrequency of accidents probably plays a part.

“MRI accidents are not common, and there are few injuries, which is a good thing. But these accidents and incidents are unnecessary and entirely avoidable. If they would be more common, then at least someone would step in and say this is unacceptable,” he says.

The increasing number of MRI procedures should also be taken into consideration. “In the U.S., we’re doing 30 million MRI exams on an annual basis. If your denominator is 30 million it doesn’t take a big numerator to wind up producing a lot of injuries,” says Gilk. In addition, magnet strength, gradient power and radio frequency transmissions in the machines have increased as a result of improvements in MRI technology, but those improvements

could make the rare injury more serious.

According to data from Med-Watch, the FDA safety information and adverse event reporting program, the number of complaints about MRI burns, thermal discomfort or direct thermal injury have skyrocketed since 1992. This was the same year the first sequences that increased power deposition in the machines were approved.

Gilk and Kanal reviewed two years' worth of MRI accident data from the FDA and found that the majority of MRI accident fit into three categories: Burns, projectiles and hearing damage.

"I was surprised that these three accident types comprised more than 90 percent of all reported accidents and that these are almost universally preventable through existing best practice standards," says Gilk.

Kanal, who was the chair of the ACR MR Safety Committee from

Roughly 20 states have adopted guidelines for design and construction of new health care facilities that have the potential to benefit patients and providers

2001 through 2012, has performed dozens of MR site safety reviews. "Usually I am called in after the horse is already out of the barn", he says. "Once the incident has already transpired, the powers that be call me in to review their MR safety and suggest guidance for future improvements. Only a few have the foresight to recognize how much more practical—and in the long run far less expensive—it is to call me in before a serious adverse event transpires, when it can be anticipated, avoided, and designed or defended against."

Examples of recent accidents include: an infant receiving a burn so severe that she ultimately lost an

arm; scissors flying out of a responding assistant's pocket and getting embedded in the technologist's head; and burns inside a patient's brain that resulted in a comatose state.

While severe, those accidents weren't fatal. But fatalities, while very uncommon, do occur. Perhaps the best known MRI tragedy is the death of 6-year-old Michael Colombini in 2001. He was taken to a New York area hospital for a routine MRI test after having a brain tumor removed. An oxygen tank, mistakenly taken into the room, was attracted by the machine's 10-ton magnet magnetic field, went airborne propelling through the air at 20 to 30



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Kopp ferromagnetic detection on doorway

What's really cost-effective?

As much as the industry wants to move in the right direction, current economic factors will undoubtedly get in the way of securing safe MRI environments across the board.

Expenditures that might normally get approved become harder to obtain when money is tight. This includes MRI safety devices, locks on doors, and educational opportunities for MRI technologists.

MRI safety device manufacturers, like the ones interviewed for this story, are well aware of their customers' concerns about money and have introduced ferromagnetic screeners at lower price points.

"Budgets are always a concern, but not implementing preventative measures can be more expensive when litigation, increased insurance premiums and professional reputation are considered if an accident does happen," says ETS Lindgren's Berg.

After involvement as an expert witness and consultant in more than 300 MRI safety-related legal cases to date, Kanal says that "prospective MR safety planning and implementation of basic MR safety policies is by far the safest and most cost effective outcome for all parties involved."

- Online: dotmed.com/dm19385

CMS keeps mum

Last October, the FDA held a public meeting on MRI safety. But before it took place, CMS and the FDA had been in talks about what quality rules should be applied across radiology. This included things specific to MRI.

"The ultimate goal was that CMS would release these interpretive guidelines by the end of the year last year," says Gilk.

But no one has heard anything since. Gilk speculates that the timing might not be right.

"My understanding is that there are a set of interpretive guidelines for radiology patient safety that are sitting on someone's desk at CMS that haven't been acted upon. I think the feds see this as the wrong time to implement any new regulations or interpretive guidelines. They want things to simmer down a little with the ACA [Affordable Care Act]. So if and when they will implement these is anyone's guess."



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To learn more about these systems and see other models not shown, please visit: www.dotmed.com/metaldetector

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