

Radiology Administrator's

Compliance & Reimbursement Insider

Safety audit

Prevent accidents and injuries in the MRI suite

In 2001, a boy died after a metal oxygen container was drawn into an MRI unit (by the MRI magnet's extreme power of attraction) at Westchester Community (NY) Medical Center. The ensuing seven-year case heads to trial this spring.

In March, The Joint Commission (formerly JCAHO) issued a Sentinel Event Alert identifying increased accident risks in the MRI environment. The increase is due to several factors, says **Tobias Gilk**, an architect at MRI-Planning in Kansas City, MO. And because the recent alert identifies these factors, now is the perfect time to conduct a safety audit of your MRI suite.

Safety risks stem from greater attractive forces found in newer magnet systems, more varied uses of MRI technology, and growing numbers of sedation or anesthesia orders for patients.

Although the capabilities of the MRI scanner are well-known, its inherent dangers are not, says Gilk.

"The most important step ... is to recognize that MRI safety is a larger-scale issue than originally appreciated," says **Kenneth Powers**, media relations manager for The Joint Commission. "You need to proactively educate your staff and patients regarding these issues."

Be prepared for increased regulation

MRI use has not had significant regulation in the past, says Gilk. There are no current building codes or standardized operational requirements for MRI facility safety, he notes.

But the regulatory landscape is changing. The new Sentinel Event Alert references standards set by the American Col-

Protect patients and staff members with this model safety policy on p. 3.

lege of Radiology's (ACR) *White Paper on MR Safety* published in 2004, and its recently issued replacement, the *ACR Guidance Document for Safe MR Practices: 2007*, notes Gilk. The ACR document could soon become the industry's standard of care, says Gilk, due to its reference in the March alert.

Site surveys will start to focus unprecedented levels of attention on MRI, so staff members should be prepared for questions such as:

- Do you adhere to the ACR recommendation for ferromagnetic detection (FMD) screening of patients?
- Does your cryogen venting system conform to the MRI manufacturer's current engineering standards?
- How recently have you physically inspected the cryogen venting/exhaust systems?
- Is each piece of clinical and incidental equipment appropriately labeled with the current American Society for Testing and Materials standards for MRI safety?

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Imaging Weekly

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HCPPro

Safety audit

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- What methods are in place for identifying the safety of patient implants?
- What are your provisions for physically screening patients, visitors, and objects entering the suite?
- When was your last safety drill?
- Does your facility adhere to the ACR standard four-zone safety screening principle?
- Is access to your MRI suite effectively controlled for unscreened patients and staff members?
- How do you handle medical gasses in the scanner room?

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Types of accidents that can occur

The most common types of accidents that occur in the MRI suite and their preventions, says Gilk, are:

- **Heating:** Burns can come from improper positioning of the patient during the exam or incorrect settings on the MRI for a particular scan, says Gilk.
 - **Corrective actions:** Provide insulation between the patient and the MRI, ensure proper body positioning, and review scan parameters.
- **Implants:** Active implants, such as pacemakers, and passive implants, such as aneurism clips, can present dangers to patients exposed to static (unchanging) or time-varying magnetic fields, says Gilk. Other implants, such as the leads (wires) used in cardiac devices or nerve stimulators, can become significantly heated as a result of the normal radio-frequency energies used during the MRI examination process.
 - **Corrective actions:** Carefully review the patient's medical record, conduct patient interviews, educate referring physicians, and scrutinize all identified surgical procedures, says Gilk.
- **Projectiles:** Despite the near-universal awareness of an MRI magnet's extreme power of attraction, patients, and even staff members, still bring objects containing steel into MRI rooms, where they are sucked into the MRI scanner. Often, these objects are small enough to be removed by hand, but larger objects require expensive service calls. However, even small objects, such as bobby pins and nail clippers, can cause injuries if they strike patients or staff members.
 - **Corrective actions.** Staff members must increase vigilance in screening patients and objects prior to entering the MRI. The use of contemporary FMD systems specifically designed to find projectile threats in the MRI suite is recommended by the Sentinel Event Alert, says Gilk. (For links to all three manufacturers of FMD systems, see www.MRI-Planning.com/vendor_links.html.)

Liability risks may increase

The Joint Commission Sentinel Event Alert increases the degree of foreseeability of many common accidents and incidents for all MRI facilities, says Gilk. Foreseeability is one legal indicator of the likelihood that an event will occur. It relates to the reasonable precautions your facility needs to take to prevent accidents and injuries, he says.

The presence of The Joint Commission Alert, coupled with best practice standards for patient safety, could increase an MRI facility's liability exposure in the event of an accident, particularly if it does not take appropriate preventive steps, says Gilk.

Conduct a safety audit

To conduct a safety audit, you'll first need to set patient safety as a top priority and become better educated on the specific nuances of MRI safety, says Powers.

The staff and leadership should then review, in detail, your current processes of MRI management and compare these practices with accepted standards of practice so that they can establish updated policies and procedures to improve the MRI environment.

Given the importance of MRI safety issues, it behooves you to conduct a safety audit, says Gilk. This allows you to identify, plan, and remediate any safety deficiency prior to your next Joint Commission or state survey.

Conducting a safety audit can also improve your facility's productivity, says Gilk. Lost throughput from poor practices could cost an MRI facility close to \$20 per minute in technical fees alone, he says. For example, if you stop a procedure because a patient hasn't removed hairpins, this wastes time. Even worse, costs associated with serious incidents start at more than \$20,000 in vendor engineering expenses, he says. Accidents involving equipment damage easily reach the six-figure range, he adds.

Thus the return on investment for safety improvements in the MRI suite can be achieved very quickly, Gilk says.

Poor operational practices and accumulated minor safety events can result in large annual lost revenue. Serious accidents might result in multimillion dollar lawsuits and years of litigation, Gilk says. Remember, the Westchester Community case is only now coming to court.

Of course, each facility is different, so each safety audit will focus on different risks and needs. You may either want to hire a professional or have in-house staff members conduct the audit. ■

Insider sources

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Model policy

Set policy to comply with MRI safety requirements

To ensure that your MRI suite operates safely, your facility should develop a policy to reflect the recommendations of your safety audit. The following policy is based on recommendations from The Joint Commission (formerly JCAHO) and is reprinted with permission. Review your policy with your attorney and safety auditor.

MRI safety policy

The facility shall follow the Joint Commission recommendations for reducing MRI accidents and injuries:

1. Restricted access. Access is restricted to all MRI sites, pursuant to the four-zone concept as defined in the

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MRI safety

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American College of Radiology *Guidance Document for Safe MR Practices: 2007*. The four-zone concept restricts access to the MRI scanner according to the following zones:

- Zone I: General public
- Zone II: Unscreened MRI patients
- Zone III: Screened MRI patients and personnel
- Zone IV: Screened MRI patients under constant direct supervision of trained MRI personnel

2. Patient screening. Trained personnel shall screen all nonemergent patients twice to provide separate opportunities for them to answer questions about the following items they may have on them:

- Metal objects
- Implanted devices
- Drug delivery patches
- Tattoos
- Electrically, magnetically, or mechanically activated devices

If the patient is unconscious or unable to answer questions, staff members must question the patient's family member or surrogate decision-maker. If this person is unsure, staff members must use other means to determine whether the patient has implants or other devices that could be negatively affected by the MRI scanner (e.g., looking for scars or deformities, using plain-film radiography or ferromagnetic detectors to assist in the screening process, etc.)

3. Patient medical history. The MRI technologist shall review the patient's complete and accurate medical history to ensure that the patient can be safely scanned. The technologist must check all implants against product

labeling or manufacturer literature specific to that implant or peer-reviewed published data regarding the device or implant in question. The director of radiology shall ensure that the technologist has ready access to this information.

4. Patient assistance. A specially trained staff person who is knowledgeable about the MRI environment shall accompany any patients, visitors, and other staff members who are not familiar with the MRI environment inside the MRI suite at all times.

5. Safety education. Annually, provide safety education to all medical and ancillary staff members who may be expected to accompany patients to the MRI suite and provide all staff members and patients and their families with appropriate materials (e.g., guidelines, brochures, posters) that explain the potential for accidents and adverse events in the MRI environment.

6. Burn precautions. Staff members shall take the following precautions to prevent patient burns:

- Ensure that no items (such as leads) are formed into a loop since magnetic induction can occur and cause burns
- If the patient's body touches the bore of the MRI scanner, use nonconductive foam padding to insulate the patient's skin and tissues
- Place a cold compress or ice pack on EKG leads, surgical staples, and tattoos that will be exposed to radiofrequency irradiation during the MRI process

7. Equipment safety. Staff members shall only use equipment (e.g., fire extinguishers, oxygen tanks, physiologic monitors, and aneurysm clips) tested and approved for use during MRI scans.

8. Critically ill patients. Staff members must plan for managing critically ill patients who require physiologic monitoring and continuous infusion of life-sustaining drugs while they are in the MRI suite. Never attempt to run a cardiopulmonary arrest code or resuscitation within the MRI magnet room itself.

9. Ear plugs. Provide all MRI patients with ear plugs. ■

Questions? Comments? Ideas?

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FDA panel set to examine benefits of CAD device use

An FDA panel conducted hearings March 4–5 about computer-aided detection systems (CAD). The FDA panel focused on CAD technology evaluation, says **John Smith, MD, JD**, a healthcare attorney and practicing radiologist with Hogan & Hartson in Washington, DC. Because CAD technology continues to evolve, the FDA sought input from the panel and the public in preparation for drafting guidance that will describe the types of data necessary to characterize CAD performance for future marketing applications. Currently, there is no projected date for the guidance; the FDA panel didn't reach any conclusions during the hearings. "Consensus is elusive right now," says Smith. Also, keep in mind that the panel is advisory, and the FDA could release guidance that does not comport with panel findings.

FDA CAD regulation is evolving

Today, there is increased scrutiny of CAD, says Smith. The agency's regulatory standard for evaluating these products may be changing, he says, but it's too early to draw conclusions. In part, this is because the FDA is broadening the scope of what it considers a CAD. The FDA panel represented the largest panel ever convened for such a hearing, Smith says.

The FDA has turned its attention to this technology based on recent positive and negative reviews. For example, on a positive note, study results of colon CAD systems are encouraging. But questions still remain regarding the effect of false-positive CAD detections on reader performance and variations in flat-polyp morphology. Members of the panel did agree on the benefits of CAD in aiding diagnosis. The FDA has approved some CAD technology in the past few years. For example:

- In 2004, the FDA approved the Kodak Mammography CAD ENGINE, which uses software that helps radiologists who read mammograms to highlight suspicious areas that might otherwise have been missed
- In 2007, the FDA approved the PET VCAR (Volume Computer Assisted Reading), a PET/CT software

package, to assist in diagnosis, staging, treatment planning, and monitoring treatment response

- In 2006, the FDA gave 510(k) clearance to Medisight ColonCAR 1.2.1, an image analysis software tool designed to be used with CT colonography (virtual colonoscopy) to assist radiologists in searching for and measuring potential colorectal polyps

Panel probes testing methods

The panel discussed issues about the general methodologies for CAD, including:

- How CAD devices are used in clinical decision-making
- How the devices are tested
- Ways to avoid or account for statistical bias
- The information needed to properly assess their safety and effectiveness

Following the general discussion, the panel discussed and made recommendations about future specific CAD devices for radiological mammogram images, chest x-rays, and CT images of the lungs or colon. These discussions also included how the different types of CAD devices are used and the published literature regarding these devices, with focus on:

- Testing issues
- Appropriate ground truth
- The relative roles of stand-alone and reader performance testing for the clinical evaluation of CAD devices
- Suggestions of other types of performance testing
- Enrichment of clinical study datasets
- Clinical study designs that account for different reader paradigms (e.g., radiologist reading images with CAD after an unaided reading vs. concurrent CAD reading)
- The effect of a device's indications for use on the clinical study design and device labeling ■

Insider source

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Licensing RACC credentials continues to grow

If you have not obtained your certified radiology administrator (CRA) credentials from the Radiology Administration Certification Commission (RACC), now is the time to do so. With changing government regulations, increasing technology, and decreasing reimbursement, adding RACC's credential offers you an opportunity to demonstrate your industry knowledge, says **Kathryn Keeler**, certification administrator at RACC for the CRA exam.

Benefits of certification

The CRA program is designed to elevate professional standards, enhance individual performance, and recognize administrators who demonstrate knowledge essential to the practice of medical imaging management, says Keeler. Here are the benefits of becoming certified:

- **Proves competency in changing field.** The exam, the preparation process, and the professional development requirements ensure that you are aware of the most recent developments in radiology, says Keeler.
- **Sets example for new staff members.** Since you expect new staff members to be certified, set a strong example and be certified yourself, says Keeler.
- **Brings positive publicity to your facility.** Whether you're director of a hospital radiology department or head of an imaging center, the certification offers you a chance to promote yourself. The RACC sends out a news release to specialty publications that you can adapt and send to local news agencies, forward on to referring physicians, and use in further marketing efforts.
- **Aids employment search.** More and more radiology groups and hospitals seek the CRA certification when hiring radiology administrators. And even if you're not seeking new employment you may need the credentials in the future.

About the test

The test consists of 185 questions. Approximately 30% of the questions are based on accumulated knowledge of

radiology procedures, 40% test application skills (problem solving), and 30% involve analysis. The test focuses on five domains, says Keeler:

- HR management
- Asset resource management
- Fiscal management
- Operations management
- Communication and information management

To maintain the credentials, CRAs must submit 36 continuing education credits and pay a \$150 renewal fee every three years. For more information about the CRA program and the RACC preparation material, visit www.crainfo.org and click on Study Reference Materials.

Application due dates: Applications for the November 2008 CRA exam will be due 45 days prior to the first day of the testing month. You can download the CRA application at www.crainfo.org. The cost of the CRA exam is \$300, plus a \$50 application fee to verify eligibility.

Eligibility requirements: To qualify to take the exam, candidates must meet experience, education, and other credentials requirements. Eligibility is based on a point system; seven points are needed to sit for the exam. RACC calculates eligibility based on the following:

- Education points are not cumulative for each level of education; only the point(s) for the highest education applies. For example, if you have a certificate and a bachelor's degree, you may only claim the three points earned for holding a bachelor's degree.
- Experience is defined as management, supervisory, or administrative experience in radiology or medical imaging with responsibility for three of the five domain areas of the exam. At least one point must be from education, or more than 10 years experience with no education points. ■

Insider source

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Ask the Insider**How to determine possible anti-kickback statute violations**

Consider: A radiology group furnishes services to a small critical access hospital on an exclusive basis. The hospital, via teleradiology, transmits digitized images of hospital patients to the radiology group for interpretation.

The radiology group interprets the images, prepares written reports, and bills third-party payers, including Medicare and Medicaid. It does not charge the hospital for the written reports.

The hospital certifies that, overall, its exclusive relationships are at fair market value in arm's-length transactions.

In this situation, does the radiology group's preparation of the written reports violate federal anti-kickback laws?

According to the Office of Inspector General's (OIG) Advisory Opinion 07-19, delivered January 3, the above arrangement could have potentially generated prohibited remuneration under the anti-kickback statute if there were intent to induce or reward referrals of federal healthcare program business, says **Michael F. Schaff, Esq.**, a healthcare attorney at Wilentz, Goldman & Spitzer, P.A., in Woodbridge, NJ.

If a situation is absent this intent (such as the above situation), the OIG would not impose sanctions, according to the opinion. (For a copy of this opinion, see <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-19C.pdf>.)

Keep in mind that whether the OIG ascertains fraud will be dependent on all the facts in an arrangement, says Schaff.

The OIG explained how an arrangement could violate the federal anti-kickback statute: The hospital receives something of value from the radiology group (free written reports) in return for referring Medicare patients to the group for radiology services.

Arrangements between hospitals and radiologists or other hospital-based physicians "may implicate the

anti-kickback statute if the hospital solicits or receives something of value—or the physicians offer or pay something of value—for access to the hospital's federal health care program business," the OIG noted.

However, according to the OIG, in this case, written reports the group provides to hospital Medicare patients

The OIG cautions that other hospitals and radiology groups should not rely on this opinion. Talk to your attorney about the facts of your case.

do not constitute remuneration and, so, cannot implicate the anti-kickback statute. According to the OIG (regarding this case):

- **CMS rules obligate radiologists to prepare reports for Medicare reimbursement.** CMS will not pay a radiology group for its interpretation unless the radiologist prepares a written report for inclusion in patients' medical records. Thus preparation of the report "is part of the covered professional service that is reimbursed to the radiologist under Medicare Part B, and the radiologist is obligated to prepare a written report for such patients in order to receive Medicare reimbursement," the OIG stated.
- **The radiology group would receive double payment if reimbursed.** The free reports are not remuneration to the hospital. The hospital, a critical access hospital, must maintain the written report within its clinical records system, but is not obligated to prepare a written report for the group's radiology services. The radiology group's preparation of the written report at its own cost is proper, according to the applicable payment rules. In fact, the OIG notes that if the hospital reimbursed the radiology group for costs incurred for preparing the written report, the group would receive double payment

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Violations

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for the reports, that is, a payment from the hospital and a payment from Medicare.

➤ **The radiology group is not relieving the hospital of financial obligation.** The OIG also noted that by preparing a written report for inclusion within the hospital's records, the radiology group is not relieving the hospital of any financial cost the hospital is otherwise obligated to incur for Medicare patients. But if the radiologist was performing a service that a hospital was obligated to perform, the outcome could be different.

Keep in mind that the OIG would not reach the same definitive conclusion with respect to whether reports prepared for non-Medicare patients by the group and provided to the hospital constitute remuneration, says Schaff. But the OIG stated that the arrangement poses a low risk under the anti-kickback law.

First, the OIG noted that preparation of the reports at issue appears to be a reasonable and limited service that directly relates to the professional radiology services provided by the group to the hospital.

Second, the arrangement is unlikely to result in over-utilization because the group's ability to "generate additional Medicare Part B billings to recoup the costs it incurs for the written reports for non-Medicare beneficiaries provided to the hospital is limited by the nature of its hospital-based specialty," according to the OIG.

In conclusion, the OIG stated: "In the circumstances presented here, the group's preparation of such reports without charge appears to be a reasonable and limited service that directly relates to the professional radiology services provided by the group under its exclusive relationship with the hospital."

Tip: There are caveats to this opinion. Keep in mind that each scenario is different, says Schaff. For example, the opinion may not apply to another situation, he says. The OIG cautions that other hospitals and radiology groups should not rely on this opinion. Talk to your attorney about the facts of your case. ■

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