Auditing and Evaluating MRI Facility Safety Programs

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MRI Safety is a Serious Problem

- Colombini "Incident" Fatal Accident
- Patient burns are frequent
- Frequent "near misses" with ferrous objects





Medical Physicists Have an Emerging Role in MRI Safety

 ACR MRI Accreditation Program Requirements (28-OCT-2013):

"The annual medical physicist/MR scientist performance evaluation must also include an assessment of the MRI safety program (signage, access control, screening procedures and cryogen safety) as well as an inspection of the physical and mechanical integrity of the system."

 (Joint Commission 2015 update mentions MR safety program but doesn't require the physicist to be involved)





Medical Physicists Have an Emerging Role in MRI Safety

- ACR medical physicist forms posted 17-APR-2015:
- Physicist must verify that written MRI safety policy addresses a range of items
- ACR Criteria for Compliance:
 - Written policies are present and readily available to facility staff
 - Written policies are reviewed and updated on a regular basis
 - Facility has appropriate MR safety warning signage and methods of controlled access
 - (Physicist: check Yes/No/NA to each of these)
 - Physicist: Check overall "Pass" or "Fail" for safety program assessment





Important questions:

- What is the proper role of the medical physicist related to the other members of the clinical MR team?
- How can MP adequately evaluate MR safety?
- What standards and resources should we use?
- What is the responsibility and liability for the medical physicist in performing such evaluations?





The Approach:

- 1. Achieve *compliance* with applicable requirements
- 2. Provide *value* in medical physicist participation





One Proposed Model:

ACR Guidance Document on MR Safe Practices is <u>THE</u> standard for evaluation:

- 1. Use approach of radiation safety/RAM audits
- 2. Review documents and observe routine facility operations
- 3. Interview technologists

Report: State observations and limitations





Before you start...

- MUST familiarize yourself with 2013 ACR Guidance Document on MR Safe Practices
- J. Magn. Res. Img.
- Free download from ACR website

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501-530 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

Expert Panel on MR Safety: Emanuel Kanal, MD,^{1*} A. James Barkovich, MD,² Charlotte Bell, MD,³ James P. Borgstede, MD,⁴ William G. Bradley Jr, MD, PhD,⁵ Jerry W. Froelich, MD,⁶ J. Rod Gimbel, MD,⁷ John W. Gosbee, MD,⁸ Ellisa Kuhni-Kaminski, RT,¹ Paul A. Larson, MD,⁹ James W. Lester Jr, MD,¹⁰ John Nyenhuis, PhD,¹¹ Daniel Joe Schaefer, PhD,¹² Elizabeth A. Sebek, RN, BSN,¹ Jeffrey Weinreb, MD,¹³ Bruce L. Wilkoff, MD,¹⁴ Terry O. Woods, PhD,¹⁵ Leonard Lucey, JD,¹⁶ and Dina Hernandez, BSRT¹⁶

Because there are many potential risks in the MR environment and reports of adverse incidents involving patients, equipment and personnel, the need for a guidance document on MR safe practices emerged. Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. As the MR industry changes the document is reviewed, modified and updated. The most recent version will reflect these changes.

Key Words: MR safety; MR; MR safe practices J. Magn. Reson. Imaging 2013;37:501–530. © 2013 Wiley Periodicals, Inc.

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THERE ARE POTENTIAL risks in the MR environment, not only for the patient (1,2) but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. (3-6). There have been reports in the medical literature and print-media detailing Magnetic Resonance Imaging (MRI) adverse incidents involving patients, equipment and personnel that spotlighted the need for a safety review by an expert panel. To this end, the American College of Radiology originally formed the Blue Ribbon Panel on MR Safety. First constituted in 2001, the panel was charged with reviewing existing MR safe practices and guidelines (5-8) and issuing new ones as appropriate for MR examinations. Published initially in 2002 (4), the ACR MR Safe Practice Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. These were subsequently reviewed and updated in May of 2004 (3). After reviewing substantial feedback

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http://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety

Visit the Department

- Look at simple, obvious things with fresh eyes
- Think like RCA or a "conspirator"
 - How could this situation become unsafe?





Policies and Procedures









Documentation review

ACR Accreditation Checklist for Medical Physicist

The site's written MRI safety policy addresses the following:	Yes/No/NA
Designated MR medical director	
Site access restrictions (MR Zones)	
Documented MR Safety education/training for all personnel	
Patient and non-MR personnel screening	
Pediatric patients	
Magnet quench	
Cryogen safety	
Acoustic noise	
Pregnant patients and staff	
Contrast agent safety	
Sedations	
Thermal burns	
Emergency code procedures	
Device and object screening	
Designation of MR Safe/MR conditional status	
Reporting of MR safety incidents or adverse incidents	
Patient communication	
Infection control and medical waste	

Checklist based on ACR Guidance Document sections

\checkmark	Esta	stablish, Implement, and Maintain Current MRI Safety Policies & Procedures				
	\checkmark	Apply to all magnets				
	1	Reviewed and updated as needed for changes in site/practice				
	1	MR Medical Director appointed and given adequate authority				
	\checkmark	Adverse event reporting procedures in place.				
\checkmark	4-z(one safety areas established				
	\checkmark	Access to Zone 4 is restricted to screened and trained personnel				
	1	Access to Zone 3 is appropriately restricted				
1	Que	ench policies & procedures established				
NA	Lev	Level 1 safety training for Level 1MR personnel established				
	NA	Repeated annually				
	NA	List of trained individuals maintained				
	NA	Trained individuals have appropriate access to MR areas				
	Level 2 safety training for Level 2 MR personnel established					
•	1	Repeated annually				
	1	List of trained individuals maintained				
	\checkmark	Trained individuals have appropriate access to MR areas				
1	Screening of patients					
	\checkmark	Appropriate forms				
	1	Appropriate procedures				
	1	Appropriate policies				





FRVF

Policies and Procedures Review

Compliance

- Review of documents
- Does each required policy exist?
- Does MRI medical director review, sign off regularly?

Value-Added

- Talk to the staff
- Are they aware of the policies?
- Observe the staff at work
- Do actual activities match the written procedures?





Access Control

- Facility access control per ACR 4-zone design
- Critical: restricted access entering <u>Zone 3</u> to prevent unauthorized persons or objects from getting near the magnet room
 - <u>Stopping them at the door from Zone 3 to Zone 4 is too</u> <u>late – NEAR MISS HIT!!!</u>
- Are lockable doors unlocked?
- Are doors routinely left open which are supposed to be closed?





Access Control

Compliance

- Zones identified via floor plan
- Zone information posted

Value-Added

- Arrive 15 minutes early (especially for your first time)
 - In-house MP: Drop into department unannounced
- See if you could get into a magnet room without anyone stopping you





Signage ("Posting/Labeling")

- Signs posted in Zone III / Zone 3 identifying the area?
- Signs posted on entrances to Zone IV / Zone 4 magnet areas clearly identifying the hazard?
- Do signs clearly communicate:
 - A hazard?
 - Restricted access?
 - Magnet is always on?





Zone Signage









Pay Attention!











MRI Room Signage









MRI Room Signage











Ferrous items/equipment kept in Zone 3 and 4? ("Posting/Labeling")

- Safety category labeled on items?
- Unsafe items controlled/supervised by trained personnel?
 - And/or tethered?







Training

- All personnel working in MRI have had safety training?
- When was their last refresher?
- Do they remember taking it?

- Records of training available?
- Training materials available?
- Medical Director approval, sign-off, and periodic review of training materials and requirements?





Screening

Compliance

- Screening policy and forms exist
- ALL individuals entering MRI area screened
 - Not just patients!

Value-Added

- Observe screening of patient or visitor
- Is the form used?
- Is the policy/procedure followed?
- What support is available for unusual findings?





Clinical operational issues:

- Policies and procedures need to address and staff must know – how to deal with:
 - Patient and staff pregnancy
 - Safety specific to pediatric patients
 - Medical emergencies in MRI patients
 - Quench, fire, and other environmental emergencies
 - Safety of emergency first responders
 - Patients with implants (stick around for this session!)
 - Hearing protection
 - Claustrophobia
 - (For full list see ACR Guidance Document)





Incident reporting and monitoring

Compliance

 A policy and mechanism exists to collect and review data on adverse events in MRI

Value-Added

- Ask if staff know when, how, and to whom to report
- Ask to see prior incident reports (do they exist?)
- Ask what was done as result of past reports/reviews.





Evaluation Report

DO:

- Review all findings with lead/chief MRI technologist before preparing report
- Address report to MRI Medical Director, who has ultimate authority, responsibility for MR safety program
- Describe in detail *observations* INCLUDING areas you feel may be outside your area of expertise
- If warranted, make *recommendations* using references





Evaluation Report

DO:

- Include the ACR accreditation review checklist (if ACR-accredited facility)
- State that observation and document review cannot identify and prevent all possible safety issues
- Identify individuals who were observed, participated in interviews, reviewed findings, or provided information





Evaluation Report

DO NOT:

- State concretely that the overall program is "Safe" or "Unsafe"
- Make *recommendations* about subjects you feel are outside your area of knowledge or expertise





Physicist's Responsibility

- Fulfill ACR accreditation requirements (complete the form)
- Provide all services established in contract or employment/job description
- Accurately report observed facts
- Make only those recommendations within scope of expertise
- Identify limitations





MRI Safety Liability

- Liability for the MRI safety program rests with the facility and the MRI Medical Director
- Medical Physicist evaluates program as MRMD's "eyes and ears"
- Similar to auditor / RSO relationship in RAM/nuclear medicine
- (DISCLAIMER: not legal advice)





Role of "MR Safety Officer"

- Emerging role, not yet fully defined; *usually*:
- Day-to-day presence in department (senior RT)
- *Reports to* MR Medical Director
- Oversees day to day safety
- *NOT* comprehensive authority of a Radiation Safety Officer

Think: Medical Director : MRSO = RSO : NM Lead Tech





Review

- Medical physicists are required to evaluate the MR safety program for ACR-accredited facilities
- Physicist's MR safety program audit can simply review policies and procedures
- By observing department activities and practices, physicist can help MR Medical Director uncover improvement opportunities
- Physicists should not hesitate to help
 - Liability can be limited
 - Expertise will develop





SAMS Questions

At which access control point is it most important to provide a physical barrier to prevent unauthorized persons or objects from entering the magnet?

2%	1.	Entering Zone 1
14%	2.	Passing from Zone 1 into Zone 2
45%	3.	Passing from Zone 2 into Zone 3
39%	4.	Passing from Zone 3 into Zone 4
0%	5.	Exiting Zone 4

At which access control point is it most important to provide a physical barrier to prevent unauthorized persons or objects from entering the magnet?

3. Passing from Zone 2 into Zone 3

References:

1. "ACR Guidance Document on MR Safe Practices", J. Magn. Reson. Imaging 2013;37:501-530 Which authority requires the medical physicist/MRI scientist to conduct an evaluation of a facility's MRI safety program?

- 1. American College of Radiology (ACR)
- 2. Joint Commission
- Centers for Medicare & Medicaid Services (CMS)
- 4. International Electrotechnical Commission (IEC)
- 5. Food and Drug Administration (FDA)



Which authority requires the medical physicist/MRI scientist to conduct an evaluation of a facility's MRI safety program?

1. American College of Radiology (ACR)

References:

1. "ACR MRI Accreditation Program Requirements", http://www.acr.org/Quality-Safety/Accreditation/MRI, version dated 28-0CT-2013. Who is responsible for the content and implementation of a facility's MRI safety program?

- ^{2%} 1. Medical Physicist or MRI Scientist
- ²[%] 2. MR Safety Officer
- ^{0%} 3. Lead or Chief MRI Technologist
- 95% 4. MR Medical Director
- ^{0%} 5. MRI Manager or Supervisor

Who is responsible for the content and implementation of a facility's MRI safety program?

4. MRI Medical Director

References:

1. "ACR Guidance Document on MR Safe Practices", J. Magn. Reson. Imaging 2013;37:501-530

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