Super Conductor or Attractive Nuisance? Real Talk about MR Safety…With No Spin

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Why Are We Here?
2003: Wheelchair and Oxygen tank
2003: Floor Buffer machine
2007: IV Pole
2011: Laundry Hamper
2013: IV Pole
Michael Colombini (2001)

Ask yourself: Why WON’T this happen here?
In the Headlines:

• “Lynbrook police: Man injured, arrested after gun goes off in MRI machine” (Long Island Herald, June 20, 2018)
• “Man Gets Sucked Into MRI Machine At Mumbai Hospital, Killed, 2 Arrested” (NDTV, January 29, 2018)

Ask yourself: Why WON’T this happen here?
Framework of Safety

• Hazards exist in the MR environment
• Controlling the hazards requires knowing:
  – The environment
  – The interactions that cause the hazards
  – Control over what enters the MR environment

• Prevent all personnel and items from encountering hazard conditions
Physical Hazards

• Strong static field gradient:
  – Missile effect
  – Ferromagnetic objects
  – Displacement of patient implants/devices
  – Lenz’s Law forces on moving nonferrous metal objects
Physical Hazards

- Static field increases rapidly near scanner ("steep")
- Active shielding
- Force on iron object:
  \[ \sim 250 \times F_g \]
- 1 lb. tool = 250 lb. attractive force

\[
\frac{F_{\text{trans}}}{F_g} = C \, B_s |\nabla B_o|, (\text{saturated ferrimagnetic objects})
\]

Physical Hazards

• Strong / fast time-varying magnetic field
  – Eddy currents → nerve stimulation
  – Acoustic noise (114-131 dBA)
    • 60 dBA: typical conversation
    • 85 dBA: permanent damage after 8 hour exposure
    • 100 dBA: permanent damage after 15 minutes’ exposure
    • 120 dBA: immediate permanent damage

http://dangerousdecibels.org/education/information-center/noise-induced-hearing-loss/
Acoustic Hazard
How Loud?

- Early MRI systems = 84-93 dBA
- “Fast” scanning = 103 – 113 dBA
- Echo Planar 1.5T = 115 dBA
- Echo Planar 3T = 126 – 131 dBA

- Hearing protection is REQUIRED for all patients and anyone else in the room during scanning

Physical Hazards

• High power RF fields:
  – Higher power $\rightarrow$ improved SNR
  – SAR: Specific Absorption Rate (W/kg)
  – RF SAR $\alpha f^2$
  – Fast scanning increases duty cycle, increasing SAR
  – Heating of tissue $\rightarrow$ burns
  – Metallic objects, loops, patient contact with bore/shroud during scan increase hazard
Burns

Physical Hazards

• Cryogens
  – Liquefied helium; heating $\rightarrow$ rapid expansion
  – Explosion
  – Flash freezing
  – Displacement of oxygen $\rightarrow$ asphyxiation
Cryogen-related hazards

March 6, 2015: “3 injured, 1 critically, when an MRI scanner exploded at a veterinary hospital in Paramus.”
Cryogen Safety

- Helium expands 1000X volume at quench
- Proper installation of quench vent pipes
- Regular *inspection* of quench vents
- Restrict access for planned quench:
  - Magnet room and surroundings
  - Quench pipe exit location
Quench Vent Inspections

- Facilities department
- MRI vendor
- Ensure line open
- Safe venting area
- Installed & terminated correctly
The legal and regulatory backdrop…

RULES & REGULATIONS
“Gold standard”: ACR White Paper

- Policies & Procedures
- Facility Layout
- Access Control
- Training
- Labeling
- Screening
- Contrast Media
- Implanted Devices

No regulations in most jurisdictions (at this time)
Agency Guidelines:

• FDA: regulates MRI scanner and implant device manufacturers
  – Tracks adverse events, issues warnings

• ACR: requires accredited sites to have safety programs
  – Convenes “blue ribbon panel”, MR Safe Practices Guidance publication
New JC MRI Safety Requirements: 2015 Diagnostic Imaging Update

• New or revised Elements of Performance for:
  – EC.02.01.01 (Safety and Security Risk Management)
  – PI.01.01.01 (Data Collection for Performance Monitoring)
JC MRI Safety Requirements

- Requires hospital to address specific hazards as part of documented MR safety program
- Requires restricted/controlled access to Zone 3 and Zone 4
- Requires control/supervision of Zone 3 and Zone 4 by MR-safety-trained personnel
- Requires signage clearly identifying Zone 3 and Zone 4 areas, “Magnet Is Always On”
The bottom line:

• NO outside agency can inspect and tell you if you’re “doing OK”
• NO outside agency can definitively tell you which rules or guidelines to follow
• Bad things WILL happen (eventually)
• WHEN bad things happen, lawsuits WILL follow
• NOT following the ACR guidelines will require painful explanations…
Access Control defines Zones

- **Zone IV**: THE MAGNET
  - No physical barrier between the magnet and the rest of the zone
- **Zone III**: Only 1 physical barrier between the magnet and the zone
- **Zone II**: Physical barrier controls access into Zone III.
- **Zone I**: “Outside world”, physically distinct from Zone II in some way.
Policies & Procedures define who & what may enter the Zones

- Must be in writing
- Under supervision of Medical Director of MRI
- Must be reviewed periodically, updated when appropriate
Access Control: Persons

• To enter Zone III or Zone IV:
  – Level 1 MR Personnel
  – Level 2 MR Personnel
  – *Screened* patients and visitors
MR Personnel

Level 1
• Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III
• (e.g., MRI department office staff, patient aides.)

Level 2
• Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients
• (e.g., MRI technologists, radiologists, radiology department nursing staff.)
Non-MR Personnel

• Patients, visitors or facility staff who do not meet the criteria of level 1 or level 2 MR personnel will be referred to as non-MR personnel.

• Specifically, non-MR personnel will refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.
Zone Access

Level 1
• May enter Zone III and Zone IV
• May accompany and supervise non-MR personnel in Zone III only

Level 2
• Full access to all Zones
• Only individuals who may accompany and supervise non-MR personnel in Zone IV
Screening

• Same for all individuals entering Zone IV
• Done in Zone II – *before* entering Zone III
• Done by 2 separate individuals who are MR personnel
Labeling & Access Control: Objects

- **MR Safe**: Completely nonmetallic
- **MR Conditional**: can be safe in MR environment under certain known conditions
- **MR Unsafe**: demonstrated attractive forces in magnetic field

Object Access

• Ferrous / MRI Unsafe items kept out of Zone III when not absolutely necessary

• MRI Unsafe items must be under constant surveillance of dedicated MR personnel when brought into Zone III or Zone IV
There is NO SUCH THING as “MRI Compatible”!!!!!!
ACR Key Points about Implant Management:

• Each site must name an MR medical director
• MR medical director is responsible for establishing MR safety policies & procedures
• Site administration is responsible for ensuring P&P’s are followed by all personnel

Ref: 2013 ACR Guidance Document on MR Safe Practices
ACR Key Points about Implant Management:

- All adverse events, MR safety events, and “near misses” must be reported to the medical director within 24 hours.
- All adverse events and MR safety events must be reported to FDA Medwatch.

Ref: 2013 ACR Guidance Document on MR Safe Practices
ACR Key Points about Implant Management:

- “Level 2 personnel” designates individuals with extensive knowledge and training in MR safety (typically to the level of an MR technologist)

Ref: 2013 ACR Guidance Document on MR Safe Practices
ACR Key Points about Implant Management:

• Implants and foreign bodies revealed by the screening process **must be positively identified** before bringing the patient into Zone III (usually the control room area).

Ref: 2013 ACR Guidance Document on MR Safe Practices
ACR Key Points about Implant Management:

• **Final determination** to scan/not to scan any given patient is to be made by:
  – the level 2 designated attending MR radiologist;
  – the MR medical director;
  – or specifically designated level 2 MR personnel following criteria for acceptability predetermined by the medical director.

Ref: 2013 ACR Guidance Document on MR Safe Practices
Questions you should be asking yourself right about now:

• What is my hospital’s policy?
• Am I level 2 personnel?
• Do I know who the MR medical director is for my facility?
• How should I make this decision if I am called?
• Where can I get information to help with these decisions?
Summary - MRI Conditional Implant Safety Assessments:

- Specific to patient and study ordered
- Specific to implant/device
- Based on implant manufacturer’s documentation
- Made by attending radiologist trained as Level 2 MR personnel
  - Or other designated Level 2 personnel for pre-approved implants and scenarios
- Documented in patient’s medical record
Burn Prevention

• “Afterward, the patient said his legs had been pressed together before he entered the MRI machine.”

Mandel et al. “A second-degree burn after MRI.” Cleveland Clinic Journal Of Medicine 84(5); May 2017
Patient Preparation and Positioning
Gowning

• You would not believe what patients stash in their underwear…
Other important issues

• Medication and sedation
• Contrast media safety and reactions
• Medical emergencies inside the scanner
Emergencies in MR Area

• Emergency situations are managed by the MRI staff
  – Medical—MRI personnel move patient from the magnet room to a safe zone for medical treatment.
  – Fire or electrical failure—MRI personnel will move patient from magnet room to safe zone and lock doors to magnet

• Nobody else may run in to help!!!
• 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 \textit{compliance} with applicable requirements
2. Provide \textit{value} in medical physicist participation
One Proposed Model:

ACR Guidance Document on MR Safe Practices is **THE 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
Visit the Department

• Look at simple, obvious things with fresh eyes

• Think like Root Cause Analysis or a “conspirator”
  – How could this situation become unsafe?
Policies and Procedures

STANDARD OPERATING
POLICIES &
PROCEDURES

MRI SAFETY

I ❤️ POLICIES
AND PROCEDURES
Documentation review

ACR Accreditation Checklist for Medical Physicist

<table>
<thead>
<tr>
<th>The site’s written MRI safety policy addresses the following:</th>
<th>Yes/No/NA</th>
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<tbody>
<tr>
<td>Designated MR medical director</td>
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<tr>
<td>Site access restrictions (MR Zones)</td>
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<tr>
<td>Documented MR Safety education/training for all personnel</td>
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<td>Patient and non-MR personnel screening</td>
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<td>Pediatric patients</td>
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<td>Magnet quench</td>
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<td>Oxygen safety</td>
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<td>Acoustic noise</td>
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<td>Pregnant patients and staff</td>
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<td>Contrast agent safety</td>
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<td>Sedations</td>
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<td>Thermal burns</td>
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<td>Emergency code procedures</td>
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<td>Device and object screening</td>
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<td>Designation of MR Safe/MR conditional status</td>
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<td>Reporting of MR safety incidents or adverse incidents</td>
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<td>Patient communication</td>
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<td>Infection control and medical waste</td>
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Custom Checklist based on ACR Guidance Document sections

- Establish, implement, and maintain current MRI safety policies & procedures
- Apply to all magnets
- Reviewed and updated as needed for changes in site/practice
- MRI Medical Director appointed and given adequate authority
- Adverse event reporting procedures in place
- 4-zone safety areas established
- Access to Zone 4 is restricted to screened and trained personnel
- Access to Zone 3 is appropriately restricted
- Quench policies & procedures established
- NA Safety training for Level 1 MR 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
  - Repeated annually
  - List of trained individuals maintained
  - Trained individuals have appropriate access to MR areas
- Screening of patients
  - Appropriate forms
  - Appropriate procedures
  - Adherence policies
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 Zone 3 to prevent unauthorized persons or objects from getting near the magnet room
  – Stopping them at the door from Zone 3 to Zone 4 is too late – NEAR MISS HIT!!!

• 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/thing stopping you
Also: Watch for Open Doors!
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?
In Zone 3: Pay Attention!

CAUTION
MRI
ZONE III
Screened MRI Patients and Personnel Only

=)

DANGER
MACHINE GUN
FIRING RANGE
KEEP OUT
MRI Room Signage

DANGER!
Restricted Area
Powerful Magnet Always On
No Unauthorized Entry
Patients Must Be Accompanied By Authorized Personnel

MAGNETOM

[Additional signage with warning icons and text about prohibited items in MRI environment]
MR Unsafe 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
Summary

• MRI risks include death and serious injury
• Medical physics support is needed to manage
• Radiation safety framework, approaches can be applied to MR safety programs