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

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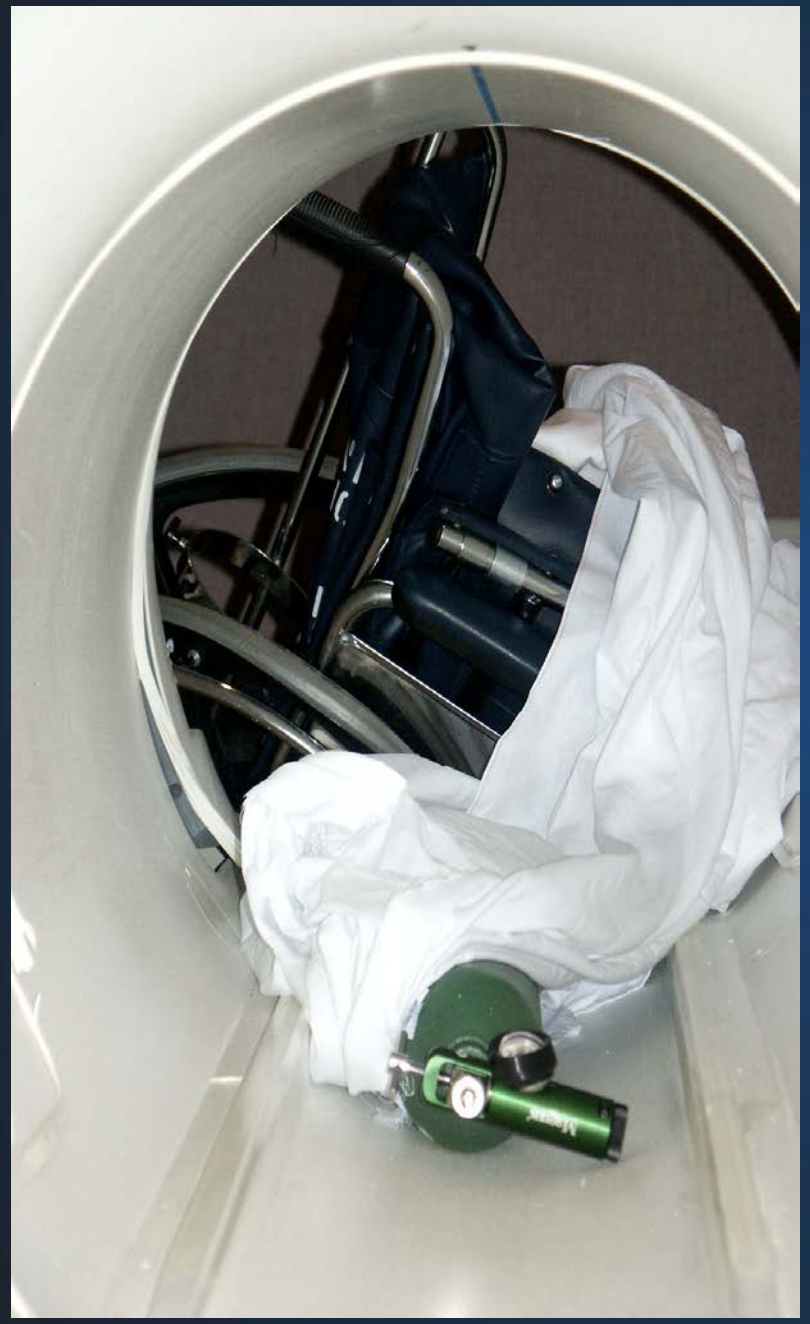
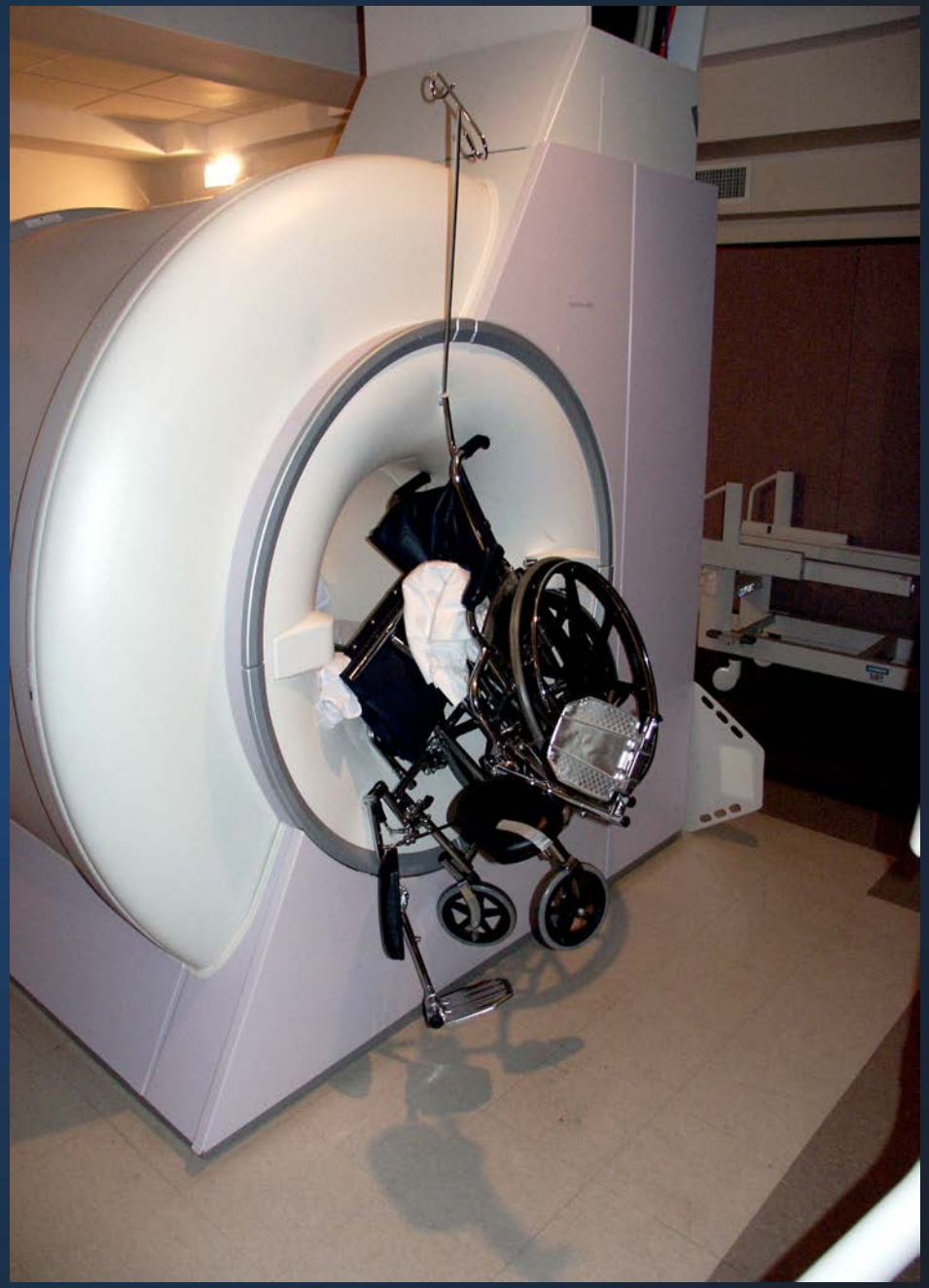
# Why Are We Here?

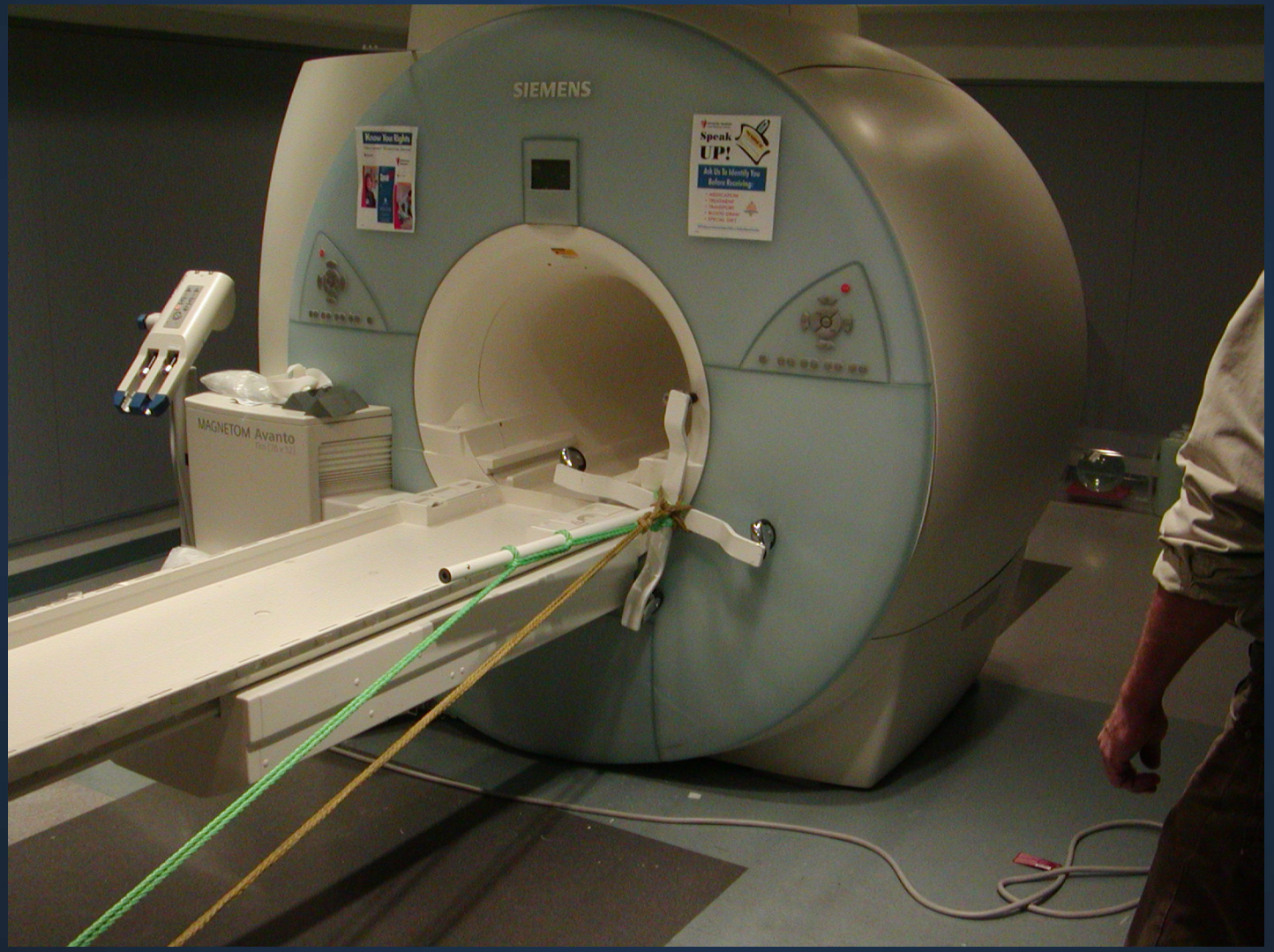
# 2003: Wheelchair and Oxygen tank



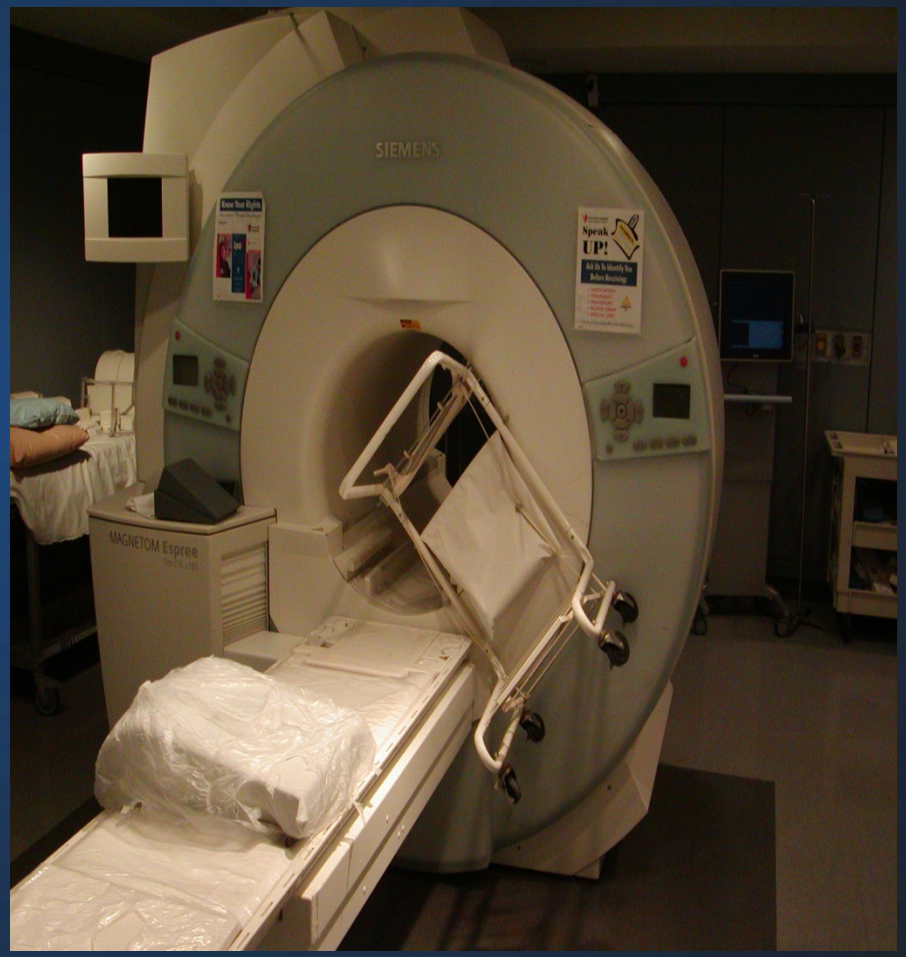


# 2003: Floor Buffer machine

# 2007: IV Pole



# 2011: Laundry Hamper

# 2013:  IV Pole


CAUTION
STOP
CLEAN
MOBILE NURSING

# 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

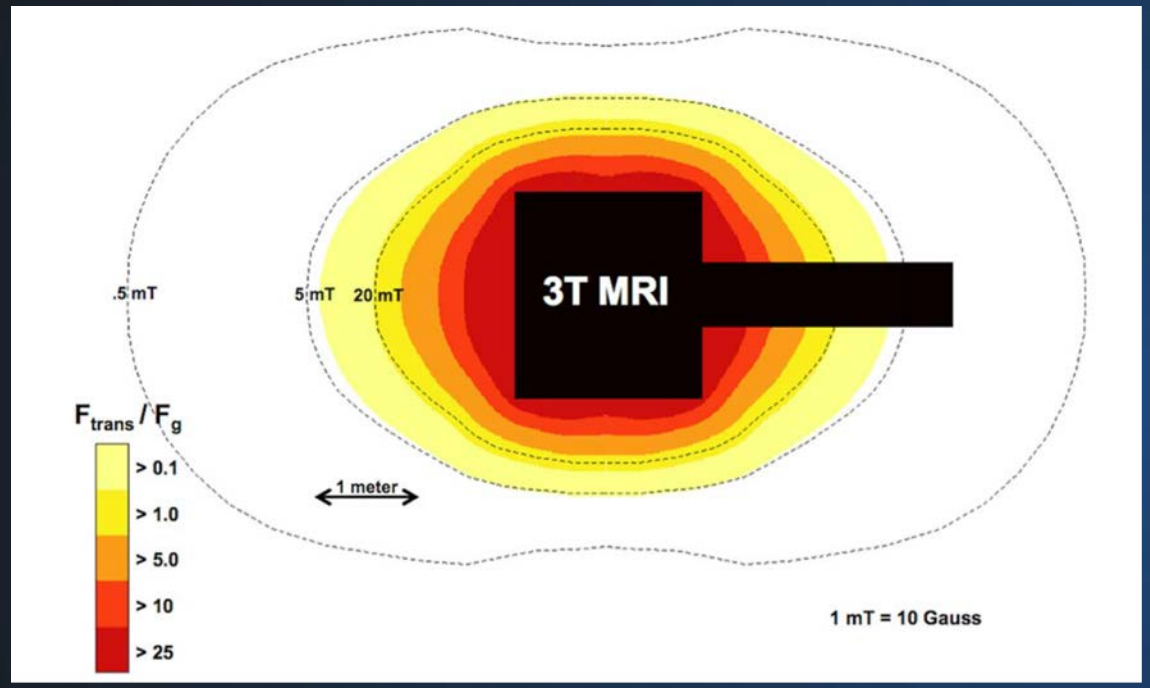
- Hazards exist in the MR environment
- Controlling the hazards requires knowing:
  - The environment
  - The interactions that cause the hazards
  - Control over what enters the MR environment

- *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




$$\frac{F_{trans}}{F_g} = C\ B_s|\nabla B_o|, (saturated\ ferrmagnetic\ objects)$$

- Static field increases rapidly near scanner ("steep")
- Active shielding

- Force on iron object: ~ 250 x $F_g$
- 1 lb. tool = 250 lb. attractive force

Panych & Madore, "The Physics of MRI Safety." J. Magn. Reson. Imaging 2018;47:28–43

# 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

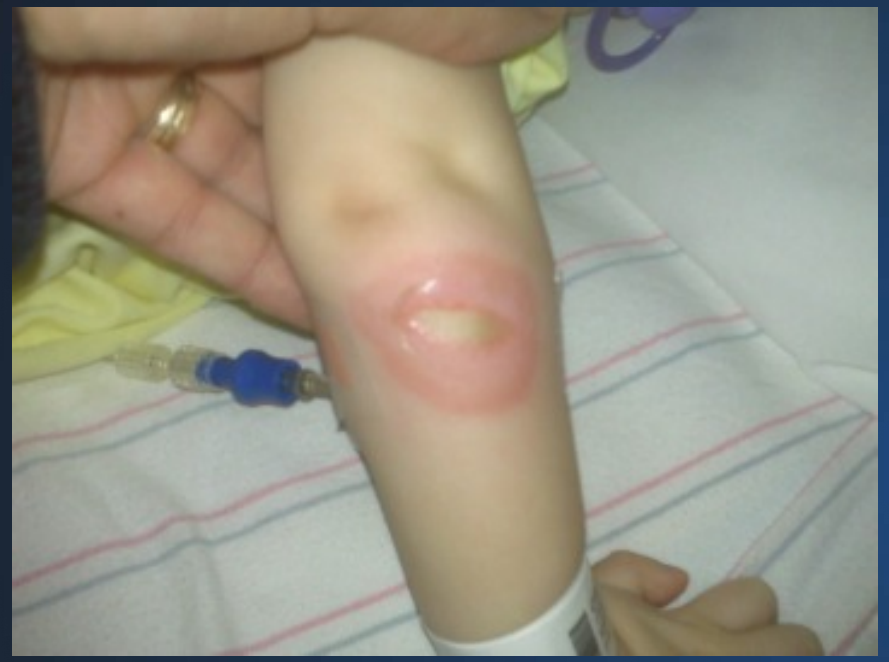
- Hearing protection is REQUIRED for all patients and anyone else in the room during scanning

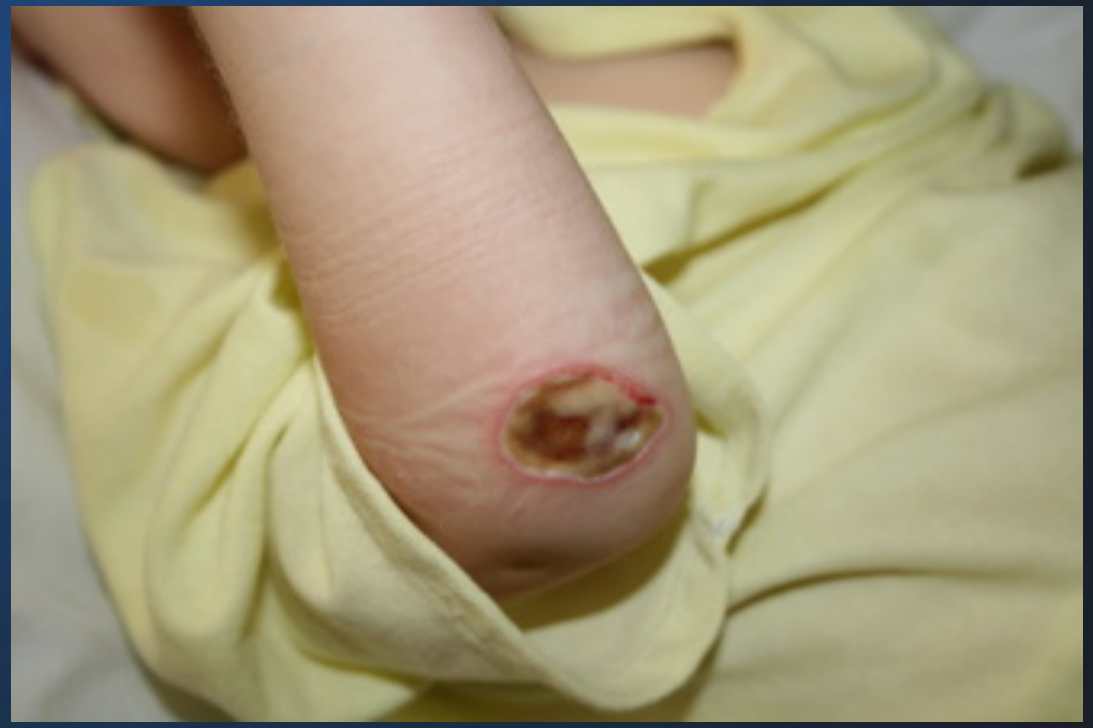
http://www.mrisafety.com/SafetyInfov.asp?SafetyInfoID=252

# Physical Hazards

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

# Burns





http://www.prayfornoah.com/noahs-mri-burn.html

# Physical Hazards

- Cryogens
  - Liquefied helium; heating → rapid expansion
  - Explosion
  - Flash freezing
  - Displacement of oxygen → asphyxiation

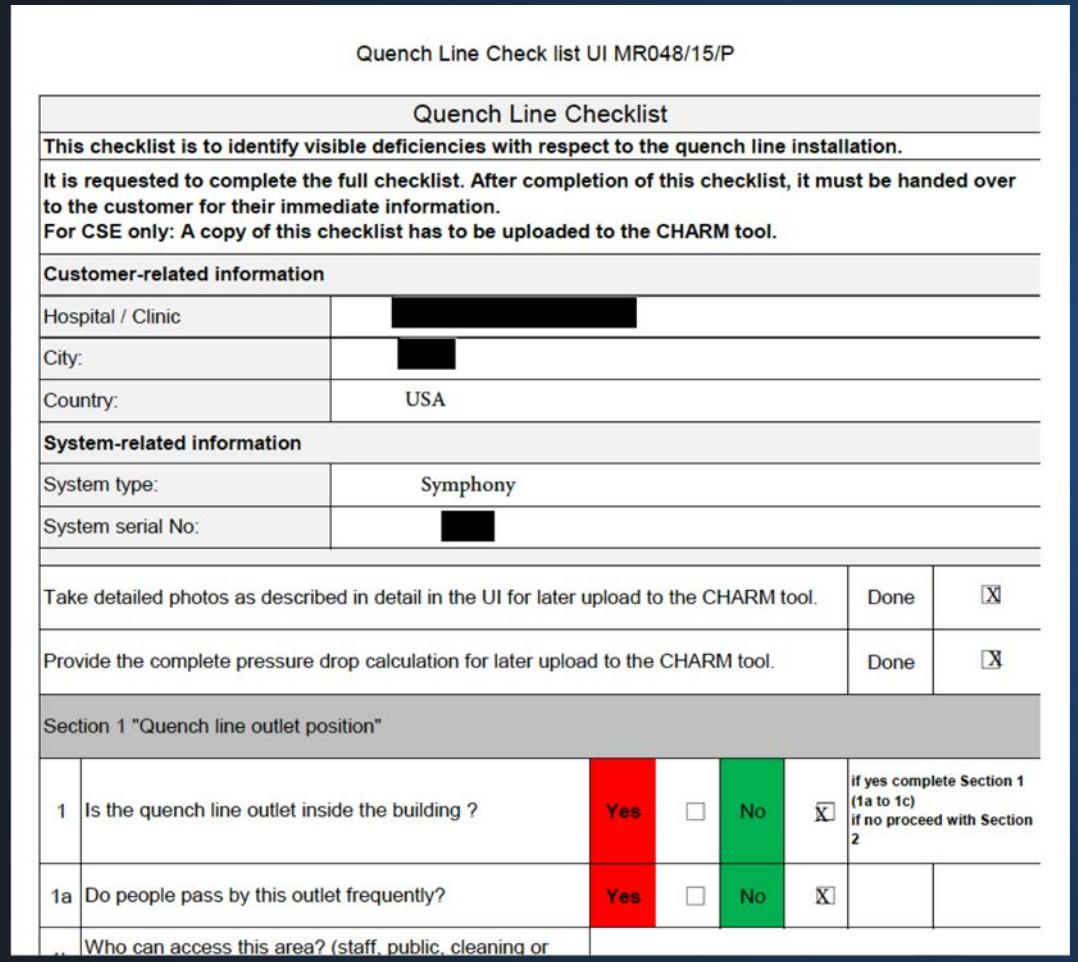
# Cryogen-related hazards


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



Quench Line Check list UI MR048/15/P

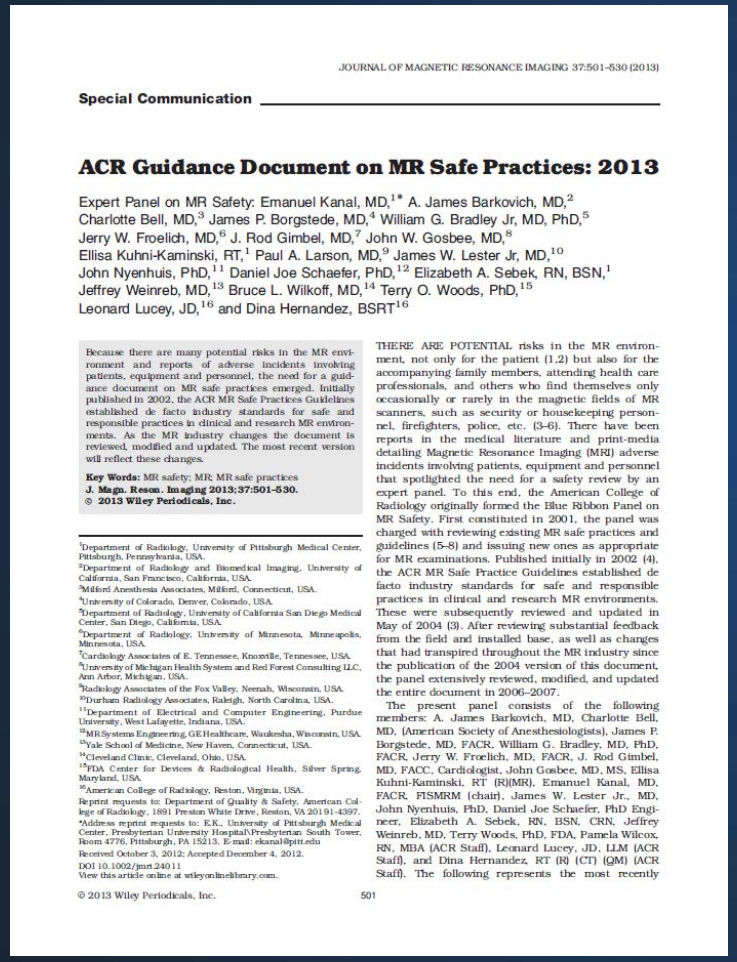
| Quench Line Checklist | | | | | | |
|---|---|---|---|---|---|---|
| **This checklist is to identify visible deficiencies with respect to the quench line installation.** | | | | | | |
| **It is requested to complete the full checklist. After completion of this checklist, it must be handed over to the customer for their immediate information.<br>For CSE only: A copy of this checklist has to be uploaded to the CHARM tool.** | | | | | | |
| **Customer-related information** | | | | | | |
| Hospital / Clinic | [redacted] | | | | | |
| City: | [redacted] | | | | | |
| Country: | USA | | | | | |
| **System-related information** | | | | | | |
| System type: | Symphony | | | | | |
| System serial No: | [redacted] | | | | | |
| Take detailed photos as described in detail in the UI for later upload to the CHARM tool. | | | | | Done | X |
| Provide the complete pressure drop calculation for later upload to the CHARM tool. | | | | | Done | X |
| Section 1 "Quench line outlet position" | | | | | | |
| 1 | Is the quench line outlet inside the building ? | Yes | ☐ | No | X | if yes complete Section 1 (1a to 1c)<br>if no proceed with Section 2 |
| 1a | Do people pass by this outlet frequently? | Yes | ☐ | No | X | |
| .. | Who can access this area? (staff, public, cleaning or | | | | | |

- 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



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, BSRT[16]

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
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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 from the field and installed base, as well as changes that had transpired throughout the MR industry since the publication of the 2004 version of this document, the panel extensively reviewed, modified, and updated the entire document in 2006–2007.

The present panel consists of the following members: A. James Barkovich, MD, Charlotte Bell, MD, (American Society of Anesthesiologists), James P. Borgstede, MD, FACR, William G. Bradley, MD, PhD, FACR, Jerry W. Froelich, MD, FACR, J. Rod Gimbel, MD, FACC, Cardiologist, John Gosbee, MD, MS, Ellisa Kuhni-Kaminski, RT (R)(MR), Emanuel Kanal, MD, FACR, FISMRM (chair), James W. Lester Jr., MD, John Nyenhuis, PhD, Daniel Joe Schaefer, PhD Engineer, Elizabeth A. Sebek, RN, BSN, CRN, Jeffrey Weinreb, MD, Terry Woods, PhD, FDA, Pamela Wilcox, RN, MBA (ACR Staff), Leonard Lucey, JD, LLM (ACR Staff), and Dina Hernandez, RT (R) (CT) (QM) (ACR Staff). The following represents the most recently




- 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

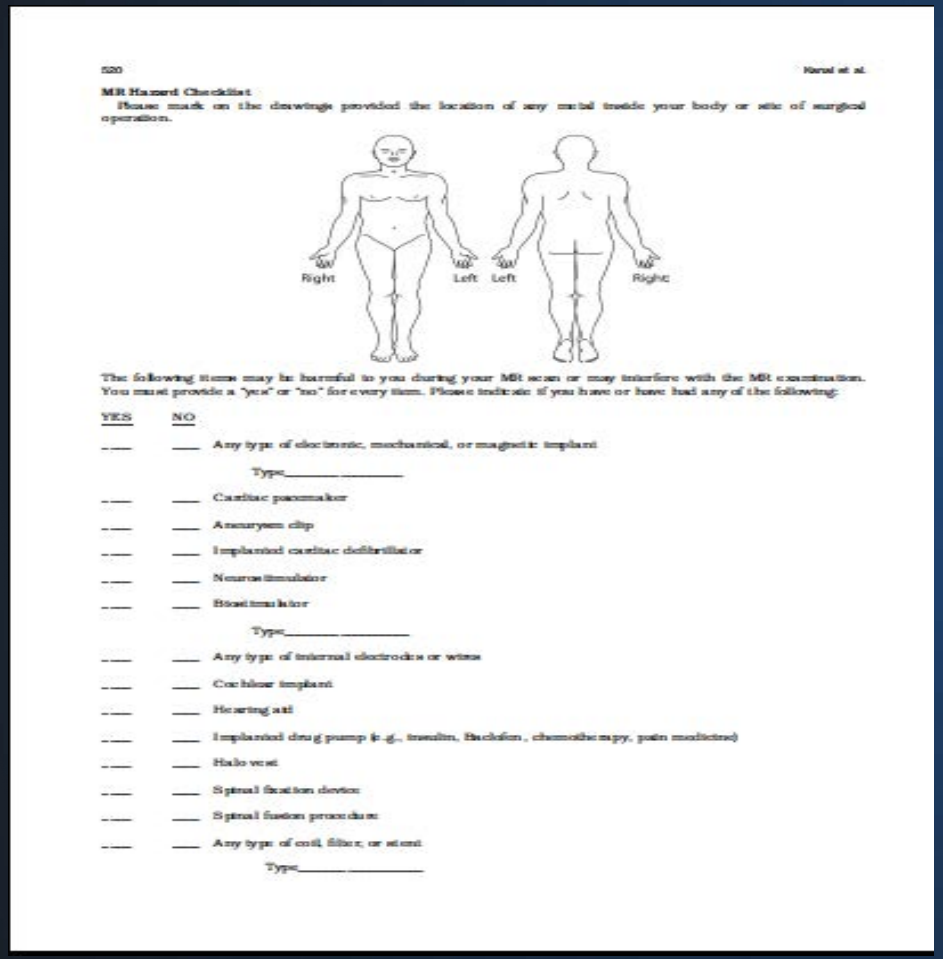
**Level 1**

- 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



520 Nanul et al.

**MR Hazard Checklist**

Please mark on the drawings provided the location of any metal inside your body or site of surgical operation.



The following items may be harmful to you during your MR scan or may interfere with the MR examination. You must provide a "yes" or "no" for every item. Please indicate if you have or have had any of the following:

| YES | NO | |
|---|---|---|
| ___ | ___ | Any type of electronic, mechanical, or magnetic implant |
| | | Type:_____ |
| ___ | ___ | Cardiac pacemaker |
| ___ | ___ | Aneurysm clip |
| ___ | ___ | Implanted cardiac defibrillator |
| ___ | ___ | Neurostimulator |
| ___ | ___ | Biostimulator |
| | | Type:_____ |
| ___ | ___ | Any type of internal electrodes or wires |
| ___ | ___ | Cochlear implant |
| ___ | ___ | Hearing aid |
| ___ | ___ | Implanted drug pump (e.g., insulin, Baclofen, chemotherapy, pain medicine) |
| ___ | ___ | Halo vest |
| ___ | ___ | Spinal fixation device |
| ___ | ___ | Spinal fusion procedure |
| ___ | ___ | Any type of coil, filter, or stent |
| | | Type:_____ |

- Same for all individuals entering Zone IV
- Done in Zone II – *before* entering Zone III
- Done by 2 <u>separate individuals</u> who are MR personnel

# Labeling & Access Control: Objects


*ACR Guidance Document on MR Safe Practices: 2013*

- 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

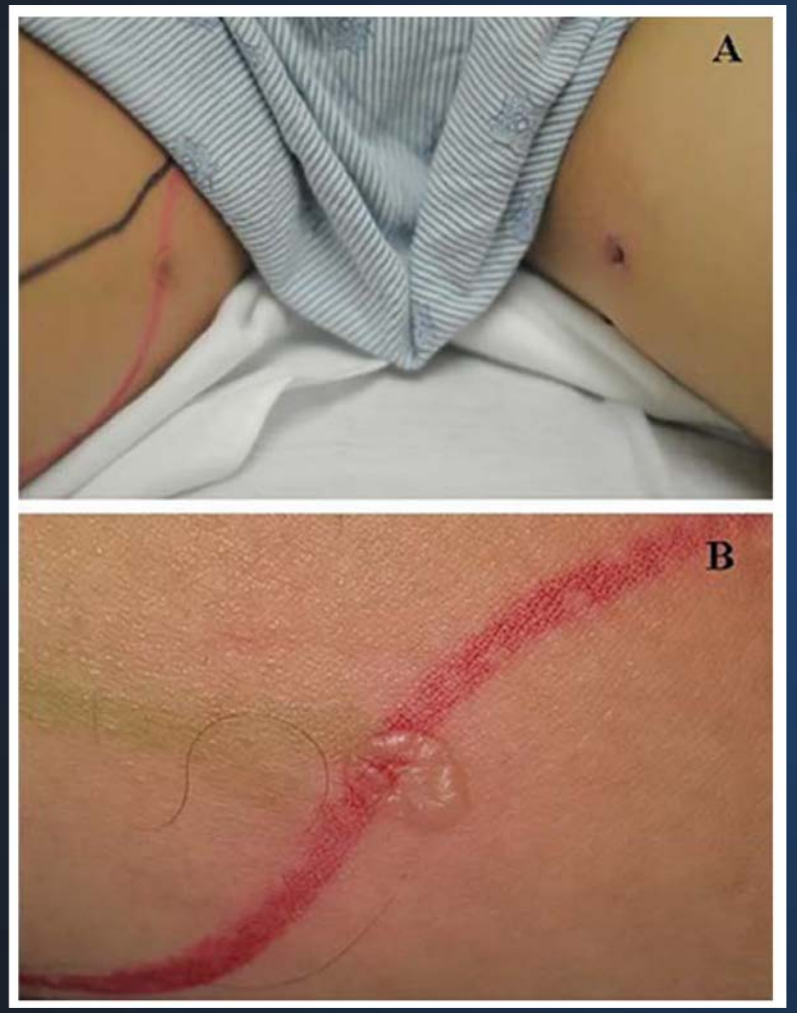
# Questions you should be asking yourself right about now:

- 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

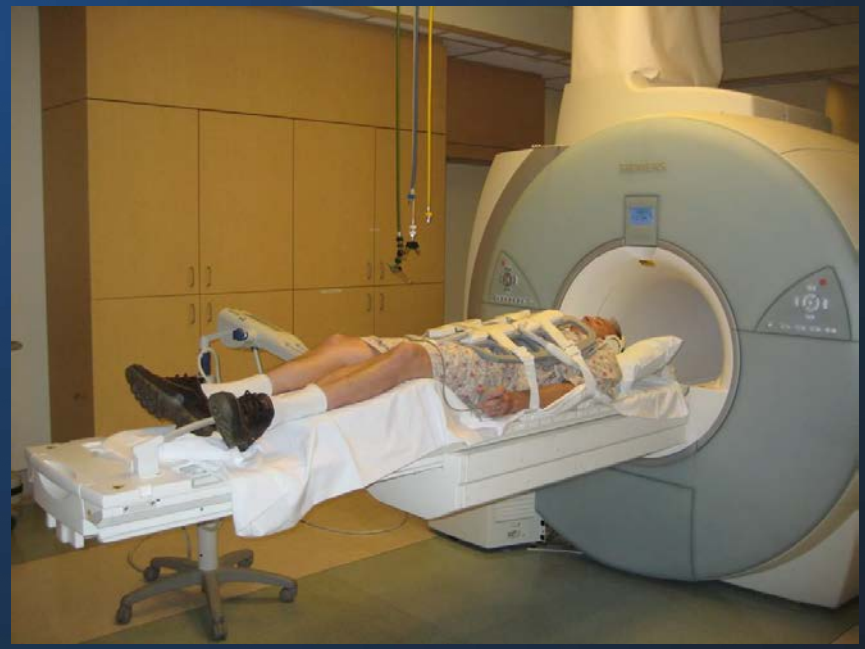
# Burn Prevention




- “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!!!

# 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 THE standard for evaluation:

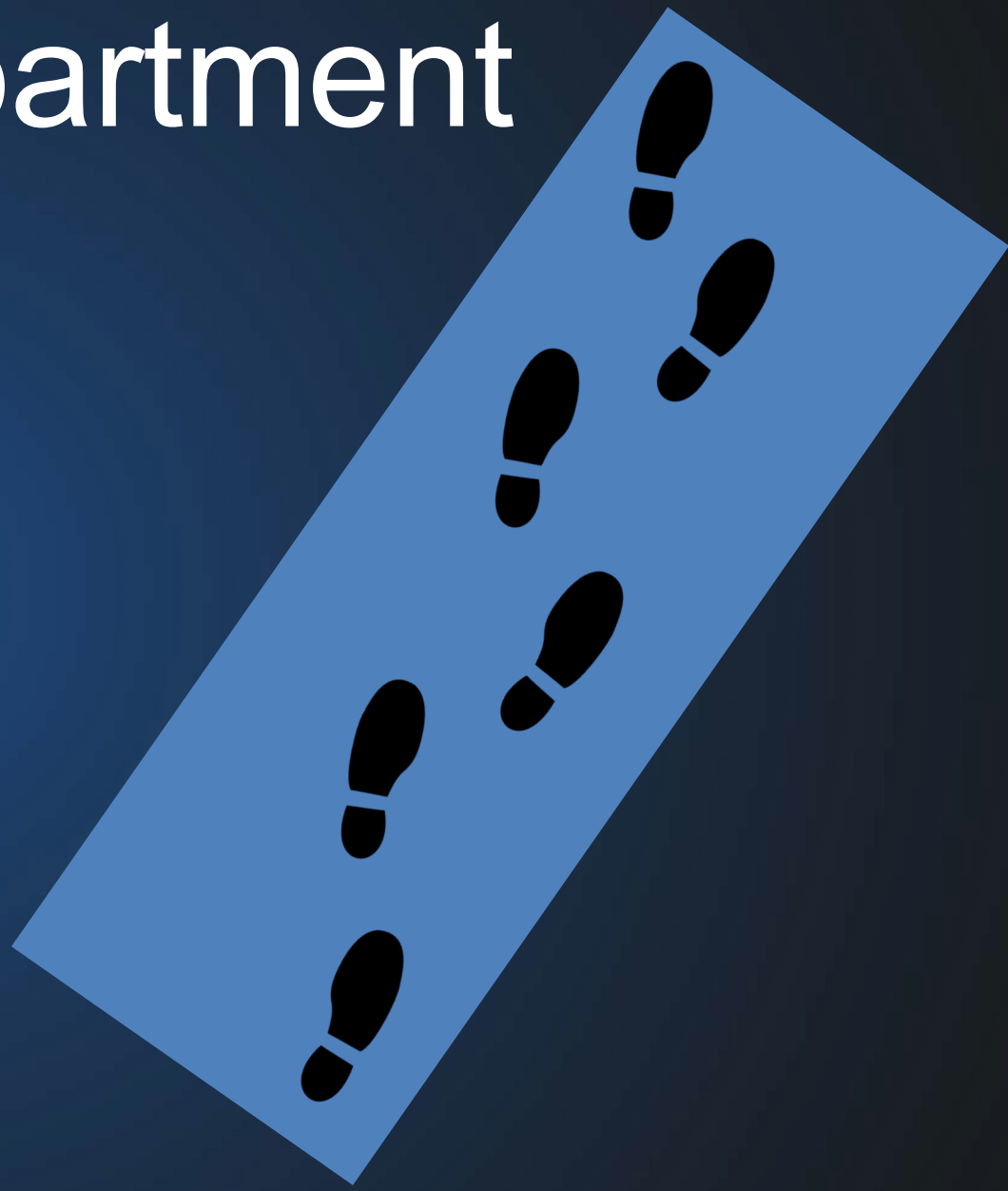
1. Use approach of radiation safety/RAM audits
2. Review documents and observe routine facility operations
3. Interview technologists

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


# 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 | |

## 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
  - ✓ MR 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** Level 1 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
  - ✓ Appropriate 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


# Zone Signage?

# In Zone 3: Pay Attention!


=

# MRI Room Signage


# MRI Room Signage


# 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