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Model MRI Safety Program

The Mayo Clinic Experience

Heidi A. Edmonson PhD

AAPM Spring Clinical Meeting
Clinical MRI Safety
Saturday, March 6, 2015: 2-4 PM

Disclosures:

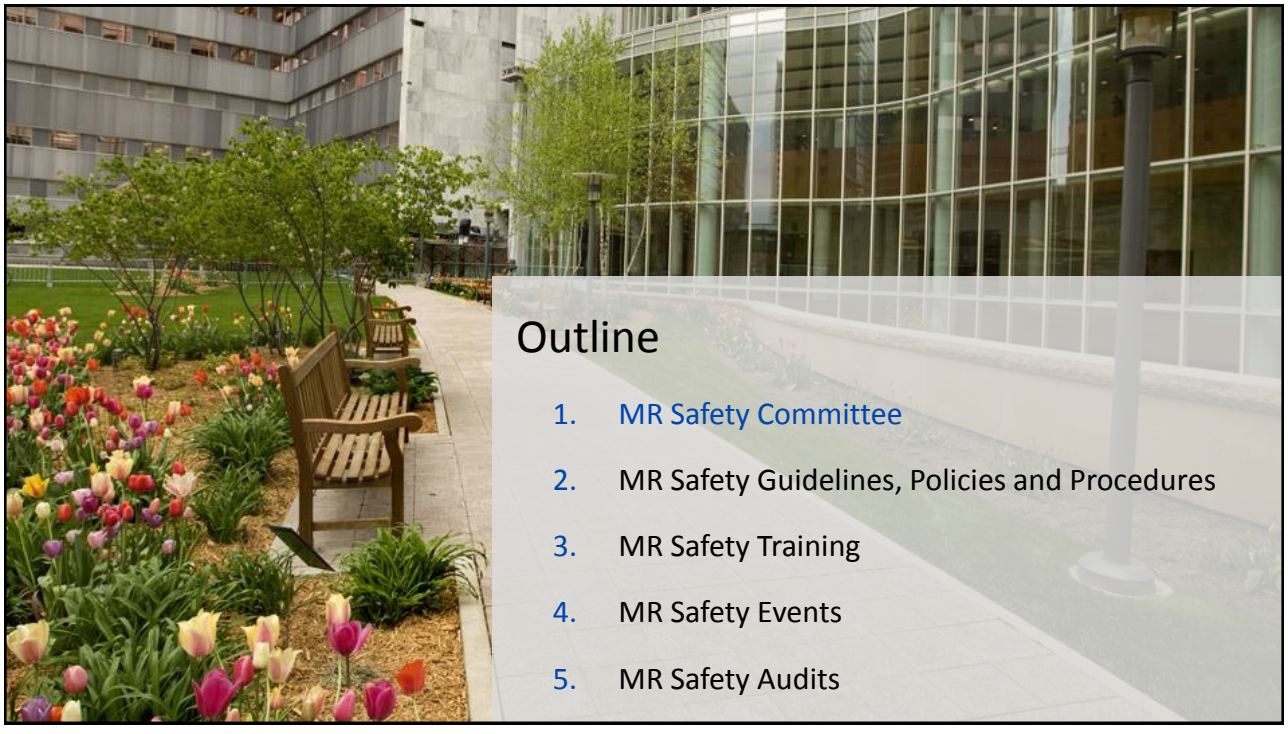
Nothing to disclose

Disclaimer:

Implantable medical devices described within this presentation are for illustrative purposes only and do not constitute endorsement

Acknowledgement:

Robert Watson MD PhD
Mayo Clinic Rochester - MR Medical Director
Chair - MR Safety Committee, Neuroradiology



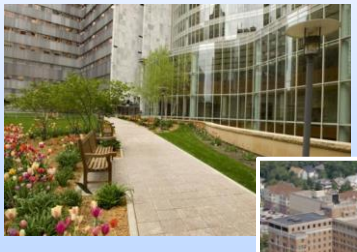
Outline

1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
4. MR Safety Events
5. MR Safety Audits

Mayo Midwest Radiology

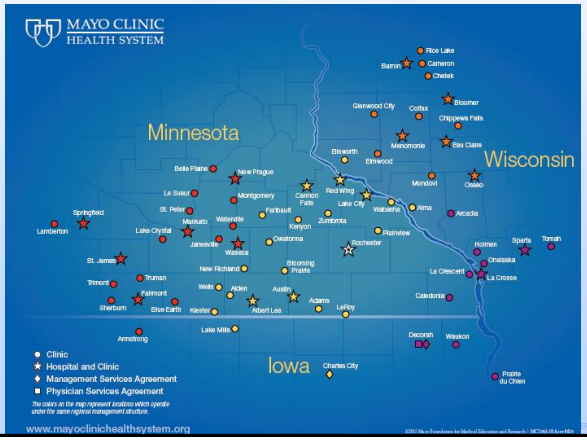
Large, multispecialty clinic

Mayo Clinic & Mayo Clinic Hospital
in Rochester, MN



Associated satellite providers

Mayo Clinic Health System

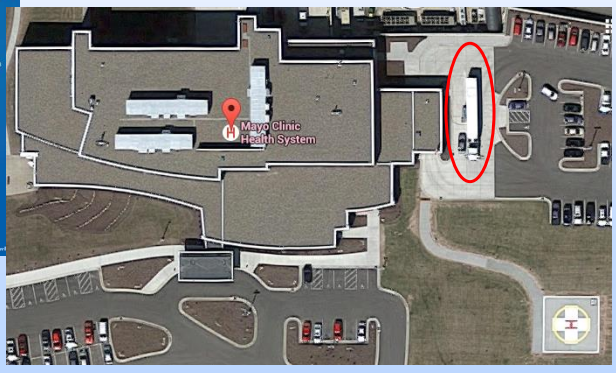


Mayo Clinic Health System

21 sites offering MRI

11 Fixed Diagnostic MR Scanners

3 Mobile Units visit 11 sites

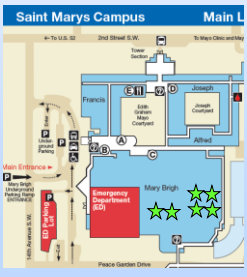


Mayo Clinic in Rochester, MN

31 Diagnostic MR Scanners

1 PET-MR

3 Research MR Scanners



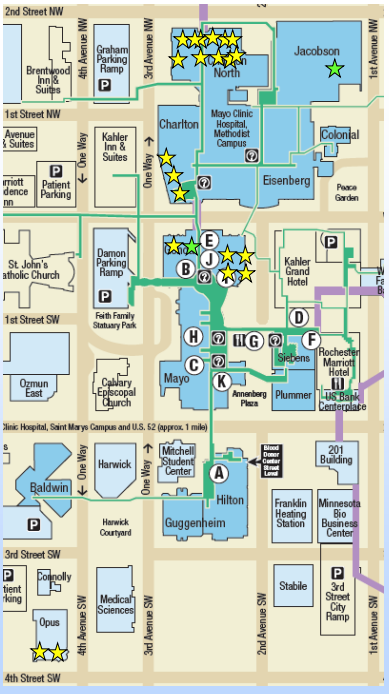
10 Blocks

Hospital Anesthesia ☆

Intraoperative MR/OR

MR-Guided:

- Cryo/laser ablation
- Focused Ultrasound
- Radiation Treatment Planning
- Breast Biopsy
- Liver/Prostate Biopsy



Mayo Clinic in Rochester, MN

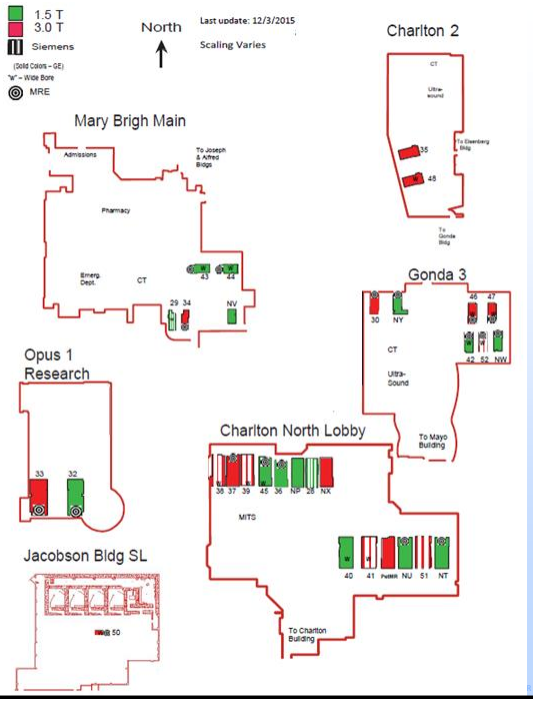
1.5 T	3.0 T
5 GE HDxt	1 GE HDxt
1 GE 450	4 GE 750
6 GE 450w	6 GE 750w
1 SMS Avanto	1 GE PETMR
1 SMS Espree	2 SMS Verio
	2 SMS Skyra
	1 SMS Prisma

A TYPICAL DAY

Number of procedures typically conducted across Mayo Clinic:

- Breast Imaging: 922
- CT: 1,852
- Diagnostic Radiography: 3,344
- Interventional: 152
- MR: 731
- Nuclear Medicine: 297
- Ultrasound: 968

~320 MRI Exams per day in Rochester



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Mayo Rochester Radiology

MRI Practice

Radiologists

- 99 staff that can be assigned to MRI
- 25 assigned to interpret MRI each day

Technologists

- 97 MRI Technologists
- Required to obtain advanced RT(R)(MR) certification

Physicists

- 7 MRI Diagnostic Physicists
- 2 assigned to clinical support on most days

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Clinical Assignments for MRI Physicists

Interventional procedures

- MR Guided Focused Ultrasound
  - Uterine fibroid
  - Prostate
  - Bone
- MR Guided Cryoablation
- MR Guided Laser Ablation

Patients with Active Implanted Devices

Pacemakers/ICDs and MR-conditional Pacemakers

- 1-2 per day M-Thurs
- ~1000 pacemaker patients now scanned

Deep Brain Stimulators

- ~50 diagnostic patients in 2015
- Increase with new MR-conditional labeling for body coil Tx (released Dec, 2015)

Auditory Brainstem Implants and Cochlear Implants

- ~45 patients in 2015

Intracranial Pressure Monitors

- Rare

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MRI / Cardiac Pacemaker practice

- Now nearly 3,000,000 pacemaker patients in US
- At least 5,000,000 worldwide
- At least 50% will have clinical reason for MRI during lifetime of the device
- Increasing number published studies supporting

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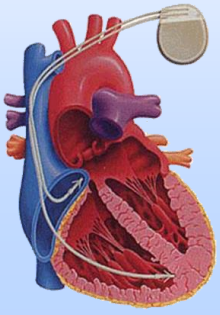
JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

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]



Unlabeled Cardiac Devices: Amongst the patients with MR unsafe CIEDs, many have conditions that would ordinarily be assessed with MRI. While many can have their medical conditions managed without MRI, in some instances, specific clinical circumstances may present compelling reasons for undergoing an MR examination (39). Should MRI be considered, it should be evaluated on a case-by-case and site-by-site basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.

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Factors permitting more confident MRI scanning in Pacemaker patients at Mayo today

- RF and gradient effects on the sensing circuits are minimized by shielding & newer engineering of the device
- Wire/lead tip heating is minimized by MRI scanner RF power limits, choice of coils (under operator control)
- Close monitoring during MRI by cardiologist, physicist & specially trained personnel

Mayo MRI / PM practice
Pre MRI

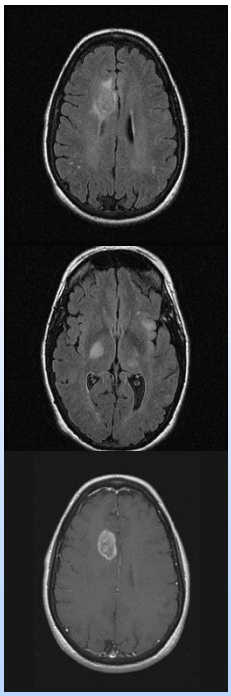
- Radiologist triages case
  - Alternative approach?
  - Consult with physicist –
    SAR, coils, monitoring equipment
- All pts have Cardiology pre-MRI evaluation
  - Checks that referring MD has note on chart attesting to medical necessity of MRI
- Formerly excluded pts → pacer dependent…

Mayo MRI / PM practice
Pre MRI

- All cases done at same hospital-based 1.5T sites
- **Cardiologist / PM nurse & Physicist** present throughout
  - Pre-MRI Pacemaker interrogation and reprogramming as necessary
  - Monitors throughout case
    - ECG, pulse ox
    - Code cart immediately available
    - Anesthesia aware of case
  - Post-MRI pt evaluation, pacemaker interrogation and reprogramming

MRI / PM practice
MRI

- **Radiologist**
  - Obtain informed consent
  - Sequence prescription / SAR constraints (with physicist)
  - Check CXR if pacing nurse detects irregularities
  - Verify that complete exam performed before patient off scanner
  - Document procedure in dictation



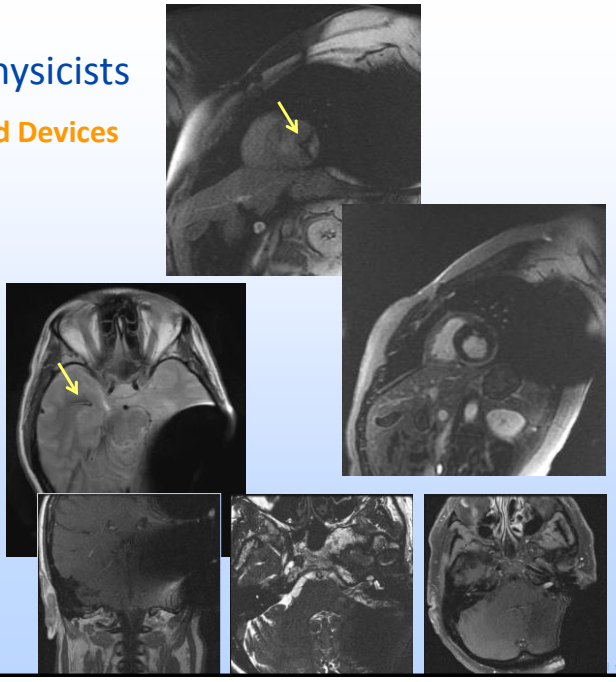
Results

- ~1000 patients now scanned at Mayo Rochester
- Proven clinical value
- No known clinically adverse events
- No device dysfunction
- No change in capture or sensing threshold
- Device/MRI interactions observed infrequently
  - Several power on resets in older devices; then reprogrammed
  - Stresses the need for close monitoring during & careful device interrogation after scanning.

Clinical Assignments for MRI Physicists

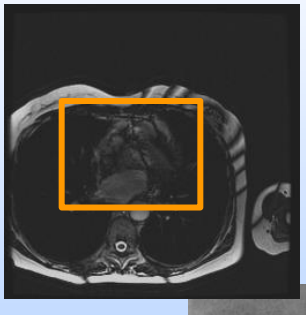
Role in MRI exams with Active Implanted Devices

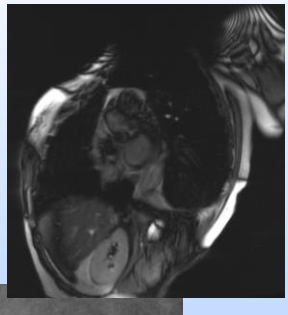
- Verify device model and MR-conditions
- Recommendation for MR coil
- Answer patient questions
- Keep MR operation within prescribed limits for the implanted device
  - SAR, B1+rms
  - dB/dt
- Maintain diagnostic quality of the exam
- Employ techniques to reduce artifacts near the device

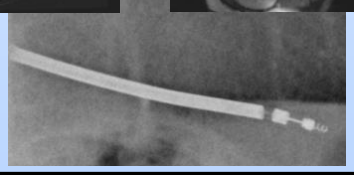


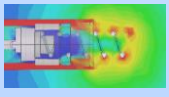
ICD - Artifacts

FIESTA/SSFP techniques – banding artifacts
- Use localized shim
- Switch to gradient echo sequences

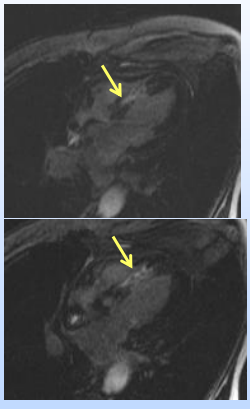








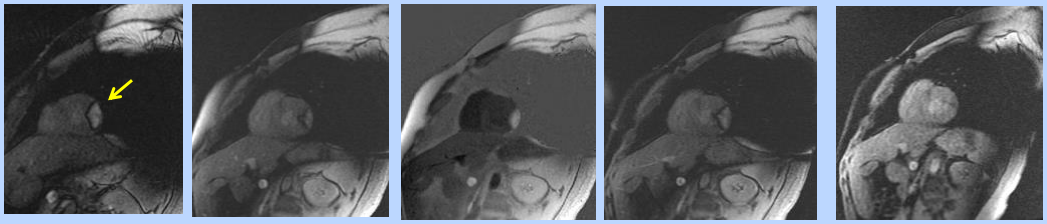
MDE – artifact near lead tip
- Interferes with B1-field
- Flip angle not correct



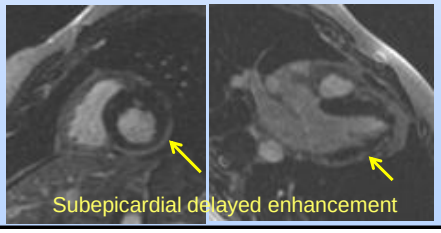
"cannot exclude the possibility of artifact from nearby intracardiac CRT-D leads"

What can an MR Physicist do? Especially working with the Radiologist!

Myocarditis/? Subsequent fibrosis (ICD)



Local Shim | Parameter changes | Phase Sensitive? No! | Type in L/R Shim Made it worse! | Type in L/R Shim opposite direction



Subepicardial delayed enhancement

Interactive troubleshooting for these exams

- Can't anticipate location of implant
- Can't anticipate disease state or scan protocol
- Geometry within the scanner very important
- Can't protocol ahead of time

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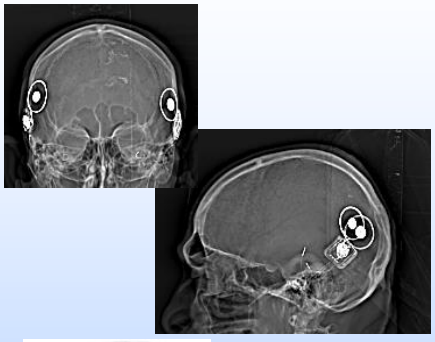
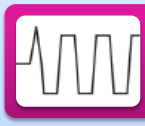
Cochlear implants (with magnets)



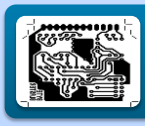
*www.Cochlear.com

B0
- Magnets! Pull and torque

B1 (RF)
- Leads! Potential for heating



dB/dt (Gradients)
- Conductive, small surface area



Active Device
- Clicks and odd noises during scanning

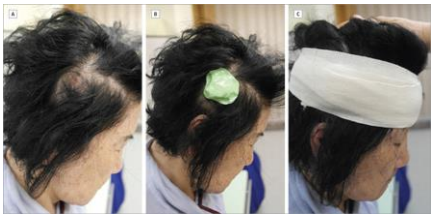
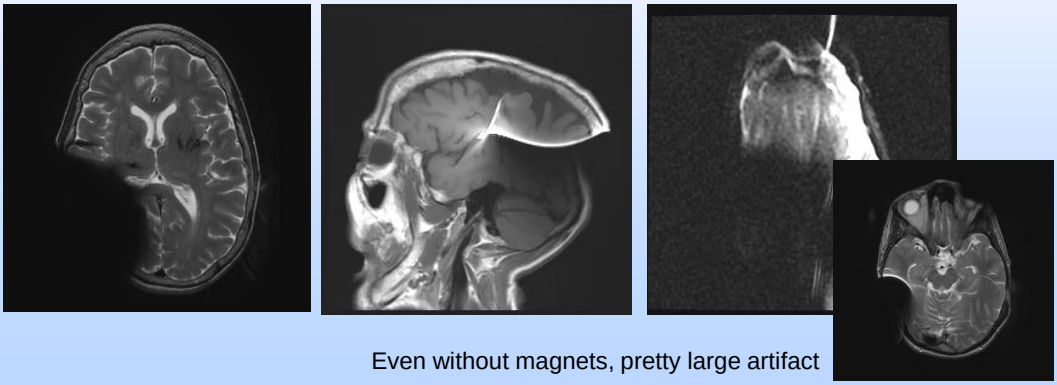


Figure Legend:

Applying Mold, Gauze, and Bandage Prior to Magnetic Resonance Imaging of Patient With Cochlear Implant (CI)A, Area over CI is identified. B, Mold is applied to the scalp directly over the internal magnet of the CI. C, Elastic bandage is then tightly wrapped around the head.

Cochlear implants (with magnets)

- Patient requested anesthesia
- Two prior MRI's- could not tolerate pain, aborted exam prior to contrast even though highly motivated to complete exam



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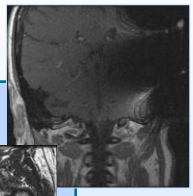
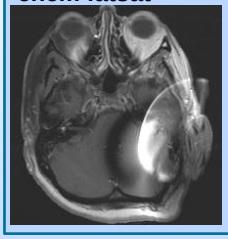
Even without magnets, pretty large artifact

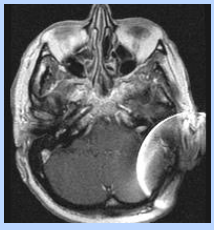
What can an MR Physicist do? Especially working with the Radiologist!

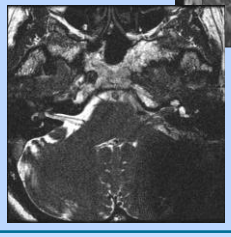
Bilateral Vestibular Schwannoma
Cochlear Implant



Prior Exam – chem fatsat



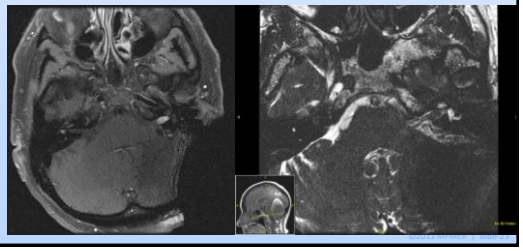




Parallel Imaging Artifact
Collapsed signal prevents accurate coil element mapping

Dixon Recon Artifact

"Interactive" Exam – Dixon and localized shimming



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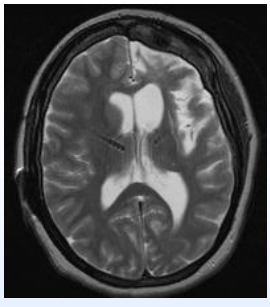
What can an MR Physicist do? Especially working with the Radiologist!



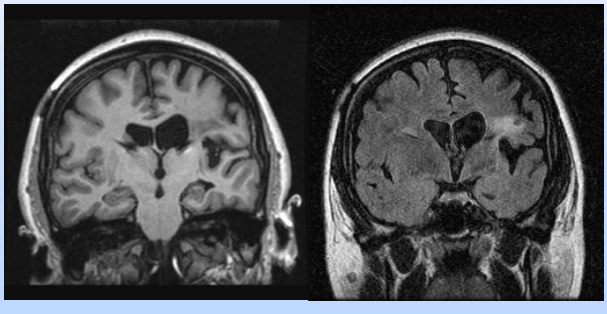
DBS 0.1 W/kg -> 3% of Normal Mode Operation

My conversation with the radiologist:

- What is the most important sequence, given the patient's indication?
- Standard 2D spin echo-based imaging techniques require about **1 minute per slice**
- Can we limit scan coverage?
- Are you OK with 3D GRE T1's with reformats? Post-gad too?
- DWI comes for free – no changes needed

1 hour exam:

MP-Rage, Cor T2 FLAIR, Ax T2 FSE, DWI, T2* GRE



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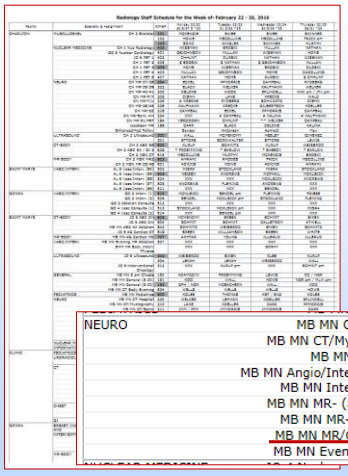
Clinical Assignments for MRI Physicists



- Construction, equipment planning and siting
- Upgrades and safety recalls
- Image Quality and artifacts
- Patient device inquiries

NEURO	MB MN CT Hospital	230	WELKER	LEHMAN	KOELLER	EPLINDELL	BLACK
	MB MN CT/Myelography	210	LANE	KOELLER	CARR	PPMORRIS	DRD / MH
	MB MN CT/Spine	211	JMM / PPM	JMMORRIS	JMMORRIS	CARR	VERDOORN
	MB MN Angio/Interventional	212	CLOFT	CLOFT	CLOFT	CLOFT	XXX
	MB MN Interventional	223	XXX	XXX	XXX	XXX	LANZINO
	MB MN MR- (am) 29/34	213	LEHMAN	HO	PORT	BLACK	PPMORRIS
	MB MN MR- (pm) V/H	215	KOELLER	GILBERTSON	RYDBERG	SCHWARTZ	EPLINDELL
	MB MN MR/OR Physics		MCGEE	MCGEE	EDMONSON	EDMONSON	XXX
	MB MN Evening MR/CT	216	LIEBO	LIEBO	LIEBO	LIEBO	LIEBO

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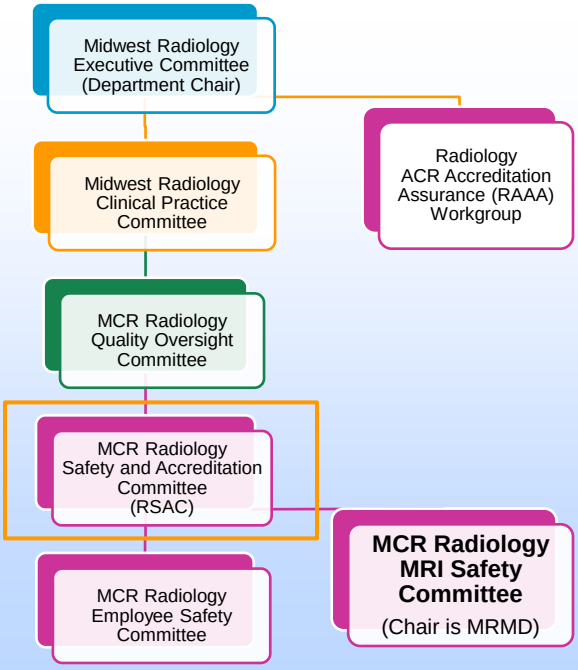
MRI Safety Committee/Rochester

Multidisciplinary Membership

- Radiologists
- Physicists
- Technologists
- Nurses
- Healthcare Technology Management (MRI Service)
- Desk staff
- Anesthesia
- Operations Manager
- 23 individuals



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Safety Event Reporting

RSAC: Major Strategic Priorities:

- Patient Safety Event Transparency
- Address TJC accreditation standards and National Patient Safety Goals

Radiology Home Page:

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Safety Event Reporting – What to Report

SERF – What to Report:

Event Type:	SERF Categories/ Examples: *list may include but is *not limited to* items listed below	National Quality Forum "Never Event" examples – mandatory to report
o Accidental Injury	-Burn -Contusion/bruise -Laceration -Skin tear	Death or serious injury: -(from) an Air embolus -Associated w/burn -Associated w/use of contaminated drugs/devices -Associated w/use of a device -Associated w/use of restraints (or lack of use) -During or immediately after an invasive procedure -Introduction of metallic object into MRI

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Safety Event Reporting – Roles and Responsibilities

Leader Expectations for SERF

	Supervisor or SERF Designee	Operations Manager/Coordinator	Division Chair or Safety Designee	Value Creation Unit	Dr. Thielen and Ron Menaker
SERFs	• Promote and ensure reporting is completed in a timely manner. Same day is desirable, w/in 24 hrs. is expected.				
	• Close the loop with SERF reporter with the actions being taken • Assign someone to follow up on the SERF (identify the process issue, not blaming individuals) within 30 days. • Review SERF Exec Summary Monthly at team meetings a. Share projects/ process changes that have resulted b. Share SERFs with lessons learned that benefit staff • Use Value Stream Maps to identify process gaps	• Review SERF Exec Summary Monthly • Review SERF Exec Summary at Ops Meetings at least quarterly and: a. Verify reporting is occurring b. Identify projects/process changes that have resulted c. Identify if any SERF follow up is incomplete d. Facilitate multidisciplinary follow up if needed	• Review SERF Exec Summary Monthly • If the SERF relates to Radiologists, assist in SERF follow up	• Receive and review each SERF • Enter MIDAS info if needed • Review daily MIDAS reports • Triage SERFs to appropriate individuals • Ensure SERFs are followed up on appropriately • Provide monthly reports to dept/leadership • Identify department trends • Develop front-line communication e.g. SBAR	• Review SERF Exec Summary Monthly • Review incomplete (>90 days) SERFs by modality
Events that trigger Root Cause Analysis (RCA)	• Attend RCA meetings and ensure appropriate staff members attend • Bring Value Stream Maps to RCA to identify process gaps	• Attendee at RCA investigation • Attendee at solutions meeting	• Participate in and/or be informed of RCA • Present RCA solutions to the Division	• Escalate and coordinate RCA • Work with QMS on cross departmental events • Coordinate Enterprise communication e.g. SBAR • Facilitate SE follow up at RSAC	• Read SBARs to be informed of Sentinel Events • Remove barriers if needed

Reviewed and Endorsed by:		Communicated at:	
RSAC	8/20/15	Radiology Division Chairs	11/16/15
QOC	8/25/15	Radiology Admin Team	11/16/15
CPC	9/22/15	Supervisors Meeting	11/17/15

Saved to Safety Webpage Link: http://intranet.mayo.edu/charlie/radiology-rst/

- Clear expectations from departmental leadership
- Roles and Responsibilities for follow up of Safety Events
- "Promote and ensure reporting is completed in a timely manner. Same day is desirable, w/in 24 hrs. is expected."
- "Identify the process issue, not blaming individuals"

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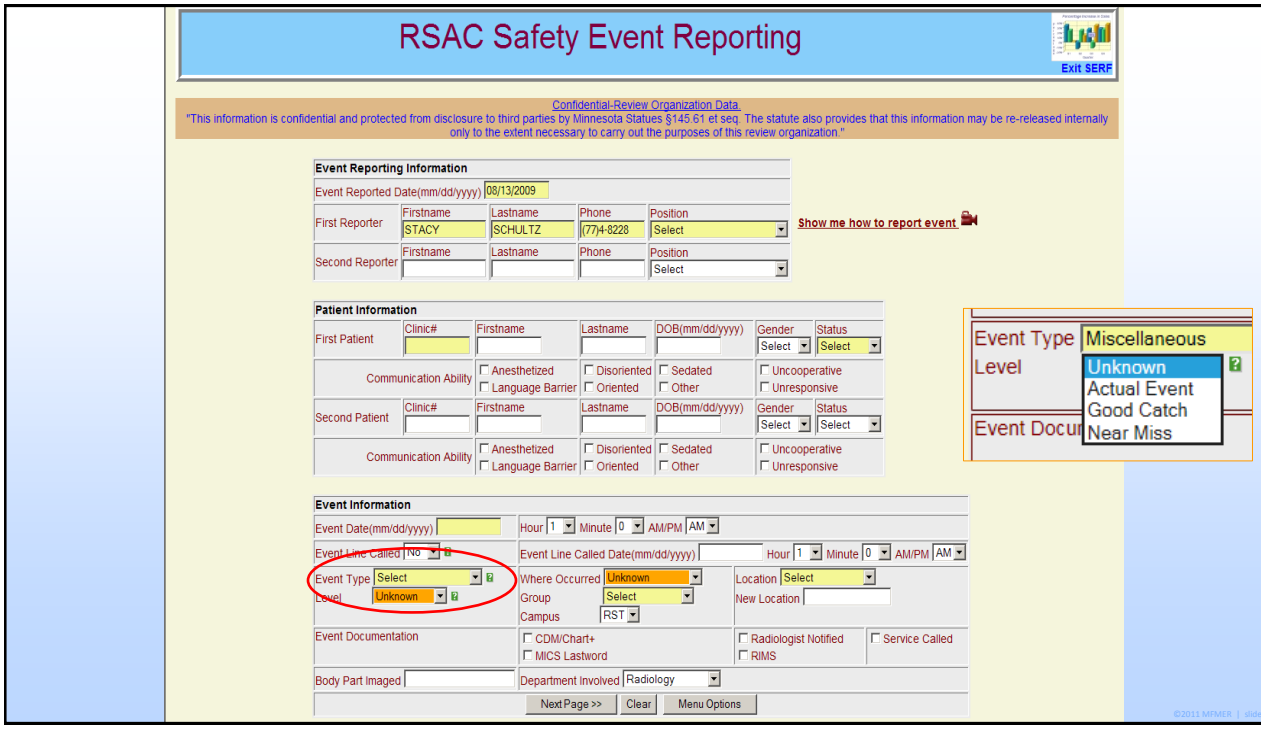
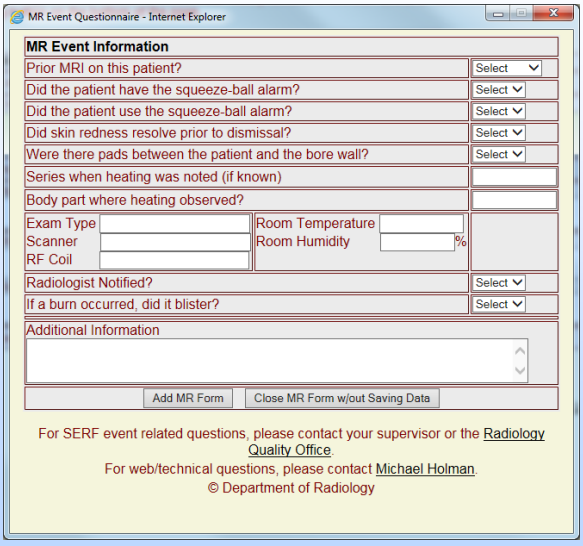


SERF – MRI Specific Info

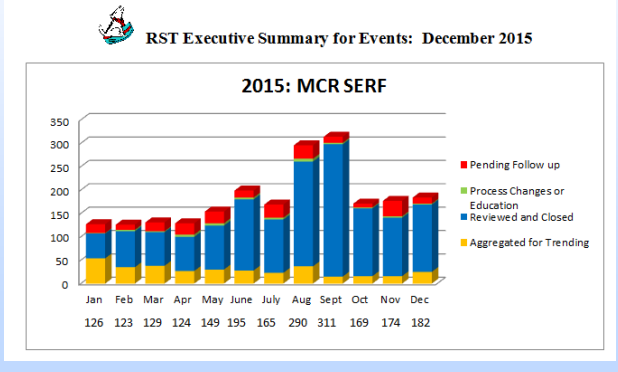


SERF – Analysis and Distribution

Events Categorized
(including near miss/good catch)

MRI YTD/2016	JAN	YTD Total
ACCIDENTAL INJURY	1	1
DELAY IN TREATMENT	8	8
FALLS	1	1
INAPPROPRIATE EXAM	4	4
IV	6	6
MEDICATION	2	2
MISCELLANEOUS	4	4
Monthly Total	26	26

And Tracked for Follow up



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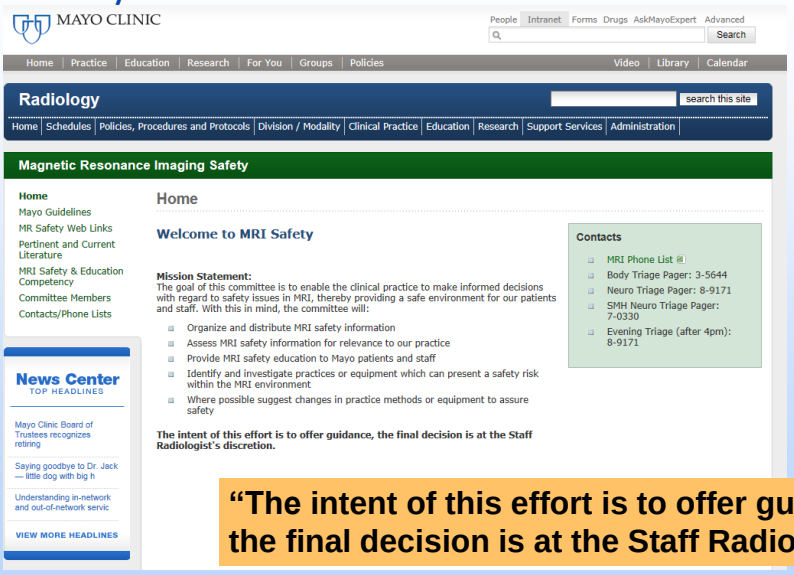
MRI Safety Committee

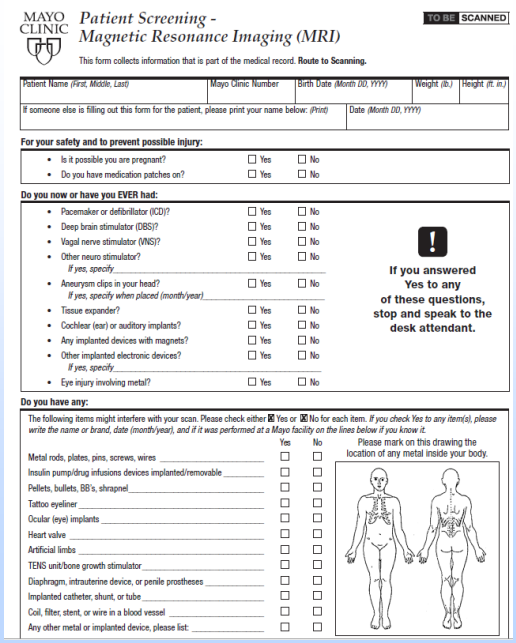


"The intent of this effort is to offer guidance, the final decision is at the Staff Radiologist's discretion."

MRI Safety Committee – Typical Agenda

- Review MRI Safety related SERFs
  - Significant Event? Invite witnesses to describe what happened
- Update/review MR Safety policies
- Identify workflow for new/revised implanted device conditions for use
- Address MRI safety concerns/questions brought forward by staff
- Identify new goals/projects to enhance MRI safety and workflow

Ferromagnetic Screeners



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Patient Screening - Magnetic Resonance Imaging (MRI)

TO BE SCANNED

This form collects information that is part of the medical record. **Route to Scanning.**

Patient Name *(First, Middle, Last)*	Mayo Clinic Number	Birth Date *(Month DD, YYYY)*	Weight *(lb.)*	Height *(ft. in.)*

If someone else is filling out this form for the patient, please print your name below: *(Print)* | Date *(Month DD, YYYY)*

For your safety and to prevent possible injury:

- Is it possible you are pregnant? ☐ Yes ☐ No
- Do you have medication patches on? ☐ Yes ☐ No

Do you now or have you EVER had:

- Pacemaker or defibrillator (ICD)? ☐ Yes ☐ No
- Deep brain stimulator (DBS)? ☐ Yes ☐ No
- Vagal nerve stimulator (VNS)? ☐ Yes ☐ No
- Other neuro stimulator? ☐ Yes ☐ No
  If yes, specify
- Aneurysm clips in your head? ☐ Yes ☐ No
  If yes, specify when placed (month/year)
- Tissue expander? ☐ Yes ☐ No
- Cochlear (ear) or auditory implants? ☐ Yes ☐ No
- Any implanted devices with magnets? ☐ Yes ☐ No
- Other implanted electronic devices? ☐ Yes ☐ No
  If yes, specify
- Eye injury involving metal? ☐ Yes ☐ No

If you answered Yes to any of these questions, stop and speak to the desk attendant.

Do you have any:

The following items might interfere with your scan. Please check either ☒ Yes or ☒ No for each item. *If you check Yes to any item(s), please write the name or brand, date (month/year), and if it was performed at a Mayo facility on the lines below if you know it.*

	Yes	No
Metal rods, plates, pins, screws, wires	☐	☐
Insulin pump/drug infusions devices implanted/removable	☐	☐
Pellets, bullets, BB's, shrapnel	☐	☐
Tattoo eyeliner	☐	☐
Ocular (eye) implants	☐	☐
Heart valve	☐	☐
Artificial limbs	☐	☐
TENS unit/bone growth stimulator	☐	☐
Diaphragm, intrauterine device, or penile prostheses	☐	☐
Implanted catheter, shunt, or tube	☐	☐
Coil, filter, stent, or wire in a blood vessel	☐	☐
Any other metal or implanted device, please list:	☐	☐

Please mark on this drawing the location of any metal inside your body.

- Redundancy
  Oral, paper form
- Ferromagnetic screeners
- No extraneous metal objects in the scan room!
- Anything metallic gets screened by a hand magnet before entering Zone IV

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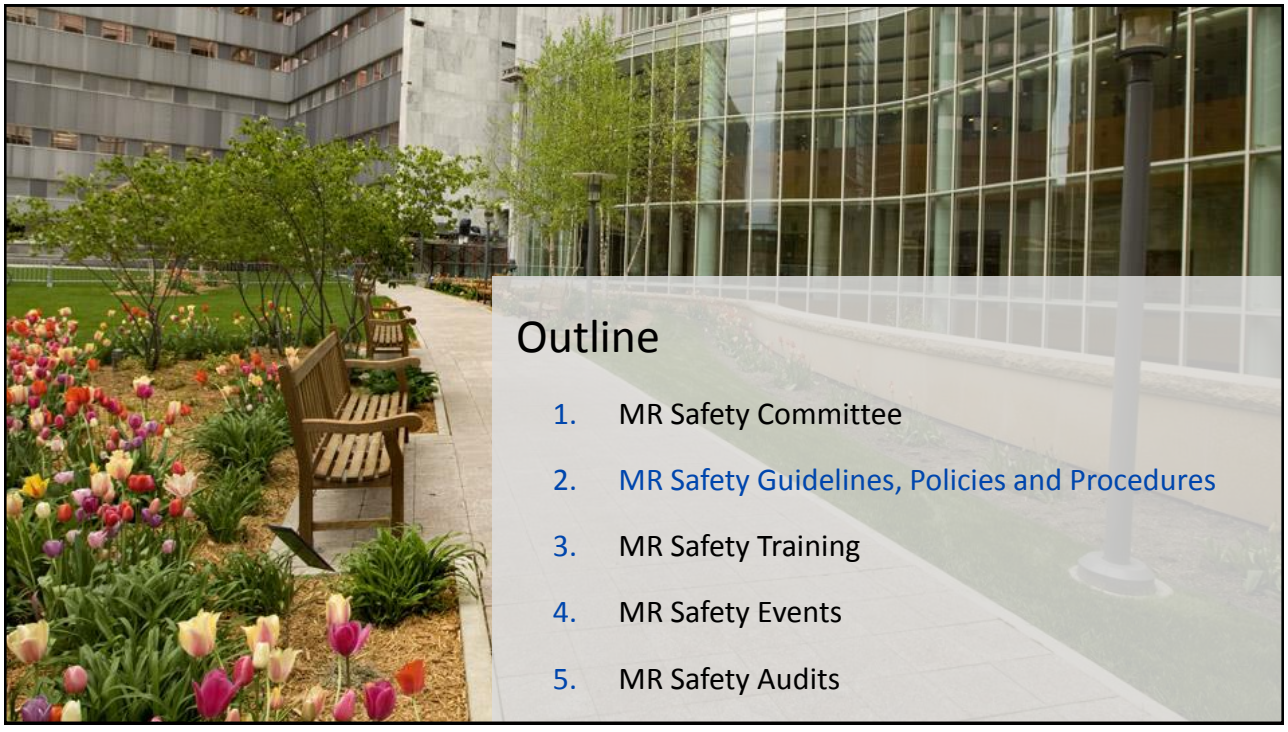
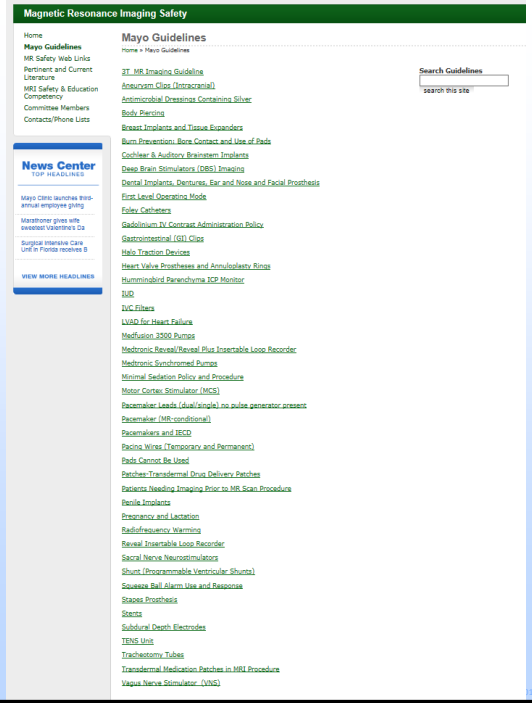
Enterprise MRI Safety

- Radiologists
- Physicists
- Technologists
- Regional Operations Managers

- Quarterly WebEx meetings to:
  - Standardize guidelines, policies, and best practices
  - Discuss safety events



Mayo MRI Scan Guidelines updated to reflect new and frequently changing devices and processes

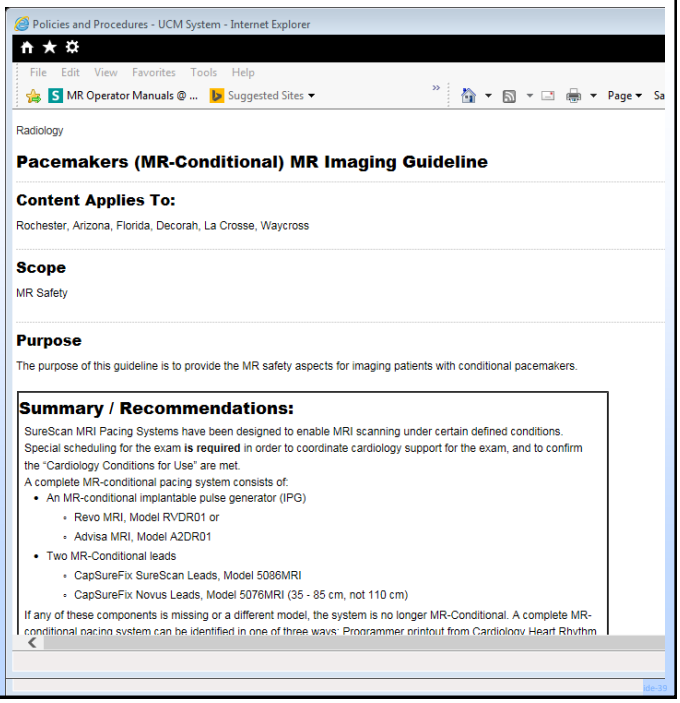


Mayo Guidelines

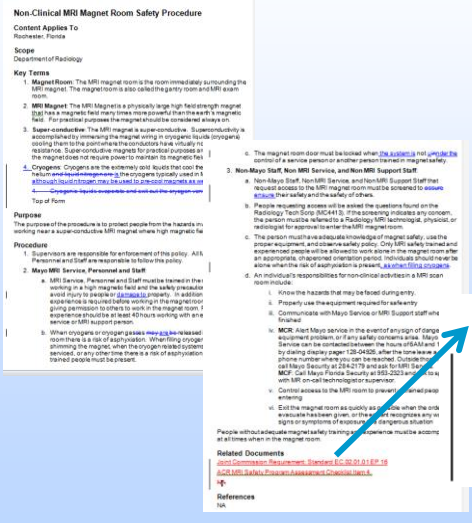
- Quick overview for reference
- Standardized formatting

  Summary/Recommendations
  Important Notes
  Checklist

  In-depth info + references
- Includes Mayo-specific info
  - Notes for report
  - Mayo staff contacts



Policy Review


Non-Clinical MRI Magnet Room Safety Procedure

Content Applies To
Rochester, Florida

Scope
Department of Radiology

Key Terms
1. Magnet Room: The MRI magnet room is the room immediately surrounding the MRI magnet. The magnet room is also called the gantry room and MRI exam room.
2. MRI Magnet: The MRI Magnet is a physically large high field strength magnet that has a magnetic field many times more powerful than the earth's magnetic field. For practical purposes the magnet should be considered always on.
3. Super-conductive: The MRI magnet is super-conductive. Superconductivity is accomplished by immersing the magnet wiring in cryogenic liquids (cryogens) cooling them to the point where the conductors have virtually no resistance. Super-conductive magnets for practical purposes are the magnet does not require power to maintain its magnetic field
4. Cryogens: Cryogens are the extremely cold liquids that cool the helium and liquid nitrogen are is the cryogens typically used in although liquid nitrogen may be used to pre-cool magnets as a
4. Cryogens liquids suspected and exit out the cryogen vent

Top of Form

Purpose
The purpose of the procedure is to protect people from the hazards in working near a super-conductive MRI magnet where high magnetic fie

Procedure
1. Supervisors are responsible for enforcement of this policy. All Personnel and Staff are responsible to follow this policy.
2. Mayo MRI Service, Personnel and Staff:
   a. MRI Service, Personnel and Staff must be trained in the working in a high magnetic field and the safety precaution avoid injury to people or damage to property. In addition experience is required before working in the magnet roo giving permission to others to work in the magnet room. experience should be at least 40 hours working with an e service or MRI support person.
   b. When cryogens or cryogen gasses may be released room there is a risk of asphyxiation. When filling cryoge shimming the magnet, when the cryogen related systems serviced, or any other time there is a risk of asphyxiation trained people must be present.

c. The magnet room door must be locked when the system is not under the control of a service person or another person trained in magnet safety.
3. Non-Mayo Staff, Non MRI Service, and Non MRI Support Staff:
   a. Non-Mayo Staff, Non MRI Service, and Non MRI Support Staff that request access to the MRI magnet room must be screened to assure ensure their safety and the safety of others.
   b. People requesting access will be asked the questions found on the Radiology Tech Scrip (MC4413), if the screening indicates any concern, the person must be referred to a Radiology MRI technologist, physicist, or radiologist for approval to enter the MRI magnet room.
   c. The person must have adequate knowledge of magnet safety, use the proper equipment, and observe safety policy. Only MRI safety trained and experienced people will be allowed to work alone in the magnet room after an appropriate, chaperoned orientation period. Individuals should never be alone when the risk of asphyxiation is present, as when filling cryogens
   d. An individual's responsibilities for non-clinical activities in a MRI scan room include:
      i. Know the hazards that may be faced during entry.
      ii. Properly use the equipment required for safe entry.
      iii. Communicate with Mayo Service or MRI Support staff whe finished
      iv. MCR: Alert Mayo service in the event of any sign of dange equipment problem, or if any safety concerns arise. Mayo Service can be contacted between the hours of 8AM and 1 by dialing display page 128-04526, after the tone leave a phone number where you can be reached. Outside this call Mayo Security at 284-2179 and ask for MRI Service MCF: Call Mayo Florida Security at 953-2323 and ask to with MR on-call technologist or supervisor.
      v. Control access to the MRI room to prevent untrained peop entering
      vi. Exit the magnet room as quickly as possible when the orde evacuate has been given, or the system recognizes any w signs or symptoms of exposure to a dangerous situation

People without adequate magnet safety training and experience must be accomp at all times when in the magnet room.

Related Documents
Joint Commission Requirement: Standard EC.02.01.01 EP 16
ACR MRI Safety Program Assessment Checklist Item 4.
NA

References
NA

- For future policy reviews, include reference to relevant standards (ACR, TJC, CMS)
- Reviewer then knows the purpose and how changing or removing the policy may lead to non-compliance.

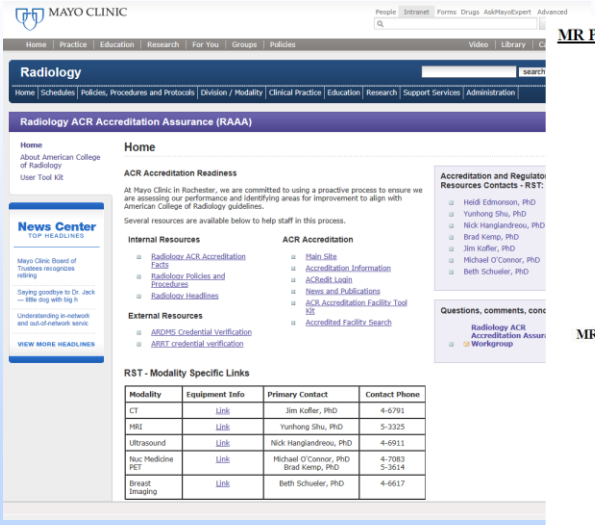
Related Documents

Joint Commission Requirement: Standard EC.02.01.01 EP 16

ACR MRI Safety Program Assessment Checklist Item 4.

~~NA~~

RAAA Workgroup – Proactive alignment with ACR Guidelines



Toolkit for Practice Sites

MR Policies and Procedures

MRI Safety

1. Radiology MR Safety Web site
2. Radiology Policy- Non-Clinical MRI Magnet Room Safety Procedure

❑ Policy on unforeseen ferrous objects in MR scanner room

1. Equipment Safety Straps Policy
2. Mayo Clinic MRI Safety- Education and Competency

❑ Policy on thermal burns and SAR

on 3/9/2015

1. Policy for Performing MRI Scans on Patients When Pads Cannot Be Used
2. Mayo Clinic MRI Safety- Education and Competency
3. Warming/Burn Incidents on a MRI Scanner Procedure

MR Policies and Procedures Continued

❑ Policy on response of personnel during and after a quench

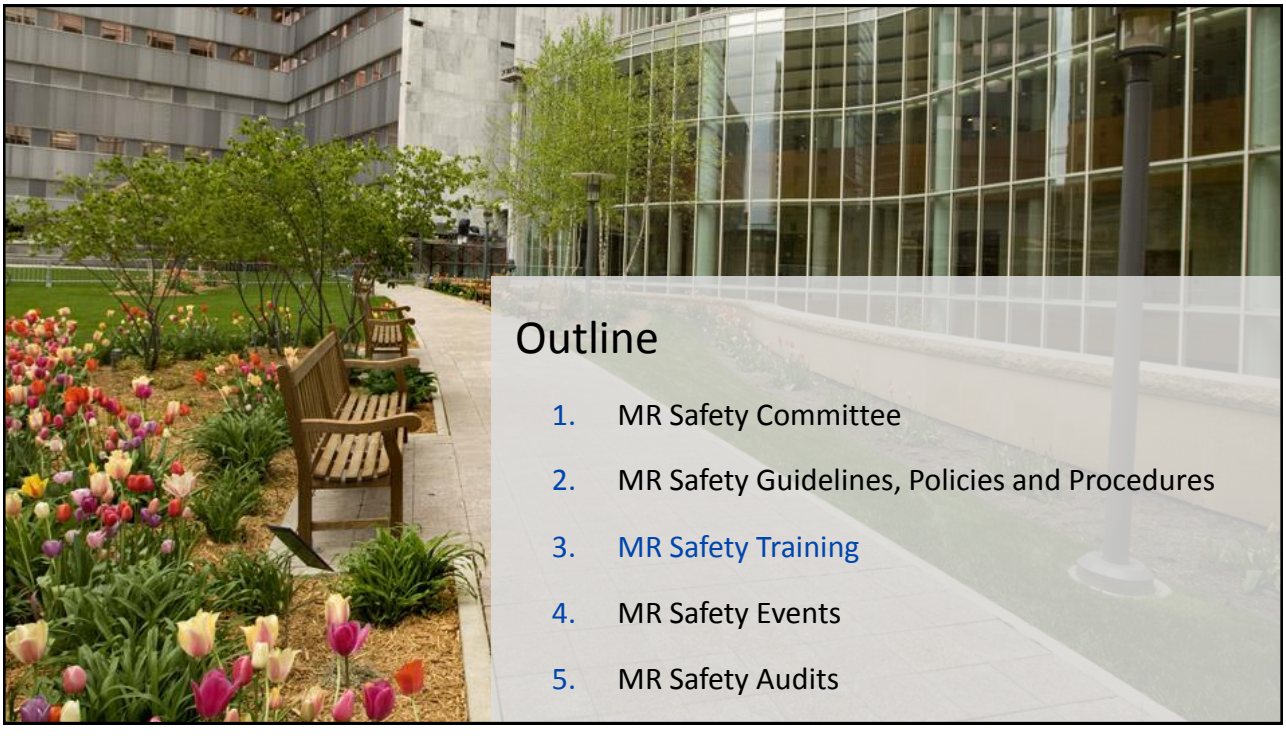
1. Mayo Clinic MRI Safety Emergency Procedures

❑ Policy on reporting of MR accidents to FDA via Medwatch Program

1. MR Safety Incidents are reported to the MRI Safety Committee
2. MR Safety Incidents are reported following the Event Reporting: Medical Devices-PC.16 Procedure http://mayocontent.mayo.edu/ipm/DOCMAN-0000055952?qt=medwatch
3.

❑ Policy on hearing protection for patients/persons in MR scanner room

1. MR Patient Ear Plug Use Policy
2. Documentation of medical director/MR safety officer's name and responsibilities- MRI Safety Committee Members- Committee Chair- Dr. Watson



Outline

1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
4. MR Safety Events
5. MR Safety Audits

MRI Safety Training

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]

ACR: Annual training

Non-MR personnel defined as
not MR Safety trained in prior 12 months

MR Personnel
Level 1: Safety trained to ensure own safety in Zone III
Level 2: Safety trained in broader aspects
(thermal loading, PNS), Code drills

The Joint Commission — **Diagnostic Imaging Requirements**
August 10, 2015

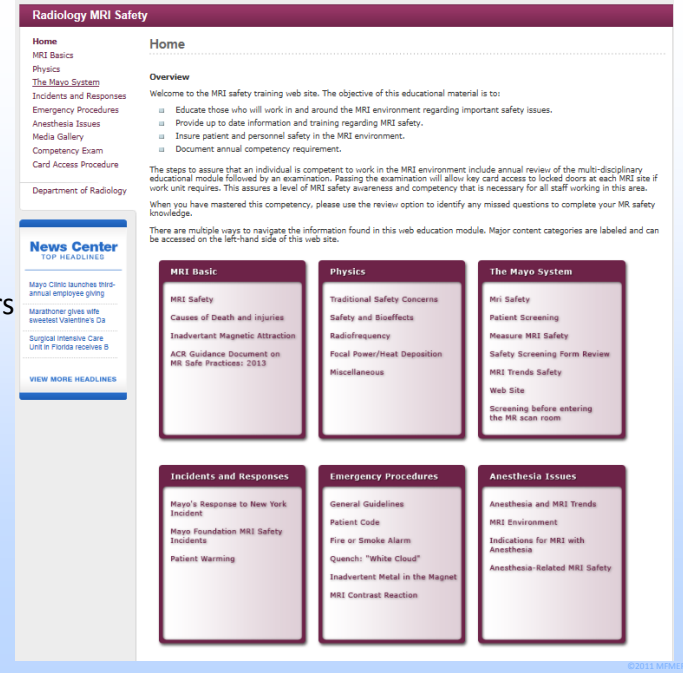
Standard HR.01.05.03
Staff participate in ongoing education and training.

C 25. Ⓓ The organization verifies and documents that technologists who perform magnetic resonance imaging (MRI) examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following: Ⓜ

- Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for Nephrogenic Systemic Fibrosis (NSF)
- Proper patient and equipment positioning activities to avoid thermal injuries
- Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional) *
- MRI safety response procedures for patients who require urgent or emergent medical care
- MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
- Patient hearing protection
- Management of patients with claustrophobia, anxiety, or emotional distress

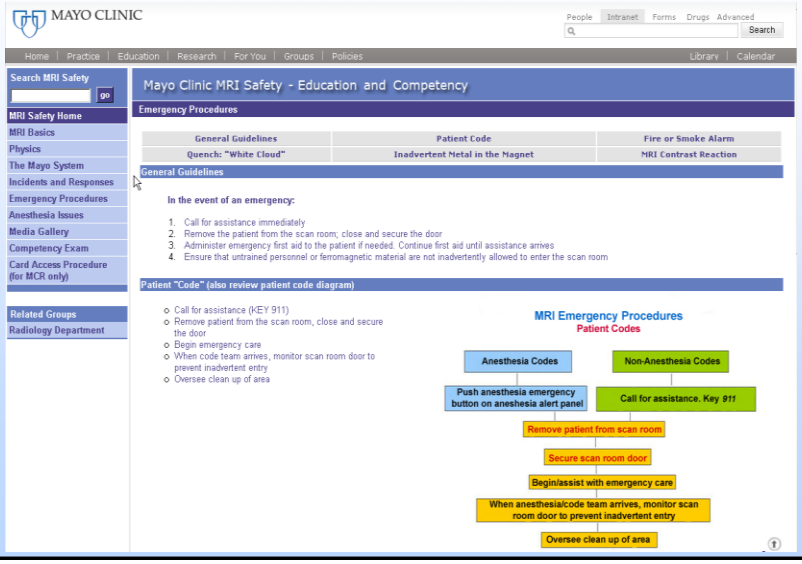
MRI Safety Training

- Web Modules
- Level I and II exams
- Lectures for incoming residents
- Lectures for language interpreters
- Technologist In-services
  (Video Recorded with
  post-viewing exams)
  - HAE – Oct 2015
    TJC Required Topics
  - HAE – April 2016
    New MR Conditional Devices
    and Existing Devices with
    Revised Labeling



1st Step: Education

Online MRI Safety competency



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MRI Safety Education

Residents / nurses

Clinical assistants / schedulers

Interpreters

Fire Department / Emergency personnel

MRI Safety 101

- *What do I need to know?*

1) The magnet is ALWAYS on!

- On MR Safety Competency Exam, this question is asked 3 times (in different forms).
- If answered incorrectly, automatically fail and cannot have card access to Zone III

Restrict access to Zone III and IV

Electronic ID keycard control of Zone III access
- Card activation tied to passing online MRI Safety test
- NOT cipher lock code which is easily disseminated

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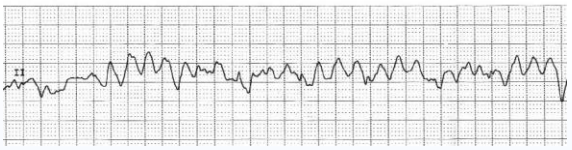

Medical Emergency in MRI

- Do NOT enter magnet room !
- Patient is removed from magnet room immediately by MRI technologists
- Treat patient OUTSIDE magnet room

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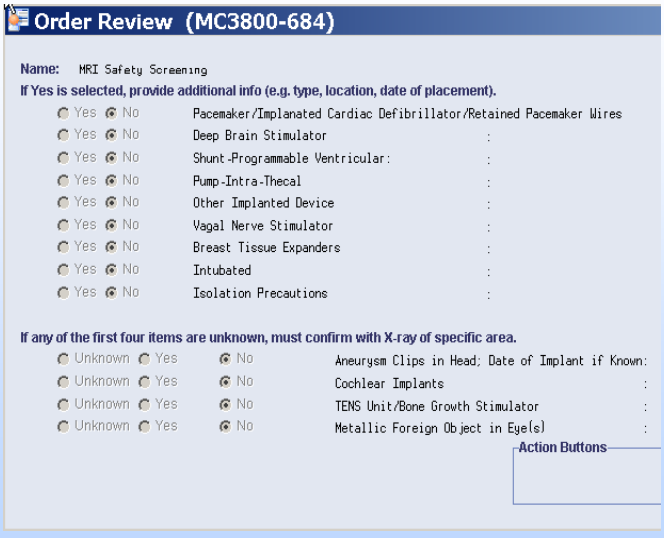
MRI Safety for Ordering Providers

- *What do I need to know?*
  - Protect your patients.
  - Give ACCURATE information about their IMPLANTED DEVICES & other METAL in body.



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MRI Safety Training

Examples from your own institution make a powerful impact during training!

Oxygen tank

Screwdriver

Needle

Situation: An unsafe ladder was brought into an MR suite by Campus Operations personnel, and it was attracted to the back side of the magnet.

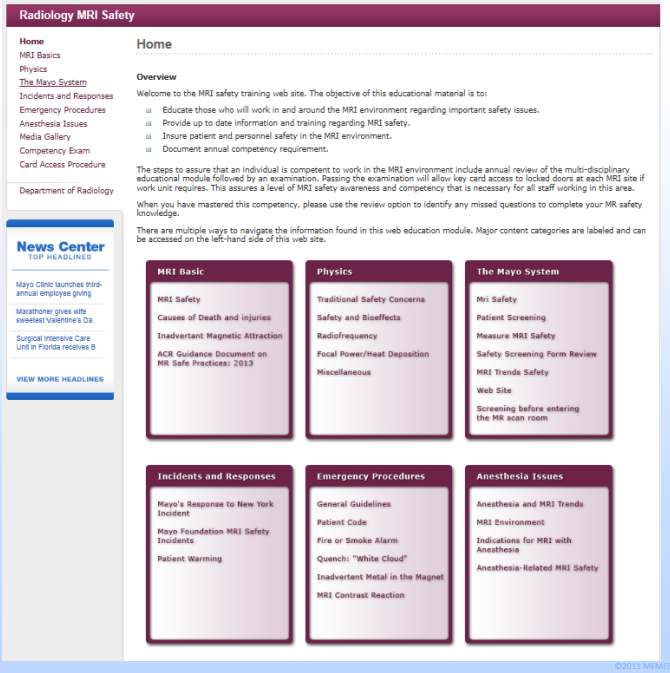
Recommendation: The cart that contained the MR unsafe ladder and light bulbs should stop outside of Zone 3. In addition, all employees should be thoroughly screened prior to entering Zone 4, regardless of experience within the MR area. The dept. will evaluate the staff not multitasking and ensure the Campus Operations staff waits until they have been fully cleared by the MR Staff.
More to come after the RCA and debrief of the situation.
After RCA debrief:

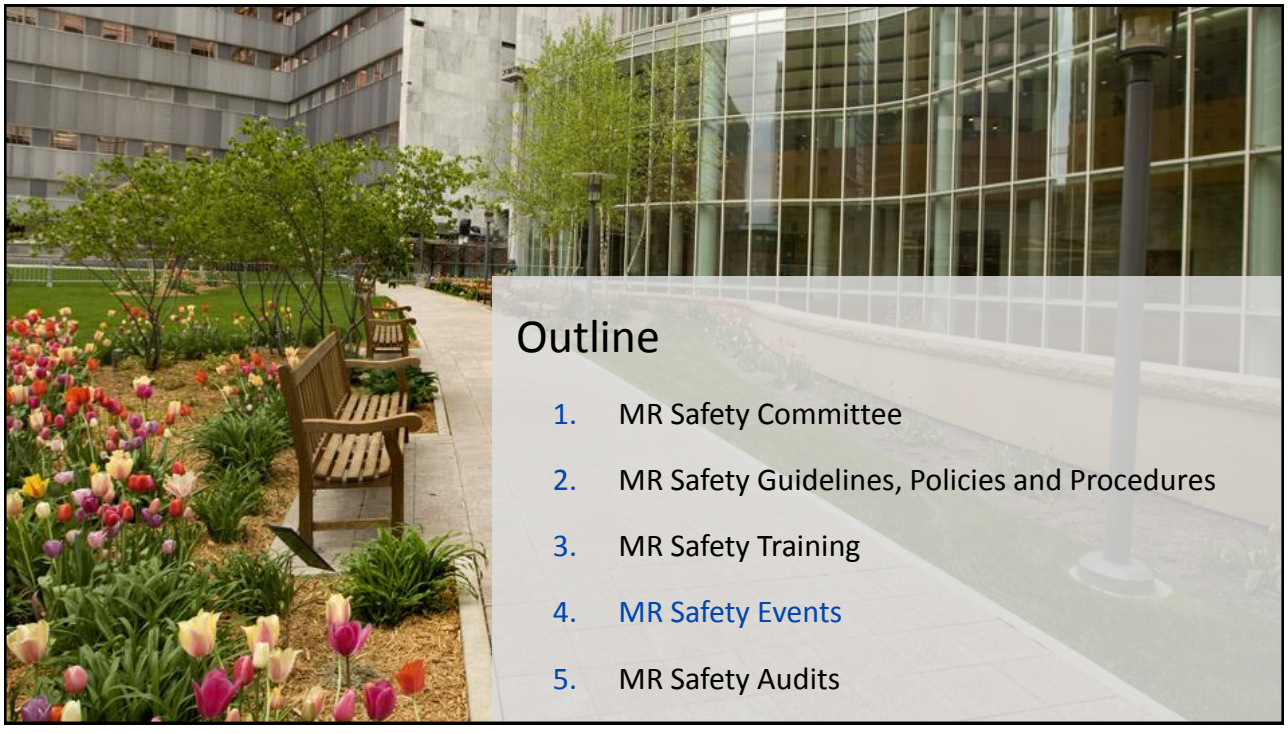
- ✓ *Light bulb cart will remain outside Zone 3*
- ✓ *Light bulbs will be stored near MR safe ladder in each of the scan areas*
- ✓ *Mini pause will be administered by MR tech prior to entry into Zone 4*
- ✓ *Use this example in upcoming Annual MR Safety Education*

MRI Safety Training

Needs:

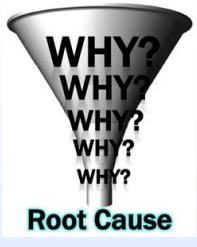
- Audience-specific MR Training
- Updating of content!
- Midwest – Generalized content, final jump to site specific info

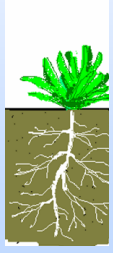




MRI Safety Events

- Projectiles
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - **Potential – patient cart (2x)**
  - Potential – ferromagnetic oxygen tank





- Environment
  - Accidental quench – inadequate button cover
- Patient care
  - Sedated patient event
  - Foil backed clonidine patch removal
  - Unread orbit screening exam
- Devices
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator

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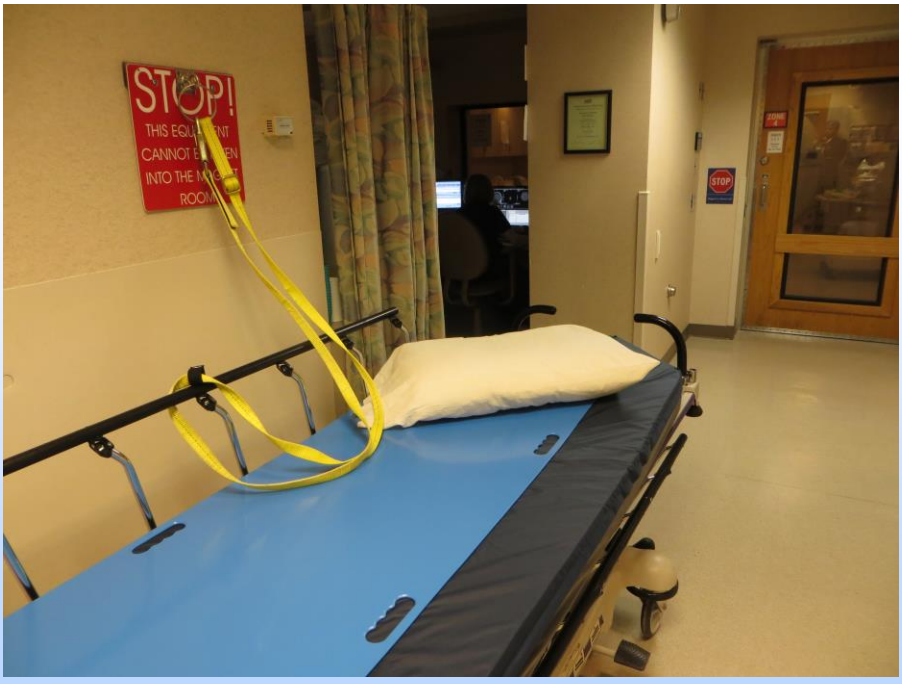

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Lock & key for access control of Zone IV when not in use

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MRI Safety Events

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Anesthesia case
Ferromagnetic tracheostomy tube stylet projectile

Event Description Summary:

•Ferromagnetic stylet was not removed from the MRI exam table after intubation.

•Stylet hidden amongst sheets.

•Scout performed and metal blowout artifact detected.

• Patient removed from scanner and lifted slightly.

• Stylet became projectile, flying into bore.

•**Injury and Description: None**

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Contributing Factors / Root Cause Analysis

- New Anesthesia personnel
- Break in routine / distracted
- Concerns about IV, concurrent with intubation
- No organized “time out” before entering MRI to ensure no MRI unsafe materials present

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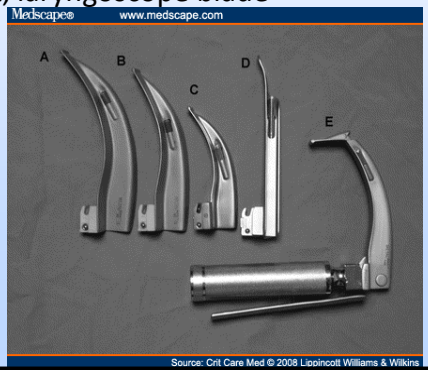
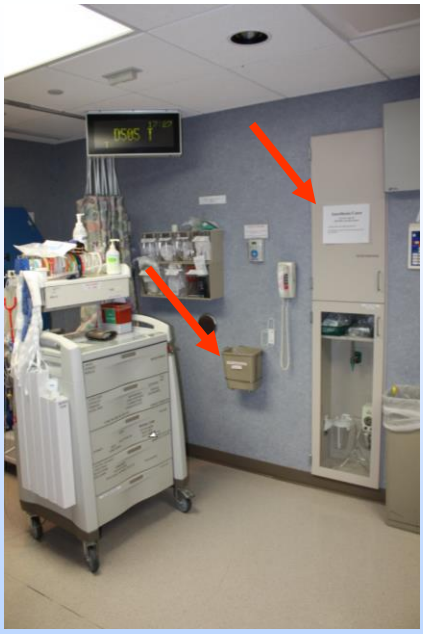
Change in procedure

- MR techs active participants
- "Time out" to mimic Universal Protocol before proceeding into Zone IV.
- Dedicated box mounted on wall to receive unsafe metallic objects
- – stylet, laryngoscope blade





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Unsecured ferromagnetic oxygen tank in Zone III

Unsecured ferromagnetic O2 tank discovered Monday morning

- Anesthesia case over weekend
- "regular" personnel not present

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Abandoned O2 tank responses

- Improved education for Anesthesia colleagues
- Empower "stop the line"

- Eliminate ferromagnetic O2 tanks
- Carts must be adapted
- Different diameters – 3/8 inch
- Ergonomic benefits

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Replacement of ferromagnetic oxygen tanks completed MCR

New Aluminum Oxygen E Cylinders

In early March, the Respiratory Therapy (RT) Department will begin to exchange empty steel oxygen E cylinders in all patient care areas within the Rochester campus with a new oxygen E cylinder. The new oxygen E cylinder is made of aluminum and is four pounds lighter than the steel cylinders. The exchange process could take months as the RT Department is replacing the cylinders once they are empty.

There are no operational differences and no extra safety precautions with these new cylinders. This change will not affect any current policies or procedures.

Direct questions to William Clark, RRT.

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Other parts on the Aluminum O2 Tanks

- Required to be in cart (prevent tip hazard, “the other missile effect”)
- Ferrous Free carts often get repaired with ferrous parts
- May be replaced with incorrect regulator
- Quarterly QC for any carts in the MRI areas, signature card and pink info tag
- Removal of ferrous O2 tanks significantly decreases attraction to magnet
  - More time to react even if in a ferrous cart

MRI Safety Events

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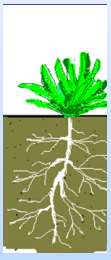

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  - **Unrecognized deep brain stimulator**

MAYO CLINIC

Medtronic Announces FDA Approval for the Only Full-Body MR Conditional Deep Brain Stimulation Systems

December 9, 2015 7:00 AM CT

Medtronic

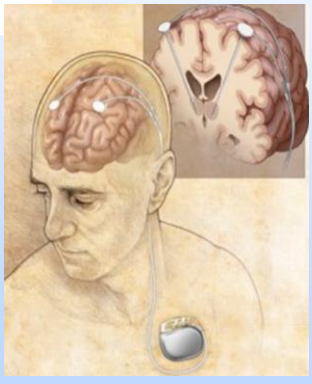
Updated Labeling Allows Greater Patient Access to MRI, a Critical Diagnostic Tool

DUBLIN - December 9, 2015 - Medtronic plc (NYSE: MDT) today announced that systems within its Activa® portfolio of Deep Brain Stimulation (DBS) neurostimulators have received FDA approval for full-body Magnetic Resonance Imaging (MRI)* under specific conditions of use. Medtronic's MR Conditional DBS systems are the only approved for full-body MRI scans. This approval expands access to MRIs, making it safe for patients receiving Medtronic DBS Therapy to also receive this important diagnostic standard of care. Additionally, this approval applies to individuals receiving new Medtronic DBS systems and to an estimated 43,000 people in the U.S. already receiving Medtronic DBS Therapy as long as updated MRI guidelines are followed.*

December 9, 2015

Some DBS systems now permit body coil transmit exams

- No longer limited to only head exams with transmit / receive head coil



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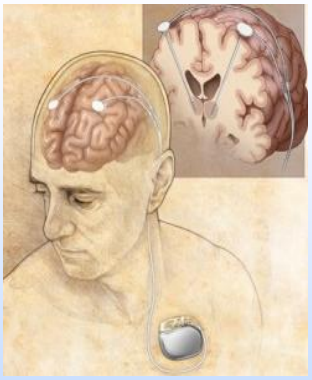
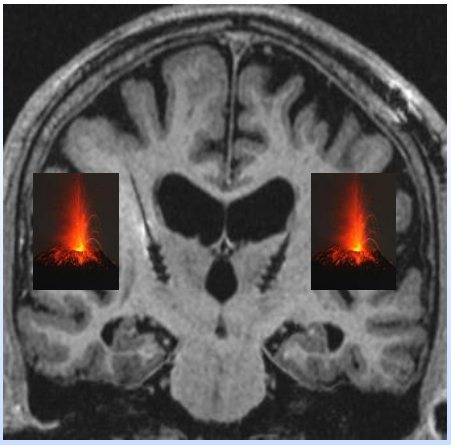
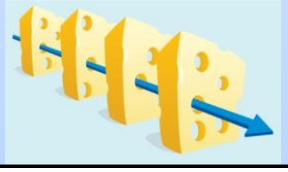
Deep Brain Stimulator Event

Patient scanned without proper DBS precautions fortunately without injury







Protective barriers at time of incident related to detecting unsafe devices in MRI

1. Order set – asks about presence of "MRI unsafe devices"
2. Radiologist protocoling case – exploring electronic medical record
3. MRI safety screening form
4. MRI technologist verbal screening

MRI order set

Does the Patient Have?

1

- Aneurysm Clip
- Deep Brain Stimulator
- Pacemaker/Implanted Cardiac Defibrillator/Retained Pacemaker Wires
- Pump-Intra-Thecal
- Programmable Ventricular Shunt
- Vagal Nerve Stimulator
- Other Implanted Device Specify:

MAYO CLINIC

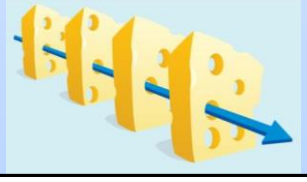
DBS event – exam ordered "no devices"

ORDERED ITEMS
Entered by:

Epilepsy Protocol 3.0T (MRI) 8-0000
Question: epilepsy
No SEDATION or MINIMAL ORAL SEDATION, if indicated (Pts 18 years and older)
No MRI Unsafe Devices on INITIAL Screening
Indications: epilepsy nos (345.90)

1

Exam pre-ordered
- DBS implanted at outside institution
- Assistant scheduled for MD
  - MRI safety questions were not asked carefully at original scheduling



Strike 1

MAYO CLINIC

2

DEMOGRAPHIC INFORMATION

DICTATED NOTE

This is a dictated note which has not been transcribed.

To listen to this dictation:

1. Dial 64064
2. When prompted to enter user ID, enter 6# (do not enter your 5-digit author ID).
3. When prompted, enter job number: 8067174, then press the # key.
4. When the dictation is available, it will automatically begin playing.
5. You may press the following keys while listening to the job:
   - Press 2 to rewind
   - Press 3 to go to end of dictation
   - Press 5 to pause
   - Press 1 to listen (after you have previously pressed 5 to pause)
   - Press 7 to go to the beginning of the dictation
   - Press 9 to go to Impression/Report/Plan (if one was marked)
6. When finished, press *9 and hang up.

The dictation is preliminary and is not the final version of the document.

Notes mentioning DBS, still in dictation at time of MRI

Strike 2

MAYO CLINIC

3

MAYO CLINIC

Patient Screening - Magnetic Resonance Imaging (MRI)

SCANNED AUTHORIZATION

This form collects information that is not part of the medical record. **Discard after use.**

Patient Name	Mayo Clinic Number	Birth Date *(Month DD, YYYY)*	Patient Weight *(lb)*	Date *(Month DD, YYYY)*

If someone else is filling out this form for the patient, please print your name below: *(Print)*

Please check the correct response:

1. Have you ever had an MRI scan done before that you know of?	☒ Yes	☐ No
*If yes, please provide date (month/year),*_____		
• Was your previous MRI scan done at a Mayo facility?	☒ Yes	☐ No
• Did you receive an injection of MRI contrast at that time?	☐ Yes	☒ No
• Did you have any problem with the contrast injection?	☐ Yes	☒ No
2. Have you ever had a pacemaker?	☐ Yes	☒ No *If Yes, please stop and speak to Desk Attendant.*
3. *Do you have aneurysm clips in your head?*	☐ Yes	☒ No
If yes, was the surgery done here?	☐ Yes	☐ No
• When (month/year)?_____		
4. Do you have any metallic foreign objects in your eyes?	☐ Yes	☒ No
5. Are you pregnant?	☐ Yes	☒ No
6. Do you have a tissue expander?	☐ Yes	☒ No
7. Any reason to leave the IV in place after this exam?	☐ Yes	☒ No

Comments_____

MAYO CLINIC

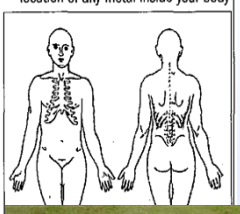
The following items might interfere with your scan. Please mark either ☒ Yes or ☒ No for each item. *If you check Yes to any item(s), please write the name or brand, date (month/year), and if it was performed at a Mayo facility on the lines below if you know it.*

	Yes	No
Metal rods, plates, pins, screws, wires	☐	☒
Insulin pump/implanted drug infusions device	☐	☒
Pellets, bullets, BB's, shrapnel	☐	☒
Dentures or other devices that have been surgically implanted with magnets	☐	☒
Tattoo eyeliner/ocular (eye) implants	☐	☒
Cochlear (ear) implants	☐	☒
Heart valve	☐	☒
Artificial limbs/joint replacement (prostheses)	☐	☒
TENS unit/bone growth stimulator	☐	☒
Diaphragm or intrauterine device	☐	☒
Penile prostheses	☐	☒
Implanted catheter, shunt, or tube	☐	☒
Coil, filter, or wire in a blood vessel	☐	☒
Do you have any medication patches on	☐	☒
Any other metal or implanted device, please list:	☐	☒

Sante study

Prior to your MRI scan, you will be asked to remove all clothing and change into a gown and robe fo
cannot be brought into the scan room. **This includes: Shoes, bra hooks or underwires, hairpins,**
back/pelvis support brace, safety pins, earrings, and removable dental braces.
GLASSES AND DENTURES MAY BE REMOVED INSIDE THE SCAN ROOM.

Please mark on this drawing the location of any metal inside your body



2

3

Strike 3

MAYO CLINIC

Sante study: DBS for epilepsy

MRI technologist verbal screening script

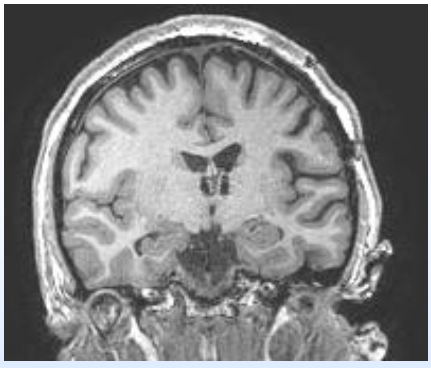
- Do you have a pacemaker or any other implanted electronic devices?
- Have you ever had a pacemaker or any other implanted electronic device removed?
- Do you have any metal in your body from surgery or an accident, including bullets, BBs or shrapnel?
- Have you had any surgery on your head, eyes, ears or aneurysm clip surgery?
- Do you have any hearing aids, hairpins, transdermal patches or dentures? (if yes to dentures, are they held in by magnets?)
- Do you have any other metal in your body?
- If you feel uncomfortable during your exam such as a tingling, pinching or hot sensation, please let me know. You can always squeeze the ball, and I will stop the scan.

4

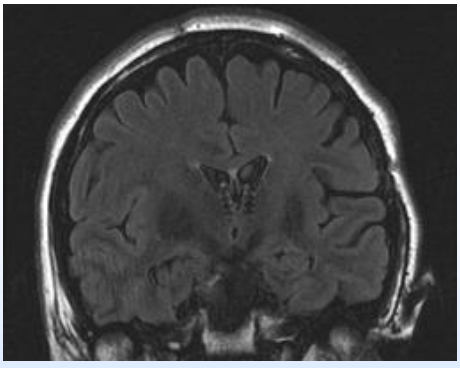
Strike 4

Patient answers no to all of the above questions

MAYO CLINIC



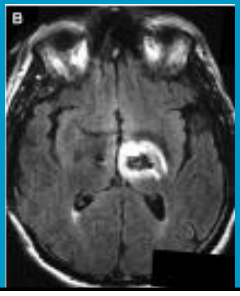
3T MRI performed without DBS precautions. **Fortunately without detectable incident**



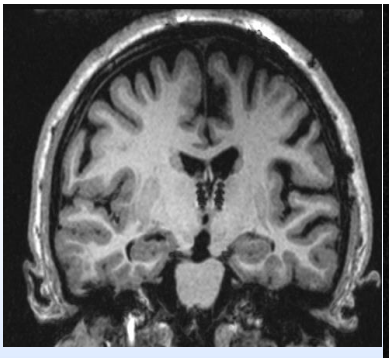
Not at Mayo, different patient

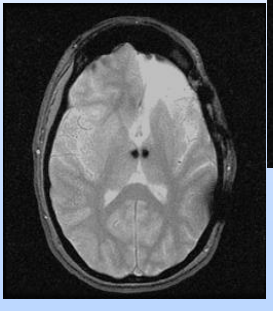
Reported thermal injury from DBS in literature:

Neurosurgery 2005



MAYO CLINIC





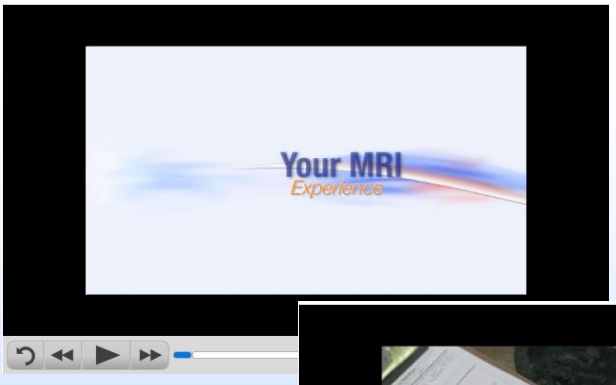
How reliable was the patient, given frontal lobe surgery or some patients in general?

Repeat 1.5T MRI performed with DBS precautions to insure no subtle damage or hemorrhage

MAYO CLINIC

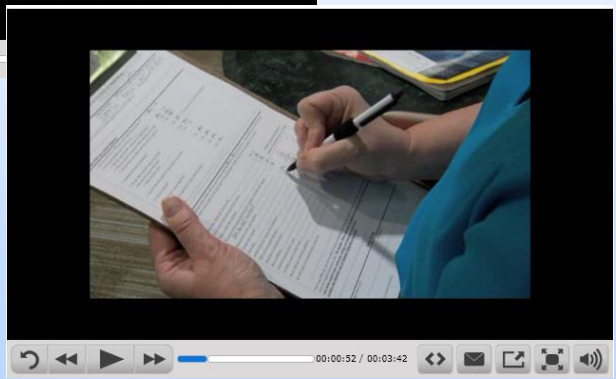
DBS event - responses

- Improved education for schedulers & MDs
- No ambiguity on MRI screening form permitted before proceeding
- Augmented patient information about potential dangers of implanted devices in patient appointment guides, with links to “MRI Experience” video
- Institution implementing Enterprise wide “Implanted Devices” module in electronic medical record



-The web link to the revised video Your MRI Experience is posted on all the MRI Patient Appointment Guides

QR code



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Allergies // Medications // Implanted Devices

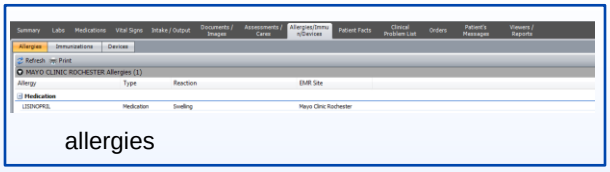
In contrast to the widely accepted need to reliably access a patient's

- allergies
- current medications

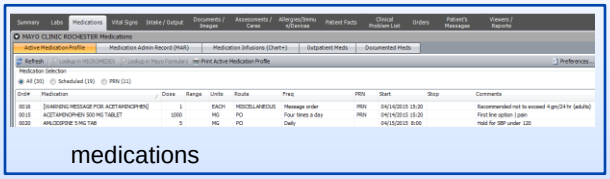
in a unique and defined site in the electronic health record (EHR), information about a patient's

- Implanted medical devices

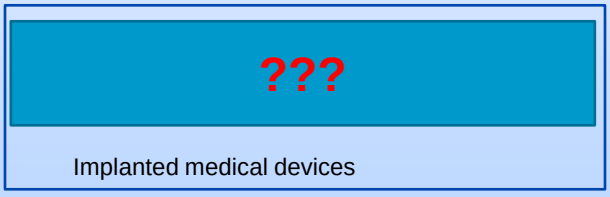
is frequently incomplete and fragmented across multiple locations in the EHR, clearly posing a patient safety risk.



allergies



medications



Implanted medical devices

for your allergy in the EMR slides

Diehn, Felix E., M.D.

Sent: Thu 10/1/2015 4:00 AM

To: Watson, Robert E. Jr., M.D., Ph.D. [RO EAST]

MAYO CLINIC ROCHESTER Allergies

Allergy	Reaction
Food	
CATS	

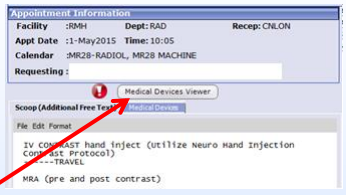
MAYO CLINIC

Devices Module // MRI

MRI Safety check and exam protocoling

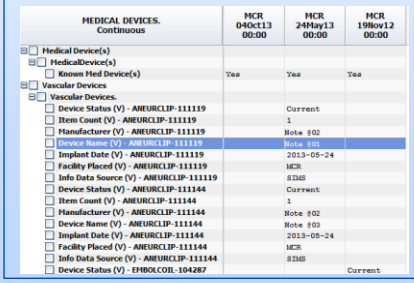
Orange flag in MRI patient list identifies presence of "high risk" device

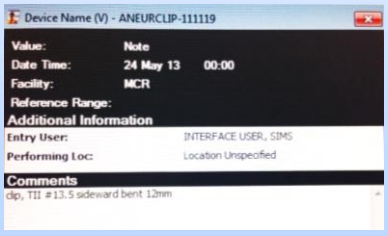
Devices module provides alerts to the presence of MRI high risk devices with and



When protocoling MRI exam, again alerts that a "high risk" device is present.

Clicking on this tab brings up screens below; in this case, identifying presence and type of an implanted aneurysm clip.





ARTICLE IN PRESS

CASE STUDIES IN CLINICAL PRACTICE MANAGEMENT

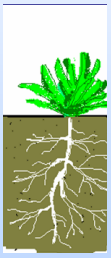
Implementing an Electronic Health Record Medical Device Module—A Critical Patient Safety Enhancement

Robert E. Watson, MD, PhD, Connie M. Cradick, PMP, Samanthie Epps, MBA, William D. Mauck, MD, Patrick H. Luetmer, MD

Transition to new EHR 2017/2018 –
Proactively working to transition device data to new platform

MRI Safety Events

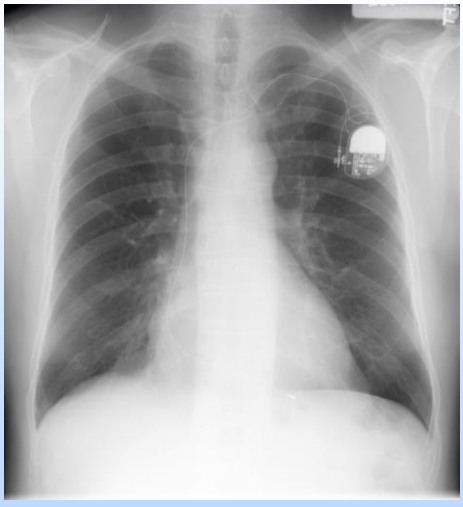
- Projectiles
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - Potential – patient cart (2x)
  - Potential – ferromagnetic oxygen tank



- Environment
  - Accidental quench – inadequate button cover
- Patient care
  - Sedated patient event
  - Foil backed clonidine patch removal
  - Unread orbit screening exam
- Devices
  - **Unrecognized cardiac pacemaker leads**
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator

MAYO CLINIC

Patient with abandoned lead scanned without precautions.



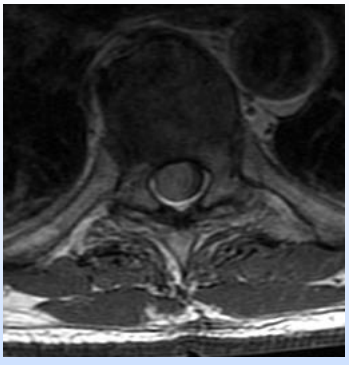
Pacemaker patient presented with myelopathic symptoms

Thoracic spine scanned with pacemaker precautions

MAYO CLINIC

Pacemaker patient scanned successfully with pacemaker precautions

Thoracic meningioma



- After tumor resection, decided that pacemaker no longer needed, and pulse generator explanted. Lead remains.

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Patient returns for post tumor resection followup MRI following removal of pulse generator – but with retained lead

WARNING: Certain implants, devices, or ob
MR procedure (i.e., MRI, MR angiography, func
or MR environment if you have any question or
Technologist or Radiologist BEFORE entering th

Please indicate if you have any of the following:

❒ Yes	❒ No	Aneurysm clip(s)
❒ Yes	☒ No	Cardiac pacemaker
❒ Yes	❒ No	Implanted cardioverter defibrillator (ICD)
❒ Yes	❒ No	Electronic implant or device
❒ Yes	❒ No	Magnetically-activated implant or device
❒ Yes	❒ No	Neurostimulation system
❒ Yes	❒ No	Spinal cord stimulator
❒ Yes	❒ No	Internal electrodes or wires
❒ Yes	❒ No	Bone growth/bone fusion stimulator
❒ Yes	❒ No	Cochlear, otologic, or other ear implant
❒ Yes	❒ No	Insulin or other infusion pump
❒ Yes	❒ No	Implanted drug infusion device
❒ Yes	❒ No	Any type of prosthesis (eye, penile, etc.)
❒ Yes	❒ No	Heart valve prosthesis
❒ Yes	❒ No	Eyelid spring or wire
❒ Yes	❒ No	Artificial or prosthetic limb
❒ Yes	❒ No	Metallic stent, filter, or coil

-Root causes

- No note in order that patient had retained lead
- MRI safety screening form did not specifically inquire about retained leads
- Patient did not disclose on oral screening that lead was present
- Prior MRI report failed to mention pacemaker precautions

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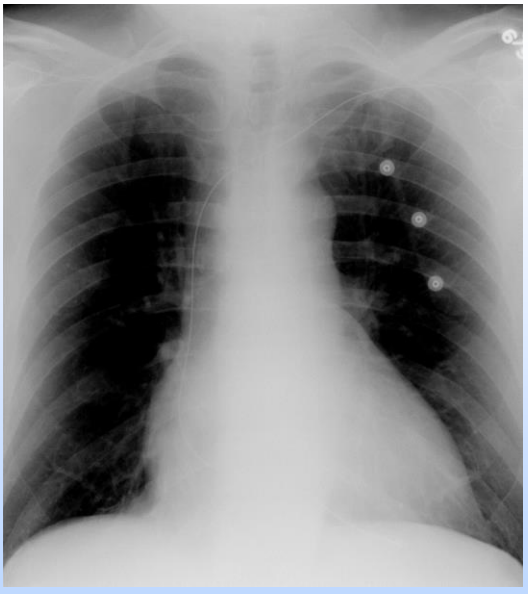

MAYO CLINIC

JOURNAL OF MAGNETIC RESONANCE IMAGING 33:426–431 (2011)

Original Research

Pacemaker Lead Tip Heating in Abandoned and Pacemaker-Attached Leads at 1.5 Tesla MRI

Deborah A. Langman, PhD,[1,2]* Ira B. Goldberg, PhD,[3] J. Paul Finn, MD,[1,2] and Daniel B. Ennis, PhD[1,2]

Purpose: To assess the risk of RF-induced heating in pacemaker-attached and abandoned leads using in vitro temperature measurements at 1.5 Tesla as a function of lead length.

Materials and Methods: Five custom lead lengths, 20–60 cm, were exposed to a uniform magnitude and phase radiofrequency electric field to examine the effect of lead length on pacemaker lead tip heating for pacemaker-attached and abandoned pacemaker leads.

Results: Abandoned and pacemaker-attached leads show resonant heating behavior and maximum heating occurs at different lead lengths due to the differences in termination conditions. For clinical lead lengths (40–60 cm) abandoned leads exhibited greater lead tip heating compared with pacemaker-attached leads.

Conclusion: Current recommendations for MRI pacemaker safety should highlight the possible increased risk for patients with abandoned leads as compared to pacemaker-attached leads.

Key Words: magnetic resonance imaging; medical device safety; pacemaker; RF-induced heating; abandoned leads
J. Magn. Reson. Imaging 2011;33:426–431.

are being precluded from diagnosis by MRI due to safety concerns about the interaction between the device and the static magnetic field (B_0), gradient magnetic field (dB/dt), and radiofrequency (RF or B_1) magnetic field used in MRI (2).

Since the first report of harmful interactions between MRI and pacemakers in 1983 there have been significant advances in pacemaker design (3). Pacemaker manufacturers have reduced the amount of ferromagnetic material, which has significantly reduced the risk of device displacement due to the static magnetic field (4). The risk of cardiac stimulation from currents induced by the gradient magnetic field has also been largely mitigated by the ability to program pacemakers to a nonsensing mode during an MRI procedure (5). Research into the risks of gradient-induced stimulation, however, is still on-going. Currently, for the newer generation of devices, the most substantial risk for patients with pacemakers arises from the RF field, which has been shown to cause pacemaker lead tip heating at the myocardial interface (6–8).

The RF field in MRI is a circularly polarized magnetic field that rotates at 64 MHz in 1.5 Tesla (T) MRI systems. The continual rotation of the RF magnetic

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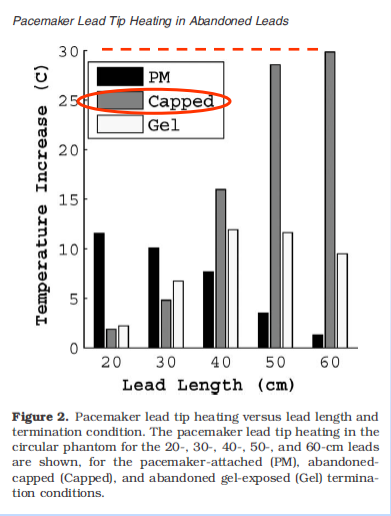

Figure 2. Pacemaker lead tip heating versus lead length and termination condition. The pacemaker lead tip heating in the circular phantom for the 20-, 30-, 40-, 50-, and 60-cm leads are shown, for the pacemaker-attached (PM), abandoned-capped (Capped), and abandoned gel-exposed (Gel) termination conditions.

In conclusion for a uniform electric field exposure, abandoned pacemaker leads, either capped or gel exposed, exhibit greater lead tip heating than pacemaker-attached leads for clinical lead lengths (40 to 60 cm) at 1.5T.

Both abandoned leads and pacemaker-attached leads show resonant heating behavior; however, maximum heating occurs at different lead lengths due to the differences in termination conditions.

Patients with abandoned leads may be at a greater risk for RF-induced thermal damage due to MRI exposure and risk assessment is complicated by the inability to fully monitor the effect of the MRI exposure for abandoned leads by measuring the pacing capture threshold.

Additional work is needed to establish whether current safety recommendations for MRI scanning of patients with implanted pacemakers can be applied to the safe scanning of patients with abandoned pacemaker leads.

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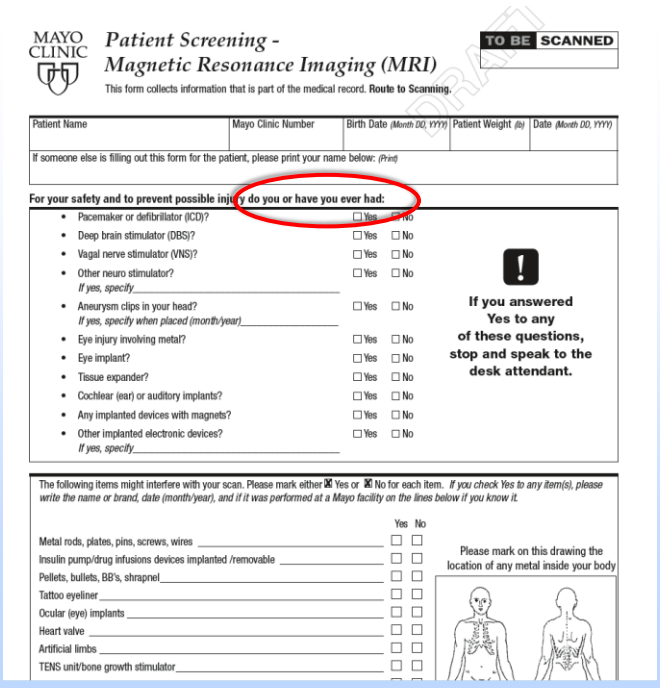
Change in practice

- Change MRI safety questionnaire

  - "Have you **EVER** had a pacemaker"

- Encourage inclusion of "technical note" at start of radiology report
  - *"Due to presence of retained intracardiac pacemaker leads, patient was scanned in presence of Cardiology personnel with monitoring, with MRI physics support…"*



MAYO CLINIC

Patient Screening -
Magnetic Resonance Imaging (MRI)

TO BE SCANNED

This form collects information that is part of the medical record. **Route to Scanning.**

Patient Name	Mayo Clinic Number	Birth Date (Month DD, YYYY)	Patient Weight (lb)	Date (Month DD, YYYY)

If someone else is filling out this form for the patient, please print your name below: (Print)

For your safety and to prevent possible injury do you or have you ever had:

- Pacemaker or defibrillator (ICD)? ☐ Yes ☐ No
- Deep brain stimulator (DBS)? ☐ Yes ☐ No
- Vagal nerve stimulator (VNS)? ☐ Yes ☐ No
- Other neuro stimulator? ☐ Yes ☐ No
  If yes, specify
- Aneurysm clips in your head? ☐ Yes ☐ No
  If yes, specify when placed (month/year)
- Eye injury involving metal? ☐ Yes ☐ No
- Eye implant? ☐ Yes ☐ No
- Tissue expander? ☐ Yes ☐ No
- Cochlear (ear) or auditory implants? ☐ Yes ☐ No
- Any implanted devices with magnets? ☐ Yes ☐ No
- Other implanted electronic devices? ☐ Yes ☐ No
  If yes, specify

If you answered Yes to any of these questions, stop and speak to the desk attendant.

The following items might interfere with your scan. Please mark either ☒ Yes or ☒ No for each item. *If you check Yes to any item(s), please write the name or brand, date (month/year), and if it was performed at a Mayo facility on the lines below if you know it.*

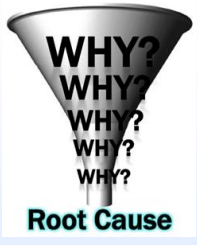
	Yes	No
Metal rods, plates, pins, screws, wires	☐	☐
Insulin pump/drug infusions devices implanted /removable	☐	☐
Pellets, bullets, BB's, shrapnel	☐	☐
Tattoo eyeliner	☐	☐
Ocular (eye) implants	☐	☐
Heart valve	☐	☐
Artificial limbs	☐	☐
TENS unit/bone growth stimulator	☐	☐

Please mark on this drawing the location of any metal inside your body

Improving MRI Safety Screening form

MRI Safety Events

- Projectiles
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - Potential – patient cart (2x)
  - Potential – ferromagnetic oxygen tank



- Environment
  - Accidental quench – inadequate button cover
- Patient care
  - Sedated patient event
  - **Foil backed clonidine patch removal**
  - Unread orbit screening exam
- Devices
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator

Transdermal Medication Patches

SEE THE BIGGER PICTURE!

- RF energy can cause foil to heat
- If using T/R head or extremity coil, removal unwarranted
- When patch removed, clear handoff communication is mandatory to assure it's reapplied properly.
- Recent event…
- Clonidine patch removed without communication handoff to floor
- Led to hypertensive episode
- Practice change: only nurses manage a medication patch including removing, replacing & documenting

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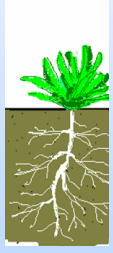
MRI Safety Events

- Projectiles
  - Inpatient – tracheostomy stylet
  - Outpatient – eyeglasses case
  - Cleaning staff – mop
  - Inpatient – Flashlight
  - Anesthesia – needle
  - Equipment Services/Maintenance – Screwdriver
  - Potential – patient cart (2x)
  - Potential – ferromagnetic oxygen tank

Enterprise Event Sharing



- Environment
  - Accidental quench – inadequate button cover
- Patient care
  - Sedated patient event
  - Foil backed clonidine patch removal
  - Unread orbit screening exam
- Devices
  - Unrecognized cardiac pacemaker leads
  - Unrecognized vagal nerve stimulator
  - Unrecognized Pillcam
  - Unrecognized deep brain stimulator

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Enterprise Event Sharing

Pad QC Program
Technologist requests anytime

Biannual QC Program

FDA poster on MRI Burn Prevention (Partnership with SMRT)

Quick reference for how to avoid burns

Mentions several suggestions from

The Joint Commission

Sentinel Event Alert

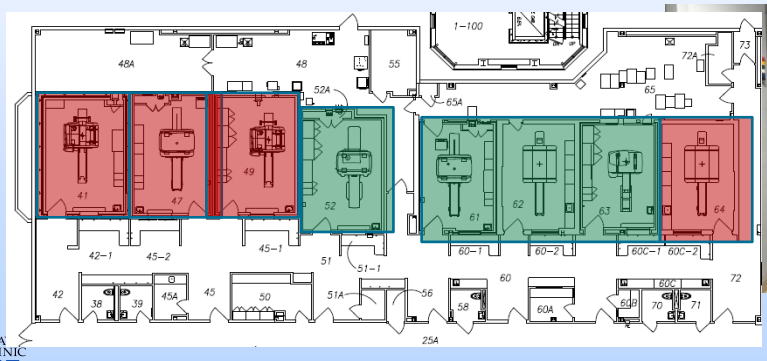
Issue 38, February 14, 2008

Preventing accidents and injuries in the MRI suite

- 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 non-conductive foam padding to insulate the patient's skin and tissues.

Technologist Safety Concerns: "Bowling Alley"

- Mix of vendors, mix of field strengths
- "Where am I working???"
- Distracting environment
- New Signage
- Avoid scheduling implants to that row of scanners

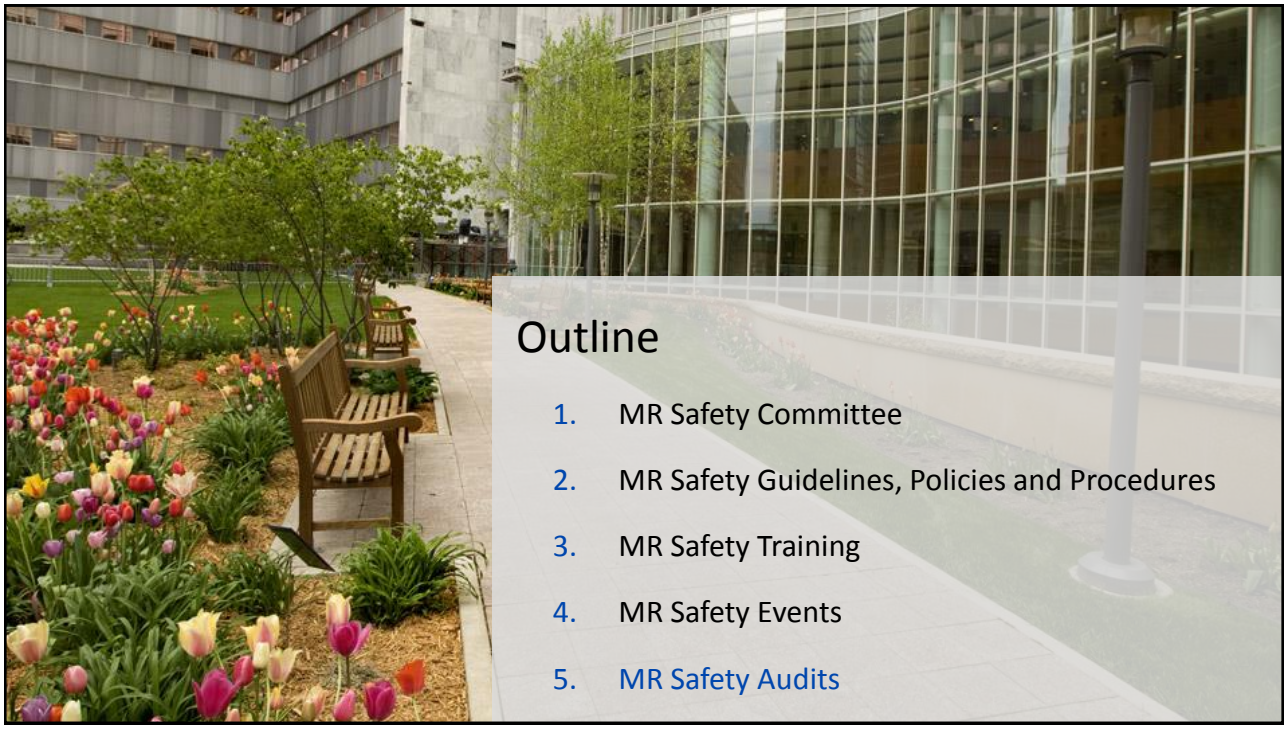


Joint Commission Sentinel Event Alert #38, recommends the following precautions to prevent patient burns during scanning:

A. Ensure that no items are formed into a loop
B. Modify the pulse sequence to minimize RF deposition.
C. Use non-conductive padding to insulate patient from contact with the scanner bore.

20%	1.	C only
20%	2.	A and B
20%	3.	A and C
20%	4.	B and C
20%	5.	A, B, and C

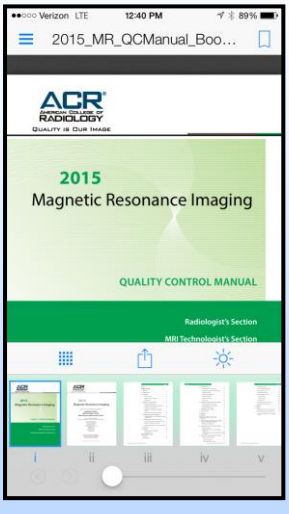
10



Outline

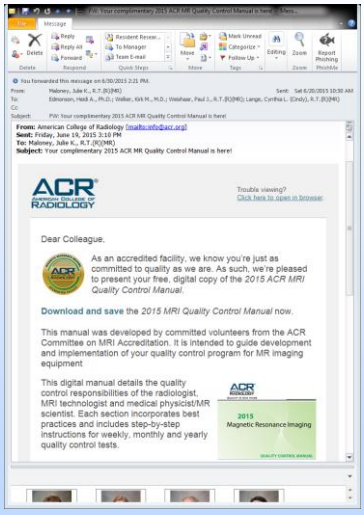
1. MR Safety Committee
2. MR Safety Guidelines, Policies and Procedures
3. MR Safety Training
4. MR Safety Events
5. MR Safety Audits

New ACR Quality Control Manual for MRI



Requirements go into effect July 1, 2016

"Technologist Contact Person" should have received a link to the digital copy:



Dear Colleague,

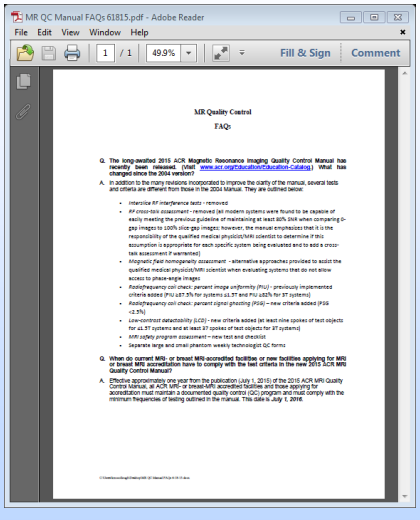
As an accredited facility, we know you're just as committed to quality as we are. As such, we're pleased to present your free, digital copy of the *2015 ACR MRI Quality Control Manual*.

Download and save the *2015 MRI Quality Control Manual* now.

This manual was developed by committed volunteers from the ACR Committee on MRI Accreditation. It is intended to guide development and implementation of your quality control program for MR imaging equipment

This digital manual details the quality control responsibilities of the radiologist, MRI technologist and medical physicist/MR scientist. Each section incorporates best practices and includes step-by-step instructions for weekly, monthly and yearly quality control tests.

FAQ document on ACR website
Describes changes between 2004 and 2015 versions



Q. The long-awaited 2015 ACR Magnetic Resonance Imaging Quality Control Manual has recently been released. (Visit www.acr.org/Education/Education-Catalog.) What has changed since the 2004 version?

A. In addition to the many revisions incorporated to improve the clarity of the manual, several tests and criteria are different from those in the 2004 Manual. They are outlined below:

- *Interslice RF interference tests* - removed
- *RF cross-talk assessment* - removed (all modern systems were found to be capable of easily meeting the previous guideline of maintaining at least 80% SNR when comparing 0-gap images to 100% slice-gap images; however, the manual emphasizes that it is the responsibility of the qualified medical physicist/MRI scientist to determine if this assumption is appropriate for each specific system being evaluated and to add a cross-talk assessment if warranted)
- *Magnetic field homogeneity assessment* - alternative approaches provided to assist the qualified medical physicist/MRI scientist when evaluating systems that do not allow access to phase-angle images
- *Radiofrequency coil check: percent image uniformity (PIU)* - previously implemented criteria added (PIU ≥87.5% for systems ≤1.5T and PIU ≥82% for 3T systems)
- *Radiofrequency coil check: percent signal ghosting (PSG)* – new criteria added (PSG <2.5%)
- *Low-contrast detectability (LCD)* - new criteria added (at least nine spokes of test objects for ≤1.5T systems and at least 37 spokes of test objects for 3T systems)
- *MRI safety program assessment* – new test and checklist
- Separate large and small phantom weekly technologist QC forms

MR Safety Program Assessment (pgs 111-113)

luminance values should be ≥ 90%.

The resolution, linearity, contrast, and distortion criteria described above should be met.

For more details regarding evaluation of the SMPTE test pattern, see Medical Physicist/MRI Scientist's Appendix, Section VI.C.

MEDICAL PHYSICIST'S/ MRI SCIENTIST'S SECTION

F. MR Safety Program Assessment

OBJECTIVE

To minimize risks in the MR environment to patients, health care professionals, and any others that may encounter the fields of the MR scanner, each site must establish, implement, and maintain current safety policies and procedures. Information regarding establishment of a quality MR safety program can be found in the ACR Guidance Document for Safe MR Practices: 2013 [35]. The hazards in the MRI suite maybe divided into three categories: 1) facility design, 2) operational, and 3) clinical. Facility design refers to the facility layout in which zones are identified with appropriate signage and strategies for controlled access. Operational refers to procedures for screening both personnel and objects that may be introduced to the MR suite. Clinical refers to procedures that can be used to determine the MR safety and compatibility of implants and other medical devices.

IV. Annual MRI System Performance Evaluation

METHOD

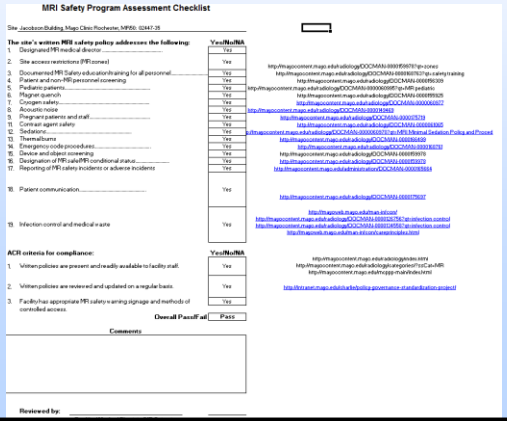
At the time of the annual performance testing, the qualified medical physicist/MRI scientist must review the site's written safety policies and determine that the written policies are readily accessible to facility staff. The categories listed below should be addressed in the policies.

CRITERIA FOR COMPLIANCE

1. Written policies and procedures are present and are being reviewed and updated on a regular basis.
2. Facility has appropriate signage and methods of controlled access.
3. Documentation of regular MR safety training for all MR-designated personnel.

ACR 2015 New Requirements

- Additional form for Annual Report
- Sent to sites two weeks prior to Annual Testing
- Keep links to policies in the spreadsheet for easy review



MRI Safety Program Assessment Checklist

Site:

The site's written MRI safety policy addresses the following:	Yes/No/NA
1. Designated MR medical director	
2. Site access restrictions (MR zones)	
3. Documented MR Safety education/training for all personnel	
4. Patient and non-MR personnel screening	
5. Pediatric patients	
6. Magnet quench	
7. Cryogen safety	
8. Acoustic noise	
9. Pregnant patients and staff	
11. Contrast agent safety	
12. Sedations	
13. Thermal burns	
14. Emergency code procedures	
15. Device and object screening	
16. Designation of MR safe/MR conditional status	
17. Reporting of MR safety incidents or adverse incidents	
18. Patient communication	
19. Infection control and medical waste	

ACR criteria for compliance:	Yes/No/NA
1. Written policies are present and readily available to facility staff.	
2. Written policies are reviewed and updated on a regular basis.	
3. Facility has appropriate MR safety warning signage and methods controlled access.	
Overall Pass/Fail	

Comments

Reviewed by: _____ _____
Qualified Medical Physicist/MR Scientist Date

ACR 2015 New Requirements

- QMP "must review the site's written safety policies and determine that the written policies are readily accessible to facility staff."
- Is the QMP reviewing for content?
  - No: QMP is not necessarily familiar with site's processes and procedures
  - No: QMP is not qualified to assess quality of policies on:
    - Pediatric patients (sedation, anesthesia)?
    - Pregnant patient medical decision making
    - Cryogen safety (deliveries, refills)
    - Contrast agent safety, esp with new info coming out every day
    - Infection control and medical waste
- QMP is reviewing for existence and to make sure updates are being made

MRI Safety Program Assessment Checklist

Site:

The site's written MRI safety policy addresses the following:	Yes/No/NA
1. Designated MR medical director	
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2. Written policies are reviewed and updated on a regular basis.	
3. Facility has appropriate MR safety warning signage and methods controlled access.	
Overall Pass/Fail	

Comments

Reviewed by: _____ _____
Qualified Medical Physicist/MR Scientist Date

The ACR 2015 MRI Quality Control Manual MRI Safety Program Assessment Checklist should include a review of the following policies **EXCEPT**:

20%	1. Contrast Agent Safety
20%	2. Cryogen Safety
20%	3. Pediatric patients
20%	4. Pregnant patients
20%	5. Obese patients and patient lifts

Answer: Obese patients and patient lifts

Reference: American College of Radiology 2015 Magnetic Resonance Imaging Quality Control Manual, page 112.

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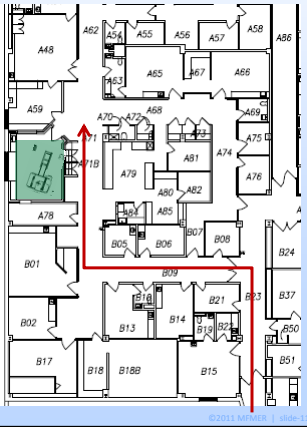
Findings from initial MRI Safety Program Assessments

- RST – Policy regarding pregnant staff had vanished (not specifically requested for MRI in "Toolkit for Practice Sites")
- Helpful for obtaining approvals for construction
  - Acquired hospital came Zone III-free
  - Sign off on "Facility has appropriate…methods controlled access"?
- Review with Mobile MRI Technologist:
  - Patients were changing in scan room (Zone IV) for privacy
  - Patient screening challenges lack of access to medical records



MR Safety Policies and Procedures should include considerations for the following **EXCEPT**:

20%	1. MRI Staff Training
20%	2. MRI emergency response
20%	3. MRI Imaging Protocol Review
20%	4. Patient screening criteria
20%	5. Non-MRI-staff screening criteria

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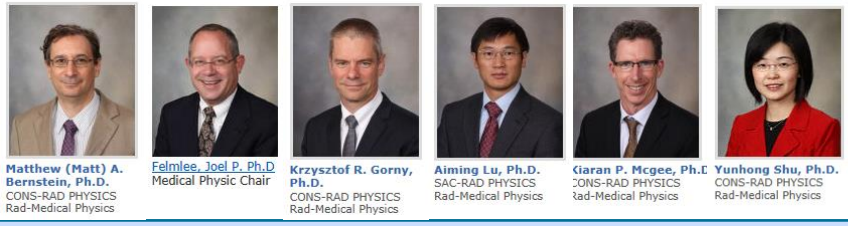
Thank you!

Thanks to my fellow Clinical MRI Physicists:



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