MRI Safety: Inherent Dangers and Preventative Measures

Thursday, February 13th, 2014
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Learning Objectives

1. Explain the TJC sentinel event alert that was issued for preventing accidents and injuries in the MRI suite

2. Describe recommendations to improve MRI safety
Hoag Hospital in California fined by state Dept of Public Health after patient was taken to MRI on a metal gurney

Patient was pulled into the imaging machine breaking her lower leg

Leg was trapped for three minutes and spent 3 days in the hospital and magnet quenched

Had adopted new procedure and checklist before entering MRI room

Has installed cameras for monitoring

Fined $50,000 in 2010
Hoag fined in MRI accident

By COURTNEY PERKES
THE ORANGE COUNTY REGISTER
cperkes@ocregister.com

Hoag Hospital has been fined $50,000 by the state Department of Public Health after an MRI patient on a metal gurney was magnetically pulled into the imaging machine, the hospital said Friday.

In a memo to staff, Dr. Richard Atable, chief executive officer of Hoag Memorial Hospital Presbyterian, described the scenario and policy changes to prevent future incidents. He was in Los Angeles on Friday and could not be reached for comment.

Atable said that last January a woman was taken into an MRI room on a metal gurney that was not compatible with the machine. The powerful magnet in the MRI pulled the gurney into the machine and the patient's leg was trapped for about three minutes. She was taken to the emergency room and spent three days in the hospital for treatment of fractures in her lower leg and foot.

Hoag failed to follow its policy of not allowing gurneys that are not MRI safe in the hallways outside the testing room, Atable said. The hospital has adopted new procedures including a checklist that must be done before entering the MRI room and installation of a camera for
MAUDE EVENT REPORT (FOI)

SORTED BY DATE OF EVENT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2243669-2009-00002
Mfr Name: SIEMENS MEDICAL SOLUTIONS USA, INC.

Event Date (B3): 12-Jan-2009
Report Date (B4): 13-Jan-2009
Report Date (F8): 13-Jan-2009
Date Mfr Rec’d (G4): 13-Jan-2009

Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): N
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): NA - NOT APPLICABLE
Device Operator: HEALTH PROFESSIONAL
Event Location (F12):
Report Source (G3): USER FACILITY

Product Code: (RA)-SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING (LMH)
Device Age (F9):
Expiration Date:

Manufacture Date (H4):
Single Use (H5): N
Device Usage (H8): ^

Event Description (B5):

Concomitant Medical Products:

Mfr Name: SIEMENS AG
Address: 127 HENKESTRASSE ERLANGEN GERMANY

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H8):
Additional Mfr Narrative (H10 & H11):
Prevention Costs Less

- “The costs of the safety provision to help prevent these accidents are peanuts when compared to the costs of accidents”

- Do you use a ferromagnet detector?

- Cost to restore the magnet after the quench, cost of down time, and lost revenue, lawsuit costs, fines, cost to investigate is greater than cost of prevention

- Source: Gurney Crashes MRI, Patient Injured, Hospital Fined $50 K, Tobias Gilk, MRI Safety Director, Mednovus Inc., MRI Metal Detector Blog
Officer Hurt When MRI Pulls Gun

Police Say Off-Duty Officer Was At Beaches Open MRI With Her Mom

POSTED: Thursday, October 1, 2009

JACKSONVILLE, Fla. -- An off-duty Jacksonville Sheriff's Office deputy was hurt Wednesday when her hand was trapped between her police-issued Glock handgun and the powerful magnet inside an MRI machine.

Police said Joy Smith was in the MRI room with her mother when she apparently forgot about her gun, which was pulled by the magnetic force of the machine, trapping her hand between the gun and the MRI.

Smith was able to free herself, but the gun remained stuck for hours while the machine was powered down, which takes 24 hours. Jacksonville Beach police said Smith's hand was injured and she had difficulty bending her thumb, but it was not known if she sought medical treatment.

"It's a huge magnet. The whole thing just has a plastic case around it," said Beth Ratliff, who operates the MRI machines at Shands.
Scissors in Forehead

- Flying scissors had be surgically removed from technologist’s forehead
- This is not the real x-ray of the injury that occurred
- http://mrimetaldetector.com/blog/tag/maude/
- Thanks to Tobias Gilk for his input on this presentation
Death of Engineer by MRI

- Field engineer called to fix blower motor due to MRI making noise
- Arrived at 2100 and guard check and no response and he left after making no investigation
- Found next day dead pinned by MRI machine
- Reported to GE Healthcare

IV Cart in MRI Machine

FDA Notification

Recent Incident Published by the FDA

Device:
Type: MRI, 1.5t
Manufacturer: Philips Medical Systems
Brand: Philips Achieva

Problem:

IV nurse entered MRI suite and brought her metal IV cart halfway in doorway of MRI suite. The force of the MRI magnet caused the IV cart to lift up and it flew through the air, on to the MRI machine. Patient was lying outside of the MRI, on the MRI table at the time. The cart did not hit him. Another Nurse was on right side of patient and was looking for venous access in his right arm at the time of the incident. She was not injured. No injury for any individual - lots of potential for injury!

The IV nurse had been called to access the patient located in MRI. She did not realize the power of the MRI magnet especially when the patient was not in the MRI. She intended to leave the cart at the door, but should not have entered the room.

This is being reported not because of a device malfunction but as an alert of an incident regarding an MRI and need for better vigilance and perhaps education regarding the fact that MRI magnets are ALWAYS on and the need for better safety.

October 10, 2009 MRI Risk Assessment Newsletter
FDA’s Data from Maude

- 4th consecutive year with substantial increases in rates of MRI accidents
  - A 30 percent increase from last year
  - This was an increase in the number of reports to FDA of MRI accidents
- There was a 240 percent increase from 2004 to 2008
- There are at least 148 reports from MRIs
- One expert suggests this represents about 14,800 real world accidents

Source: http://mrimetaldetector.com/blog/?p=329

MRI Scanner Eats an ICU Bed
FDA MAUDE Database

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm
The FDA has a MRI website that includes information on the following:

- Uses and description
- Risks and benefits
  - Dyes from tattoos or tattooed eye liner
- Information for patients
- Information for professionals, laws, standards
  - MRI safety, MRI contrast agents containing gadolinium, and nephrogenic fibrosis dermopathy, injuries with implanted stimulators, burns with transdermal patches, cable and electrode burns
A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DRAFT DOCUMENT
This document is being distributed for comment purposes only.
CDRH Magnetic Resonance Working Group
Draft released for comment on: February 7, 1997

The Federal Register notice reopening the comment period for this document was published May 22, 1997, and extends the comment period to August 29, 1997. Comments and suggestions regarding this draft document should be submitted to Ms. Felecia Skippec, Office of Science and Technology, HFZ-133, 12721 Twinbrook Pkwy, Rockville, MD 20852. Comments and suggestions received after August 29, 1997, may not be acted upon by the Agency until the document is next revised or updated. For questions regarding this draft document, contact Ms. Skippec at (301) 443-3649.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

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1.0 Scope/Purpose
MRI (Magnetic Resonance Imaging)

Description
- Magnetic resonance imaging (MRI) is a medical imaging procedure that uses strong magnetic fields and radio waves to produce cross-sectional images of organs and internal structures in the body. Because the signal detected by an MRI machine varies depending on the water content and local magnetic properties of a particular area of the body, different tissues or substances can be distinguished from one another in the study image.
- MRI can give different information about structures in the body than can be obtained using a standard x-ray, ultrasound, or computed tomography (CT) exam. For example, an MRI exam of a joint can provide detailed images of ligaments and cartilage, which are not visible using other study types. In some cases, a magnetically active material (called a contrast agent) is used to show internal structures or abnormalities more clearly.

Uses
- Using MRI scans, physicians can diagnose or monitor treatments for a variety of medical conditions, including:
  - Abnormalities of the brain and spinal cord
  - Tumors, cysts, and other abnormalities in various parts of the body
  - Injuries or abnormalities of the joints
  - Certain types of heart problems
  - Diseases of the liver and other abdominal organs
  - Causes of pelvic pain in women (e.g. fibroids, endometriosis)
  - Suspected uterine abnormalities in women undergoing evaluation for infertility

Risks/Benefits
- MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA, like the x-rays used in CT scans).
- There are no known harmful side-effects associated with temporary exposure to the strong magnetic field used in MRI procedures.
A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm
TJC MRI Safety Standards

- TJC implements safety standards for hospitals to manage the safety risks with MRI
- Effective July 1, 2014
- Must manage safety risks regarding;
  - Patients with anxiety or claustrophobia
  - Patients who need urgent or emergent medical care
  - Patients with medical implants, devices, or imbedded FO such as shrapnel
  - Acoustic noise and ferromagnetic objects entering the room
Revised Requirements for Diagnostic Imaging Services

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective July 1, 2014

Environment of Care (EC)

Standard EC.02.01.01
The [critical access] hospital manages safety and security risks.

Elements of Performance for EC.02.01.01

A.14. For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital manages safety risks in the MRI environment associated with the following:

- Patients who may experience claustrophobia, anxiety, or emotional distress
- Patients who may require urgent or emergent medical care
- Patients with medical implants, devices, or imbedded foreign objects (such as shrapnel)
- Ferromagnetic objects entering the MRI environment
- Acoustic noise

A.16. For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital manages safety risks by doing the following:

- Restricting access of everyone not trained in MRI safety or screened by MRI-trained staff from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
- Making sure that these restricted areas are controlled by and under the direct supervision of MRI-trained staff.
- Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI unit, by its design, can have its magnetic field routinely turned on and off by the operator.

Standard EC.02.02.01
The [critical access] hospital manages risks related to hazardous materials and waste.

Element of Performance for EC.02.02.01

A.17. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: Staff dosimetry results are reviewed at least quarterly by the radiation safety officer or diagnostic medical physicist to assess whether staff radiation exposure levels are “As Low As Reasonably Achievable” (ALARA) and below regulatory limits.

Note 1: For the definition of ALARA, please refer to U.S. Nuclear Regulatory Commission federal regulation 10 CFR 20.1003.
TJC MRI Safety Standards

- Hospital must restrict access to room of those not screened or trained
- Make sure restricted areas are controlled by and under direct supervision of MRI trained staff
- Post signs by entrance to scanner about dangers of the magnet and that it is always on
- Also statement related to PET scan, CT, or nuclear medicine services that staff dosimetry results are reviewed quarterly by the radiation safety officer or medical physicist to assess staff radiation exposure levels to be as low as possible
TJC MRI Safety Standards

- HR must make sure technologist who does MRI participates in on-going education that includes annual training on safe MRI practices that include the following:
  - Patient screening criteria that addresses ferromagnetic item, medical implants and devices
  - Risk for nephrogenic systemic fibrosis (NSF)
  - Proper positioning to prevent burns
  - Equipment and supplies that are acceptable to use in MRI suite
TJC MRI Safety Standards

- Annual training on safe MRI practices that include the following (continued):
  - MRI safety response procedures for patient who require urgent or emergency medical treatment
  - MRI equipment emergency shutdown procedures
  - Patient hearing protection
  - Management off patients with claustrophobia, anxiety, or emotional distress
  - References ASTM standards
What is an MRI?

- Noninvasive medical imaging technique used primarily in radiology
  - Can be used to image anatomy in multiple planes or slices
  - Uses magnetic fields and not x-rays or ionizing radiation
  - Used to investigate the brain, spinal cord, and vertebrae and surrounding tissue
- Originally named *zeugmatography*
  - In Greek it means “that which is used for joining”
What is an MRI?

- Many hospitals now have MRI information on their website
- Best noninvasive way to view abnormalities in cartilage, tendons, and ligaments
  - Investigating the musculoskeletal system, particularly joints
- Image the eyes and sinuses
- Identify tumors throughout the body and ascertain their stage of development
- Evaluate large and medium-sized blood vessels
The Case that Everyone has Heard

- Six year old child had an MRI in a hospital in Valhalla, New York on July 31, 2001
- Metal oxygen cylinder brought into room
- Nurse thought canister was made of nonmagnetic material like aluminum
  - No special marking on tank
- 2011 was 10 year anniversary and it was MRI week
- Oxygen tank became a missile and was drawn into the magnetic core while boy still in the machine in 2001
The Case that Everyone has Heard

- Tank struck Michael Colombini in the head
  - Caused a fractured skull
  - Child died of fatal cerebral hemorrhage
- First fatal MRI accident of its kind
- Settlement agreement wants opportunity for others to learn from this incident (settled nine years later)
- Feb 2010 article states case is settled for $2.9 Million
- 2011 was 10 year anniversary and has MRI week

1 http://mrimetaldetector.com/blog/2010/02/2-9-million-settlement-closes-colombini-mri-death-case/
$2.9 Million Settlement Closes Colombini MRI Death Case

This week the settlement documents were released — closing the chapter on the lawsuit that arose from the seminal event in MRI safety, the 2001 oxygen tank fatality of then-six-year-old Michael Colombini.

Nearly nine years after the accident, the lawsuit was settled for $2.9 million, a settlement that was likely both diminished by, and made possible by, a pre-trial motion which excused GE Healthcare as a defendant to the suit.

The county-owned hospital, which almost immediately asserted its responsibility for the accident, ultimately settled the case on behalf of all of the remaining defendants, which included the head of radiology and the technologist who administered the boy’s scan.

Perhaps now, with the lawsuit resolved, we can actually learn something about the events that precipitated this tragedy, beyond the fragmentary slivers of information gleaned from court documents and news accounts.

That’s right, despite the fact that this one event has become the touchstone for MRI safety, there has not been a single root-cause analysis to inform MRI suite design, departmental operations, regulatory and accreditation frameworks... at least not one that has been shared with the public.

Hopefully, with the lawsuit resolved and jeopardy attached for all defendants, we can have an open conversation about what contributed to the accident and what can be done, at the thousands of MRI suites across the country, to help see that this
So What Happened? NQF Never Event

- Static magnetic field generated by MR systems attracts ferromagnetic objects with considerable force
- Material can be magnetized in the presence of an external magnetic field
- This causes the object, like the oxygen tank, to move toward it
  - Called the projectile effect
- 2011 NQF updates never events or serious reportable errors to include from metallic object into the MRI area
So What Happened?

- Every hospital should show the video of the oxygen cylinder crashing or the patient gurney crashing
- It is said that a picture is worth a thousand words
- Two-minute video to show the projectile effect
- Items pulled into MRIs
  - IV poles, mop buckets, chair, ladder, laundry cart, floor buffer, pulse ox transformer, tools, scissors, sand bags, and traction weights
  - Noted on MDR reports at the time of this occurrence (ECRI Hazard Report)

¹ http://www.mri-planning.com/
Other Cases

- Woman who had an aneurysm clip in her brain died after undergoing MRI
- Welder with piece of metal embedded in his eye blinded in that eye after MRI
- 60 year old man sustained fractures to face when oxygen canister became wedged in machine against his face (awarded $100,000 in damages)

Source: Web MD article August 1, 2001
Other Cases

- Off-duty policeman arrived to have MRI done
- He told technician he was carrying a firearm so Tech intended to meet him in the waiting area to secure the weapon
- Officer entered the MR scan room and put his gun on the cabinet 3 feet from the 1.5 T magnet bore
- Gun was pulled from his hand
- Gun hit left side of bore (inside) of MRI and fired a round into the back wall of the scan room
- Luckily no one was injured

Source: Safety Concerns in the MR environment, ECRI, May 2006
Other Cases

- Patient came into ED with sweatpants and track shoes and was sent to MRI
  - The patient was moved to the MRI scanner head first
  - His legs were lifted up so his face was in the MRI doughnut
  - The Patient had sandbag ankle weights
  - When his legs were lifted up, he screamed in pain
  - The magnet was quenched (quenching can cause asphyxiation, frostbite, fire hazard and can cost $20,000 to $500,000)
History

- First adult MRI occurred in 1977
- Today more than 10 million MRIs are done in the US every year
- MRI is among safest compared to many other diagnostic procedures (Strokowski, 2005)
- Many believe number of actual adverse events is higher than reported
- Numbers of adverse events are low considering how many are done
- Field of magnetic resonance imaging has seen tremendous progress in last 20 years\(^1\)

\(^1\)Dr. Emanuel Kanal, University of Pittsburg Medical Center, MR Safe Practice Guidelines
MRI-Related Events

- Many hardware and software advances and improving contrast agents

- In 2005, ECRI analyzed FDA’s data
  - MAUDE (Manufacturer and User Facility Device Experience Database) reported data over a 10-year time span of MRI injuries

- Study found 389 reports of MRI-related events

- Nine deaths from MRI studies
  - Three related to pacemaker failure, 2 incidents of insulin pump failure and 4 implant disturbances
  - One asphyxiation from a cryogenic mishap during installation of an MR imaging system
TJC Sentinel Event Alert

- The Joint Commission issued a 3 page Sentinel Event Alert (SEA) 38, February 14, 2008
- Preventing accidents and injuries in the MRI suite
  - Review all SEAs and implement
  - Have a committee to review and address
  - Institute a policy based on the Alert
  - This and ACR MR safety are the two industry recognized MRI safety practice standards
- Sign up to receive e-mail notice when Alerts are published
  www.jointcommission.org
TJC Sentinel Event Alert  MRI Safety

- TJC set out 10 recommendations which are discussed in detail later
  - Use 4 zones for safety
  - Use trained staff to screen any non-emergent patients twice
  - Provide ear plugs and hearing protection to all patients
  - Provide at least annual training regarding MRI safety to MR personnel
    - Provide non-MR staff and patients with material, such as a flier, that explains potential for adverse events
TJC 10 MRI Safety Recommendations

- Ensure there is complete medical history to ensure patient is safe to scan
- Have specially trained MR staff who are knowledgeable about all 4 zones and the MRI safety environment issues
- Take precautions to prevent burns
  - Cold compress or ice pack on EKG leads, surgical staples, tattoos or electrically conductive material
  - Ensure no electrically conductive loops are formed in the MR scanner bore
  - Use nonconductive foam pads to insulate patient’s skin
TJC 10 MRI Safety Recommendations

- Never code a patient in the MRI magnet room
- Proactively plan for managing critically ill patients who require monitoring
  - This may include monitoring of life sustaining drugs or other medications
- Use only MR safe equipment
  - Oxygen, fire extinguishers, physiologic monitors, wheelchairs etc.
- The article recognized there are 3 more recommendations
3 Additional Recommendations

- Recommended by Dr Emanuel Kanal, leading expert on MR Safety
  - Appoint a patient safety officer who is responsible for enforcing safety procedures in MRI suite
  - Implement safe practices system such as MRI safety P&P and periodically assess compliance with P&P
  - Do not bring anything into the MRI room unless proven to be MR safe or MR conditional
TJC Sentinel Event Alerts (SEA)

www.jointcommission.org/sentinel_event.aspx
Sentinel Event Alert, Issue 38: Preventing accidents and injuries in the MRI suite

February 14, 2003

Magnetic resonance imaging (MRI) was applied to health care in the late 1970s to provide never-before-seen two- and three-dimensional views of body tissue and structures. Today, more than 10 million MRI or MRT scans are done in the United States each year. While the capabilities of the MRI scanner are well-recognized, its inherent dangers may not be as well known.

Download complete issue.

Tobias Gill, MArch, 1 and Emanuel Kanal, MD 2

When, in 2006, the Joint Commission released its Sentinel Event Alert #38 regarding MRI safety, it joined the ACR’s Guidance Document on MR Safe Practices as one of two radiology best-practice documents establishing MRI safety protections. However, particularly for MRI providers who held both mobility-level accreditation from the ACR, and enterprise-level accreditation from the Joint Commission, there has been confusion about which organization’s standard takes precedence, or whether there are inherent conflicts between the two. With the release of the 2015 update to the ACR Guidance Document on MR Safe Practices, the authors have cross-referenced the performance criteria of both MRI safety standards, and correlated the ACR Guidance Document performance criteria with the Joint Commission’s Environment of Care standards.

Key Words: MRI safety; regulation; accreditation; standard of care; standard of practice; accident; injury; adverse event; Joint Commission; Sentinel Event Alert; American College of Radiology: Guidance Document on MR Safe Practices

This study coordinates the performance criteria from the Joint Commission’s Sentinel Event Alert #38: MRI Accidents and Injuries with the 2015 update to the ACR Guidance Document on MR Safe Practices. Beyond cross-referencing the shared performance criteria, this document also references those performance criteria of the 2013 ACR Guidance Document on MR Safe Practices which are also directly applicable to the Joint Commission’s Environment of Care (EC) standards for both hospital and ambulatory accredited service providers.

By dovetailing the two industry recognized MRI safety best practice documents, it is the authors’ intent that MR providers, as well as those with regulatory, accreditation, or license responsibility for quality and safety of healthcare providers, will be equally empowered to implement the agreed upon industry best practice standards which will provide appropriate protections to all in the MRI environment.

www.acr.org/Search?q=mri safety
9. The hospital has written procedures to follow in the event of a security incident, including an infant or pediatric abduction.

10. When a security incident occurs, the hospital follows its identified procedures.

11. The hospital responds to product notices and recalls. (See also MM.05.01.17, EPs 1-4)

14. For hospitals that provide magnetic resonance imaging (MRI) services: The hospital manages safety risks in the MRI environment associated with the following:
   - Patients who may experience claustrophobia, anxiety, or emotional distress
   - Patients who may require urgent or emergent medical care
   - Metallic implants and devices
   - Ferrous objects entering the MRI environment

16. For hospitals that provide magnetic resonance imaging (MRI) services: The hospital manages safety risks by doing the following:
   - Restricting access of everyone not trained screened by staff to an area that immediately precedes the entrance to the MRI scanner room
   - Making sure that this area is controlled by and under the direct supervision of MRI-trained staff
   - Posting signage at the entrance to the MRI scanner room that conveys that the magnet is always on
Seven Injuries that Can Occur in an MRI Suite
Missile or Projectile Effect

- Ferromagnetic or metal objects are pulled into the MRI scanner
- Patients must be instructed on what should be removed
- Check under the sheets if brought to MR on cart (canes, purses etc.)
- 10 percent of 389 adverse events were projectile related
Patients Should Remove

- Purse, wallet, money clip, credit cards, cards with magnetic strips
- Electronic devices such as beepers or cell phones
- Hearing aids
- Metal jewelry, watches
- Pens, paper clips, keys, coins
- Hair barrettes, hairpins
- Eye make up
Patients Should Remove

- Articles of clothing that have a metal zipper, buttons, snaps, hooks, under wires, or metal threads
- Shoes (especially ones with roller skates inside), belt buckles, safety pins
Projectile Objects

- The following have become projectiles in VA facilities as listed in their HR Hazard Summary
  - Oxygen cylinder, IV pole, transport stretcher, traction weight, floor buffer, wheelchair, file cabinet, drill, and patient walker
  - Patient lifts, stethoscopes, infusion pumps, pulse oximeters, tools, laundry carts, scissors, pens, hair barrettes, and more
  - Hairpins and paper clips near a 1.5 Tesla MRI can reach speeds of 40 mph
Prevention of Missile Effect

Safety Information

The information on this page is limited by the terms of our disclaimer. Please Read!

Prevention of "Missile Effect" Accidents

The "missile effect" refers to the capability of the fringe field component of the static magnetic field of an MR system to attract a ferromagnetic object, drawing it rapidly into the scanner by considerable force. Obviously, the missile effect can pose a significant risk to the patient inside the MR system and/or anyone who is in the path of the projectile. Furthermore, considerable damage to the MR system may result due to the impact of ferromagnetic object.

Therefore, a strict policy should be established by the MR facility to detect metallic objects prior to allowing individuals or patients to enter the MR environment in order to avoid accidents and potential injuries related to the missile effect. In addition, to guard against accidents from metallic projectiles, the immediate area around the MR system should be clearly demarcated, labeled with appropriate warning or danger signs, and secured by trained staff aware of proper MR safety procedures.

For patients preparing to undergo MR procedures, all metallic personal belongings (i.e., hearing aids, analogue watches, jewelry, etc.) and devices must be removed as well as clothing items that have metallic...
<table>
<thead>
<tr>
<th>Dislodged Implants</th>
<th>Implant Motion</th>
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<tbody>
<tr>
<td>Injury can occur from dislodged (or twisting) ferromagnetic implants</td>
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<tr>
<td>Implants include clips, like cerebral aneurysm clips, pins in joints, magnetic cochlear implants, and drug infusion devices</td>
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<tr>
<td>Long list of devices is on the screening form</td>
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<tr>
<td>Patients should be screened before MRI is done to prevent injury</td>
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Implant Motion

- Especially a concern with implants that are strongly ferromagnetic
  - Implant can move or dislodge
  - Determine if can wait several weeks for fibrous scarring to set in
- Implants that are nonferrous in nature the risk is reduced to those resulting from Lenz’s forces alone
  - Less important to have a waiting period
Burns

- Patients have been burned from objects that can heat up during the MR procedure
  - Called RF heating—induces currents in electrically conductive material
  - Burns from contact with conductive medical equipment cables (looped and unlooped EKG cables or pulse oximeter cable)
- Other objects that can cause burns
  - Surgical staples, the inside walls (the bore) of the MRI scanner during the scan, site of pulse ox sensor that touches patient’s skin, Nitro patches which contain foil and other transdermal patches or those that deliver testosterone
  - ISMP and FDA Safety News reported
Burns

- Rare reports of burns
  - At tattoo site (including eyeliner tattoo) since tattoos contain iron oxide or other substances that can thermally and electrically conductive
  - At or near the site of implantable infusion pumps
  - At conductive looped formed with body, such as finger touched their thigh, patient’s arms were crossed, or thighs were touching

- 70 percent of the 389 adverse events were burns!
Guidelines to Prevent Excessive Heating and Burns Associated with MRI Procedures

Guidelines to Prevent Excessive Heating and Burns Associated with Magnetic Resonance Procedures

Magnetic resonance (MR) imaging is considered to be a relatively safe diagnostic modality. However, damaged radiofrequency coils, physiologic monitors, electronically-activated devices, and external accessories or objects made from conductive materials have caused excessive heating, resulting in burn injuries to patients undergoing MR procedures. Heating of implants and similar devices may also occur, but this tends to be problematic primarily for objects made from conductive materials that have elongated shapes or that form loops of a certain diameter. For example, excessive MRI-related heating has been reported for leads, guidewires, certain types of catheters (e.g., catheters with thermistors or other conducting components), and certain external fixation or cervical fixation devices.

In the United States, many incidents of excessive heating have been
Device Malfunction

- Injury or complications related to equipment or device failure
  - Magnetic field can seriously affect operation, reliability, and accuracy of medical devices
  - Battery powered devices suddenly fail to operate
  - Monitors (increased t-wave or ST segment), infusion pumps, PCA pump, ventilator, and even laryngoscopes
Device Malfunction

- Injury or complications related to equipment or device failure
  - Programmable pumps may perform erratically
  - Pacemakers and implantable defibrillators may not behave as programmed (can pace at wrong point in cycle and rapid pacing can occur)
  - Otologic implants can become demagnetized, such as neurostimulators, cochlear implants, or ocular prostheses
Device Malfunction Recommendations

- American College of Radiology (ACR) recommends that implanted cardiac pacemakers and implantable cardioverter/defibrillators should be considered a relative contraindication for MRI
  - Later will cover website that lists each device and its risks

- Use ferromagnetic detectors that may help in screening patients for objects left on them
  - Recent study shows they are about 99 percent effective
Acoustic Injury

- Can be caused by the loud knocking of the MRI scanner
  - Patients should be given ear plugs or other hearing protection
- Sound can reach 130 decibels
  - Equivalent to jet engine take off
- Four of 380 TJC adverse events were acoustic injuries
- FDA MR Guidance Document says manufactures must state hearing protection is required for all patients
Acoustic Noise and MRI Procedures

Various types of acoustic noise are produced during the operation of an MR system. Problems associated with acoustic noise for patients and healthcare professionals include annoyance, verbal communication difficulties, heightened anxiety, temporary hearing loss and, in extreme cases, the potential for permanent hearing impairment.

Acoustic noise may pose a particular problem to specific patient groups. For example, patients with psychiatric disorders may become confused or suffer from increased anxiety as the result of exposure to loud noise. Sedated patients may experience discomfort in association with high noise levels.

In addition, neonates may have adverse reactions to acoustic noise. Reeves MJ, et al. (2010) recently conducted a study to address this issue. The findings suggested that exposure of the fetus to 1.5-T MR imaging during the second and third trimesters of pregnancy is not associated with an increased risk of substantial neonatal hearing impairment or cochlear injury.

HEARING AND THE IMPACT OF ACOUSTIC NOISE
The human ear is a highly sensitive wide-band receiver, with the typical frequency range for normal hearing being between 20-Hz to 20,000-Hz. The ear does not tend to judge sound powers in absolute terms, but
Image Artifacts

- Image artifacts can cause changes to MRI images due to:
  - RF emission from equipment picked up by the MR RF receiver
  - Examples include strips on the image or decrease in contrast
  - Presence of needles near imaging site (metal biopsy needles or mascara) can produce image artifacts and mask pathology
  - Unanticipated ferromagnetic implant or FB
    - Notify medical director, safety officer or physician in charge
Patient Support Systems

- Injury or complications can occur from failure to attend to patients during the procedure
  - Especially patients who have had sedation or anesthesia in the MRI arena

- Complications include:
  - Oxygen supply is depleted
  - IV solution on infusion pump is used up

- Never run a code in the MRI suite
Adverse Events from MRI Contrast

- Patients with severe renal failure are at risk for contrast-induced nephropathy
  - Can cause Nephrogenic Systemic Fibrosis (NSF) or Nephrogenic Fibrosing Dermopathy (NFD)
  - Important to know if patient has a history of renal or liver failure
  - Important to have kidney function test like patient in the ED has a BUN and creatinine before test done
MRI Contrast Injection - Patients with Renal Impairment

A. Interpreter / cultural needs
   - An Interpreter Service is required? [ ] Yes [ ] No
   - If Yes, is a qualified Interpreter present? [ ] Yes [ ] No
   - A Cultural Support Person is required? [ ] Yes [ ] No
   - If Yes, is a Cultural Support Person present? [ ] Yes [ ] No

B. Procedure
   The following will be performed (Doctor / delegate to document - include site and/or side where relevant to the procedure):

   MRI contrast is a colourless liquid that is injected into your blood stream. MRI contrast is not actually a dye. It does not stain the inside of your body. It is used during MRI medical imaging procedures to allow your organs to be seen more clearly.

   You have been identified as having renal impairment (weakened kidneys) through the questions asked by staff and by having a blood test. People whose kidneys are poorly functioning (known

   - The injection may not be possible due to medical and/or technical reasons.

   Rare risks and complications include:
   - Allergic reactions occur within the first hour with most happening in the first 5 minutes. The reactions vary from:
     - Mild - headache, brief nausea, dizziness, hives, rash and itching
     - Moderate - wide spread hives, headaches, facial swelling, vomiting, shortness of breath
     - Severe - Severe reactions are rare but include: life-threatening heart palpitations, very low blood pressure, throat swelling, fits and/or cardiac arrest
   - Nephrogenic Systemic Fibrosis (NSF) for severe renal impaired patients only.
   - Death as a result of MRI Contrast is very rare.

   Date of birth: ____________________________
   Sex: [ ] M [ ] F [ ] I

   (Affix identification label here)
Consent Information - Patient Copy
MRI Contrast

1. What is a MRI contrast?
The medical imaging MRI procedure your doctor has asked you to have may use MRI Contrast. MRI Contrast is a colourless liquid that is injected into your blood stream. MRI Contrast is not a dye. It does not stain the inside of your body. It is used during MRI medical imaging procedures to allow your organs to be seen more clearly. Your doctor needs to use MRI Contrast to be able to get all the information needed to assist with your diagnosis.

This information sheet must be read together with the information sheet of the procedure you are booked for (if you do not have this information sheet please ask for one).

2. During the procedure
When the MRI Contrast is injected you should not feel any different.

3. After the procedure
MRI Contrast does not affect your ability to carry out normal activities; you should be able to continue with your day as normal.

5. What are the risks of MRI Contrast?
The risks and complications with MRI Contrast can include but are not limited to the following.

Common risks and complications include:
- No known common risks.

Less common risks and complications include:
- Injected Contrast may leak outside of the blood vessel, under the skin and into the tissue. This may require treatment. In very rare cases, further surgery could be required if the skin breaks down.
- The injection may not be possible due to medical and/or technical reasons.

Rare risks and complications include:
- Allergic reactions occur within the first hour with most happening in the first 5 minutes.
- The reactions vary from:
  - Mild – headache, brief nausea, dizziness, hives, rash and itching.
  - Moderate – wide spread hives, headaches, facial swelling, vomiting, shortness of breath.
  - Severe – Severe reactions are rare but include: life-threatening heart palpitations, very low blood pressure, throat swelling, fits and/or cardiac arrest.
Cryogen Handling

- Adverse events related to cryogen handling, storage, or inadvertent release
  - The magnetic scanners are always left on
  - Turning them off or quenching is expensive and dangerous
  - Cryogenic gases (cooled liquid helium) can be released and are deadly
    - Can appear as white clouds or fog around the scanner
  - For superconducting systems, in event of system quench need to evacuate everyone out of the room (ACR 2013)
Parts of MRI and Principles of Operation

- **Magnet** creates the static magnetic field

- **Gradient coils** are three sets of coils located inside the faceplate of the machine and allow spatial localization of the data obtained in the MRI process

- **Radio-frequency (RF)** coils are used to transmit and receive RF radiation as part of the image acquisition. Coils are located under the thin plastic covering in the bore (inside walls) of the magnet.

- **Patient table** and **computer system** and operator console
MR Field Strength

- Strength of the static magnetic field for clinical MR scanners is usually in the range of 0.0064 to 3.0 T
- Measured from the center of the bore where the imaging occurs
- Systems with field strength of 3.0 T and higher have been approved by the FDA and these are now more common (ACR 2013)
  - Higher field strength increases the risk of injury from both static and time varying magnetic field considerations
  - There are several magnet types such as permanent, resistive, superconductive, or hybrid
2013 ACR Guidance on Safe MR Practices

  - Free on their website
  - Published in the Journal of Magnetic Resonance Imaging 37:501-530 (2013)
  - ACR has a website on MR safety and includes MRI safety website, safety screening form, and more at www.acr.org
ACR MR Safe Practices 2013

ACR Practice Guidelines & Standards

Practice Guidelines and Technical Standards

The ACR Practice Guidelines and Technical Standards help advance the science of radiology and improve the quality of service to patients. They promote the safe and effective use of diagnostic and therapeutic radiology by describing specific training, skills and techniques. Learn More

Practice Guidelines by Modality

Practice Guidelines describe recommended conduct in specific areas of clinical practice. They are based on analysis of current literature, expert opinion, open forum commentary and informal consensus. Guidelines are not intended to be legal standards of care or conduct and may be modified as determined by individual circumstances and available resources.

- Documentation and Reporting
- General Diagnostic Radiology
  - General Diagnostic Radiology
  - Radiography
  - Computed Tomography (CT)
  - Magnetic Resonance Imaging (MRI)
  - Nuclear Medicine
  - Ultrasound
- Organ-specific and Subspecialty-specific Imaging: Pediatric and Adult
  - Abdomen – Gastrointestinal
  - Abdomen – Genitourinary
  - Breast Imaging and Intervention
  - Cardiac/Chest
  - Musculoskeletal
  - Neuroradiology
ACR 2013 MR Guidance

- Includes information on the 5 G line
- Need for P&P
- MRI 4 zones
- Training of those to enter MRI magnet room
- Patient and staff assessments
- What to do if a code occurs
- Fight fighters, police, and security safety considerations
- Device and object screening and more
The 5 G Line (The Safe Line)

- The distance from the MR system at which the static magnetic field is diminished sufficiently to **pose no physical threat** to the general public.
- Distance from MR imager where the static magnetic field has decreased to 5 gauss.
- FDA requires posting warning signs if magnetic field is more than 5 G.
- MRI room is shielded to protect MR system from equipment or devices that emit frequency similar to those emitted by protons in patient’s tissue.
Simplified illustration of an MR scan room showing the location of the 5 G line for one type of MR system. The 5 G line delineates the boundary between areas where the MR system’s static magnetic field strength is either greater than 5 G (the field strength increases dramatically as the distance to the magnet decreases) or less than 5 G. Within the 5 G line, some objects could be pulled into the magnet, and many devices will not operate properly. (Note that the static magnetic field extends in all directions around the magnet, including above and below the system.)
Zones in the MRI Suite

- Restrict access to the MRI site by implementing four zones
  - Provide for progressive restriction in access to the MRI scanner and discussed in ACR document

  - ACR has a website on MR safety and includes MRI safety website, safety screening form, and more at www.acr.org
  - Discusses four zones and has MRI functional diagram
Four Zones
ACR MR Safe Practices 2013

Four Zones

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

- **Zone II**—Unscreened MRI patients—obtain information:
  - Patients are greeted
  - Patients are not free to move throughout zone II at will
  - Answers to MR screening questions
  - Patient histories and medical insurance questions
Four Zones

- **Zone III—Screened MRI patients and personnel**
  - Access is strictly restricted since injury can occur from ferromagnetic objects or equipment
  - Includes the control room
  - Physical restriction from general public entering
    - Key locks, passkey locking systems or other reliable system to restrict access (not combination lock)
  - Prohibit physicians, non-MR personal access until trained
  - Area where strength exceeds 5 gauss should be clearly marked
Four Zones

- **Zone IV**—Screened MRI patients under constant direct supervision of trained MR personnel

  - This is the MRI scanner magnet room
  
  - Clearly marked as being potentially hazardous due to the presence of very strong magnetic field
  
  - Clearly marked with red light and lighted sign that says “The Magnet is On.”

    - On at all time with backup energy source in event of power loss
Four Zones

- **Zone IV** (continued)—MR scanner room emergency
  - In case of cardiac or respiratory arrest the certified MR personnel start basic life support or CPR while patient is moved to predetermined safe location
  - Do not recommend quenching the magnet (turning magnet off) since it takes more than a minute and this could be dangerous
  - Maintain restriction to Zones III and IV during resuscitation and other emergent situations
Types of Personnel

- There are three classifications and two levels of MR personnel
  - Non-MR personnel
  - MR personnel
    - Level 1 MR personnel
    - Level 2 MR personnel
Non-MR Personnel

- Any person (patient, visitor, staff, etc.) who has not completed sufficient training to qualify as either level one or level two MR personnel
  - Includes any individual who has not had the designated training in MR safety issues in past 12 months
- Must be under the immediate supervision and visual contact of a specifically identified level two MR staff member at all times when they are within MR zones III and IV
MR Personnel

- **Level 1**—Staff, including departmental office staff and patient aides who have undergone minimal safety education efforts, sufficient to ensure their own safety as they work in Zone III areas.
  - These staff may move freely throughout all MR zones. These people cannot be responsible for non-MR personnel in Zone IV.

- **Level two**—Staff, including MR technologists, radiologists, and radiology department nursing staff, who have undergone more extensive MR safety training.
  - These staff members are also free to move throughout all MR zones.
Level Two MR Personnel

- Must supervise and be able to visualize or talk to any non-MR person in zones III and IV

- Should be trained and educated in broader safety programs
  - Include the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients

- Medical Director’s job is to make sure these people have education and experience to qualify as Level two MR personnel
Any non-MR personnel, like a nurse or physician, who wants to enter Zone III must first pass an MR safety screening process.

Must be performed by the MR personnel before putting the non-MR person into Zone III:
- Like a ticket to enter

Screening process and forms is identical for both patients and non-MR personnel:
- Then physicians and nurses can enter the bore of the MR imager during the MRI such as child who leans into the bore or anesthetist who leans into bore to bag patient if problem occurs.
Monitoring Patients in the MRI Scanner

- Is sometimes necessary to monitor patients
- Monitoring methods should be chosen carefully
  - Concern about the risk of thermal injury associated with the monitoring equipment
- Sedated patients may not be about to tell you about any symptoms of injury
  - Potential is greater for whole body scanners of 1 Tesla and above
- Use MR conditional EKG electrodes and don’t let leads touch patient during the scan
  - Ice packs or cold compresses on electrically conductive material
GUIDELINES FOR THE MANAGEMENT OF THE POST-OPERATIVE PATIENT REFERRED FOR A MAGNETIC RESONANCE PROCEDURE

There is often confusion regarding the issue of performing a magnetic resonance (MR) procedure during the post-operative period in a patient with a metallic implant or device. Studies have supported that, if a metallic object is a "passive implant" (i.e., there is no electronically- or magnetically-activated component associated with the operation of the device) and it is made from nonferromagnetic material, the patient may undergo an MR procedure immediately after implantation using an MR system operating at 1.5-Tesla or less (or, the field strength that was used to test the device, including 3-Tesla). In fact, there are several reports that describe placement of vascular stents, coils, filters, and other implants using MR-guided procedures that include the use of high-field-strength (1.5- and 3-Tesla) MR systems.

Additionally, a patient or individual with a nonferromagnetic, passive implant is allowed to enter the MR environment associated with a scanner operating at 1.5-Tesla (or, the field strength that was used to test the device, including 3-Tesla) or less immediately after implantation of such an object. For an implant or device that exhibits "weakly magnetic" qualities, it may be necessary to wait a period of at least six weeks after implantation before performing an MR procedure or allowing the individual or patient to enter the MR environment. For example, certain intravascular and intracavitary coils, stents, and filters designated as "weakly magnetic" become firmly incorporated into tissue a minimum of six weeks following placement. In these cases, protective or counter-measures provided by tissue ingrowth, scarring, or granulation serve to prevent these objects from presenting risks or hazards to patients or individuals in the MR environment.

However, patients with implants or devices that are "weakly magnetic" but rigidly fixed in the body (e.g., bone screws, other orthopedic implants, or other devices) may be studied immediately after implantation. Specific information pertaining to the recommended post-operative waiting period may be found in the labeling or product insert for an implant or device.

Special Note: If there is any concern regarding the integrity of the tissue with respect to its ability to retain the implant or object in place or the implant cannot be properly identified, the patient or individual should not be exposed to the MR environment.

REFERENCES
Screening of Non-emergent Patients

- Outpatients or patients whose conditions are not life threatening are called non-emergent
- Should be screened on site and by at least two separate individuals (ACR 2013)
  - At least one of these people should be Level II MR personnel
- At least one of these two screenings should be performed verbally or interactively
Conscious Non-emergent Patients

- Review written MR safety screening questions prior to their introduction to Zone III
- Review questions orally with patient or family
- If patient is non-responsive discuss with family
- They must provide yes or no to each question
- Patient or family must sign these forms with no empty responses

- Note: Sample pre-MR forms are provided by ACR, MRIsafety.com, www.ismrm.org, ECRI Institute, and several other sources listed in reference
Non-emergent Patients

- Must remove all metallic personal belongings including:
  - Jewelry, cell phones, watches, contraceptive diaphragms, body piercing (if removable), pagers, metallic drug delivery devices, hooks, zippers, metallic threads, metallic particles such as make up and eye makeup, contraceptive diaphragms, metallic drug patches, etc.

- Recommend wearing hospital gown with no metal fasteners
Emergency Patients

- Emergency department critically ill or ICU critical patients
  - If ED patient is unconscious and no one present to give reliable information and test is urgent then should be physically examined by level 2 MR personnel
  - Looking for scars or deformities which might indicate an implant and can x-ray unless old films are available

- Emergent patients and their accompanying non-MR personnel may be screened only once
  - Level two MR personnel should provide the screening
  - There should be no exceptions
Safe MR Practices

- Any patient and non-MR personnel (nurses, physicians) with a history of potential ferromagnetic foreign object penetration must undergo further investigation prior to being permitted entrance to Zone III.

- Investigation includes:
  - History, plain x-rays, prior CT or MR studies of the questioned anatomical area, or
  - Written documentation as to the type of implant or foreign object that might be present.

- Determine MR compatibility or MR safety of the implant or foreign object.
Safe MR Practices

- All patients with history of orbital trauma by potential ferromagnetic FB must have their orbits cleared.
- This can be done by plain X-ray views of orbit films or by radiology review and assessment of contiguous cut prior CT or MR images obtained after trauma occurred.
Metal Detectors Ferromagnetic Detectors

- ACR does not recommend metal detector use since traditional metal detectors do not differentiate between ferrous and nonferrous magnetic materials
  - They have varied sensitivity settings
  - Skills of operators can vary
- Ferromagnetic detection systems (highly developed magnetometer type instruments) are available and simple to operate
  - Capable of detecting very small ferromagnetic objects external to the patient
  - Still need to conscientiously screen the patient
HIPAA Privacy

- If outpatient registered in radiology department, make sure NPP is given to patient once after April 14, 2003 and again after September 23, 2013
  - Medical record information is called protected health information and must be kept confidential
  - In all four zones need to be in compliance with HIPAA
  - In Zone III, there should be a privacy barrier so unauthorized person cannot view control panels (ACR 2013)
  - If patient wants copy of MR report sent to someone outside, other than ordering physician, should sign HIPAA compliant authorization form
HIPAA Privacy

- If attending physician orders MRI, and neurosurgeon comes into department to see film on outpatient, staff need to see documentation of physician-patient relationship

- HIPAA security rules also apply, so keep back-up of MRIs and have adequate security

- CMS Hospital CoPs on radiology and medical records apply to all MRIs

- Patients can now sue for money damages if HIPAA violations, secretary of state can sue, HIPAA HITECH law in effect
www.MRI safety.com is maintained and frequently updated by Frank G. Shellock, Ph.D. -- Serving the MRI Community for More Than 25 Years --

Registration or login to use this site is not required
Send an email to Frank G. Shellock, Ph.D. at frank.shellock@mrisafety.com
WELCOME to www.MRI safety.com, the premier information resource for magnetic resonance safety. This web site is the official site of the INSTITUTE FOR MAGNETIC RESONANCE SAFETY, EDUCATION, AND RESEARCH

MRI SAFETY POSTER AND MRI ARTICLES AVAILABLE TO DOWNLOAD - Visit http://www.IMRSER.org/

IMPLANT AND DEVICE TESTING-
MAGNETIC RESONANCE SAFETY TESTING SERVICES is a highly experienced MRI-safety testing company that conducts comprehensive evaluations of implants, devices, objects, and materials. For information, visit www.MagneticResonanceSafetyTesting.com

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www.MRISAFETYMODELING.com

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In AUSTRALIA, order the textbook from www.howmed.com.au

Four Different MRI Safety Training Programs are Available.

Please Visit http://cmmesded.com/mrisafety/
Safety Information on MRI

3.0-Tesla MR Safety Information for Implants and Devices
AccuRx Constant Flow Implantable Pump and Duracath Intraspinal Catheter
Acoustic Noise and MRI Procedures
ActiPatch
Activa (Neurostimulation) System (Medtronic, Inc., Minneapolis, MN)
Alfasys Intravascular Temperature Management
Ambulatory Infusion Systems
Aneurysm Clips
Baha, Bone Conduction Implant
Bioeffects of Gradient Magnetic Fields
Bioeffects of Radiofrequency Fields
Bioeffects of Static Magnetic Fields
Biopsy Needles, Markers, and Devices
Body Piercing Jewelry and MRI Safety
Bone Fusion (Spinal) Stimulator
BRAVO pH Monitoring System
Breast Tissue Expanders and Implants
Cardiac Pacemaker: Accent MRI
Intrauterine Devices (IUDs)
IsoMed Implantable Constant Flow Infusion Pump (Medtronic, Inc.)
Licox CC1P1 Oxygen and Temperature Probe, Brain Tissue Oxygen Monitoring System (Integra NeuroSciences, Plainsboro, NJ)
Magnetically Activated Implants and Devices
Medivance Nasogastric Sump Tube with YSI Series 400 Temperature Sensor
Medtronic Letter, Neuromodulation Devices, Mr. Steve Manker, Program Director - MRI
Conditionally Safe Systems
Metallic Orbital Foreign Bodies and Screening
Miscellaneous Implants and Devices
"Missile Effect" Accidents and Prevention
Modes of Operation for MR Systems
Monitoring Body Temperature During MRI
Monitoring Patients in the MR Environment
MRI Contrast Agents and Adverse Reactions
MRI Contrast Agents and Breast Feeding Mothers
MRI Contrast Agents and

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The Institute for Magnetic Resonance Safety, Education, and Research (IMRSER) was formed in response to the growing need for information and research on matters pertaining to magnetic resonance (MR) safety. The IMRSER is the first independent, multidisciplinary, professional organization devoted to promoting awareness, understanding, and communication of MR safety issues through education and research.

**Mission Statement**

- To promote awareness and understanding of MR safety,
- To disseminate information regarding current and emerging MR safety issues,
- To develop and provide materials and resources to facilitate MR safety-related education and training,
- To respond to critical MR safety issues with a sense of urgency, and
- To advance the field of MR safety through support of scientific research.

Also, visit [www.MRisafety.com](http://www.mrisafety.com) for comprehensive information on magnetic resonance (MR) safety.
Important Message - The MRI System Room

STRONG Magnetic Field
DANGER
This Magnet is Always On!

Don’t bring “magnetic” metal objects into this room.
Metal objects may cause injuries and damage the MR system.

Do not enter without permission from authorized MRI personnel.

www.MRIsafety.com
What Does MR Safe Mean?

- New classification system in 2006 was developed by ASTM International and supported by FDA
- Terminology from ASTM International
  - Old name was the American Society for Testing and Materials
  - Easy to remember because they are like colors of street light, green is go, red is stop
- New MR safe and old MR safe terms have very different meanings
What Does MR Safe Mean?

- MR safe refers to an item that poses no known hazards in all MRI environments.
- MR Safe means the device or implant is completely non-magnetic, non-conducting, and non-RF reactive, eliminating all primary potential threats during MRI procedure.
- Categories include MR safe, MR-Conditional, and MR-Unsafe.
- This is the MR safe sign.
MR Conditional

- MR Conditional refers to a device or implant that may contain magnetic, electrically conductive, or RF-reactive components that are safe for operations in proximity to the MRI
  - Provided that conditions for safe operation are defined and observed
  - Tested safe to 1.5 teslas, or safe in magnetic below 500 gauss in strength
  - RF is radio frequency—can heat the body
- Yellow sign in the MR conditional sign
MR Conditional

- Safety of the device is conditioned on a specific MR environment
- Device may not be MR conditional with more powerful or upgraded MR systems
- Object may or may not be safe for the patient undergoing an MR procedure, levels 1-7
  - Depending on the specific condition present
- Information is in subcategories to indicate the specific recommendation
MR Conditional

- Conditional 1–Object is acceptable for patient in MR environment, despite fact it showed positive findings for magnetic field interaction
  - Object is considered to be weakly ferromagnetic
- Conditional 7–Device is not intended for use during MR procedure
Unsafe

- **Unsafe**—Reserved for objects that are significantly ferromagnetic and pose threat to person and equipment in room
  - Unsafe in any MR environment

- **Unsafe 1**—The object is considered to pose a potential or realistic risk or hazard to a patient or individual in the MR environment, primarily as the result of movement or dislodgement of the object
  - Contraindicated for MRI
  - Note that the “default” static magnetic field strength for an unsafe implant or device is 1.5-Tesla
Unsafe 2

- Object displays only minor magnetic field interactions which, in consideration of the in vivo application of this object, is unlikely to pose a hazard or risk in association with movement or dislodgment
  - Presence of this object is considered to be a contraindication for an MR procedure
  - Represents potential risks such as excessive heating or other potentially hazardous conditions
    - Example: Swan-Ganz catheter melted in patient during MRI
Searching the List

- Status of objects is listed as:
  - MR-safe, Unsafe 1 and 2, and Conditional 1 through 8
- List includes manufacturer name and object category
- Examples of objects on the list include:
  - Aneurysm clips, AccuRx implantable flow pump, cochlear implants, stents, carotid artery vascular clamps, insulin pumps, IUDs, etc.
  - If you click on insulin pumps it will show you it is in category of unsafe 1 status
    - Provides safety information and instructions on what to do
Search the List for MRI Safety

www.mrisafety.com/list_search.asp
Follow ACR Guidelines and Standards 2013

- Guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients.

- Guidelines are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care.

- ACR cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

Source: [http://www.acr.org/](http://www.acr.org/), see Guidelines and Standards
Magnetic Resonance Imaging Guidelines

ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI) Res. 19 - 2011

ACR–SPR Practice Guideline for the Performance and Interpretation of Pediatric Magnetic Resonance Imaging (MRI) Res. 23 - 2011

ACR Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Abdomen (excluding the liver) Res. 16 - 2010

ACR–SPR–SSR Practice Guideline for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Ankle and Hindfoot Res. 20 - 2011

ACR–SSR Practice Guideline for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of Bone and Soft Tissue Tumors Res. 18 - 2010

ACR–NASCI SPRI Practice Guideline for the Performance of Body Magnetic Resonance Angiography (MRA) Res. 22 - 2010


ACR–ASNR Practice Guideline for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Brain Res. 20 - 2008

ACR Guidelines and Standards Sections

- Continuing medical education
- General diagnostic radiology including:
  - Expert witness in radiology
  - Communicating findings
  - Use of intravascular contrast media
  - MRI
ACR Safety

- ACR has position statement on quality control and improvement, **safety, infection control**, and patient education concerns
- P&P to provide for the safety of patients and staff
- Attention to the physical environment
  - Proper use, storage, and disposal of medications and hazardous equipment
- Methods for responding to medical and other emergencies

¹ACR Guidance Document for Safe MR Practice 2007, 27 pages
ACR Safe MR Practice 2013

- Important document to review and every hospital should have a copy of this

- All facilities should have MR policies
  - Including clinical and research sites no matter the magnet format or field strength

- Review policy when any changes such as adding faster or stronger MRI machine

- Consider national and international standards and recommendations when drafting and updating P&P
ACR Safe MR Practice

- Each facility needs a Medical Director who’s responsibilities include ensuring MR safe practice guidelines are established, current and followed

- All adverse events and near misses must be reported to Medical Director
  - Within 24 hours or 1 business day
  - May also need to be reported to risk management
  - CMS in hospital CoPs and TJC (LD standards) require reporting in incident reporting system

- All adverse events must be reported to the FDA via MedWatch program

1 http://www.fda.gov/medwatch/index.html
FDA MedWatch Program

www.fda.gov/Safety/MedWatch/default.htm
ACR Safe MR Practice

- ACR supports this requirement

- If implant is strongly ferromagnetic, concern is that of magnetic translational and rotational forces upon the implant which might move or **dislodge** the device from its implanted position

- If implant demonstrated weak ferromagnetic forces on formal testing, may be prudent to wait several weeks for fibrous scarring to set in as this may anchor the implant in position
ACR Safe MR Practice

- It is possible to find unanticipated implant or FB during exam

- May be detected by sizable field distorting artifact seen on spin-echo imaging techniques that grows more obvious on longer TE studies and expands markedly on typical moderate or long TE gradient-echo imaging sequences

- Notify Medical Director, safety officer, or physician in charge of suspected findings
ACR Safe MR Practice

- Review information and decide what course of action should be taken
- If need to remove patient go slowly in straight line
- Avoid temptation to have patient sit up as soon as out of bore
  - Wait until as far as physically possible from MRI imager
ACR Safe MR Practice

- Patients, volunteers, staff, or anyone else with implanted cardiac pacemaker, implantable cardiac defibrillator (ICD), diaphragmatic pacemaker or other electromechanically activated devices should never enter Zone IV

- Should not go past 5 gauss line unless cleared in writing by Level 2 MR personnel, designated radiologist, or Medical Director of the MR site
Prisoners

- Prisoners or parolees with metallic devices such as handcuffs and shackles or RF tracking bracelets
  - RF ID or tracking bracelets interfere with MRI study and secondary image artifact
  - Bracelet can also heat up and burn the patient
  - These need to be removed before doing the test
Firefighters, Police, Security

- Persons who respond to an emergent call at the MR site
  - Specially designated MR personnel
  - Need to be on the site prior to the arrival of the firefighters or emergency response team
- Firefighters cannot have free access to Zones III and IV, so educate fire marshals and others in advance
Firefighters, Police, Security

- May train security staff to be designated as MR personnel
  - Designated person needs to be there before others show up
- In true fire, taking air tanks, crow bars, guns, and other firefighting equipment could be catastrophic
- Need clearly marked, readily accessible MR-conditional or MR-safe fire extinguishing equipment physically stored in Zone III or IV
- All conventional fire extinguishers and other firefighting equipment not tested and verified safe in the MR environment should be restricted from Zone III
  - Use this section to draft your P&P
MR Personnel Screening and HR

- All MR personnel must undergo an MR screening process as part of their employment interview.
- MR personnel must report to the MR Medical Director any trauma, procedure, or surgery in which ferromagnetic object or device may have been introduced.
- This is done to make sure it is safe for the employee to enter Zone III.
Device and Object Screening

- Don’t let anyone bring in ferrous objects.
- Should have access to a strong handheld magnet (over 1000 gauss) or handheld ferromagnetic detection device.
- Magnet enables external and even some superficial internal testing of devices or implants:
  - Presence of grossly detectable ferromagnetic attractive forces.
  - Document testing and include date, time, and name of tester.
  - Oxygen cylinders must be positively identified in writing as MRI safe (non-ferromagnetic and safe or conditionally safe in the MR environment) or Unsafe.
Device and Object Screening

- Same testing for other objects such as MRI safe fire extinguishers and aneurysm clips
- All portable metallic or partially metallic objects that are to brought into Zone IV must be properly identified under current FDA labeling criteria developed by ASTM
- Remember the green safe sign on the label
- Treat a product marked as MR safe but with metal construction as suspicious
Device and Object Screening

- Be careful about old labeling of products with ill defined terminology

- For example, “non-magnetic,” or outdated classifications such as “MR-compatible,” should not be presumed to conform to a particular current ASTM classification

- If in doubt test it with handheld ferromagnetic detection device
Consent

- Patient with pacemaker or ICD that is not labeled as MR Conditional should be informed of the risk and provided informed consent
- If MRI is done on patients with these devices ACR recommends a fully stocked crash cart
- See additional detailed recommendations on page 517
- ACR also has detailed section on patients who may have an intracranial aneurysm starting on page 515
Screening

- Need effective screening procedure for patients before they have an MRI
- ACR has screening tool
- Should be conducted by health care worker who has been specially trained in MR safety
  - To determine if patient has an implant that may be contraindicated for the MR procedure (e.g., a ferromagnetic aneurysm clip, pacemaker, etc.)
  - To determine if there is any condition that needs careful consideration (e.g., the patient is pregnant, has a disability, etc.)
Screening

- Have P&P on screening
- Use a screening tool
- After the preliminary screening, then the patient goes through comprehensive screening
- Comprehensive patient screening uses a printed form to document this procedure
- Form includes a statement that indicates hearing protection is “advised” or “required” to prevent possible problems or hazards related to acoustic noise
- MR safety trained person reviews the form’s contents. If patient is unable to answer the questions, then discuss with closest family members.
Screening

- If no family members, then with person who is most likely to know the information
  - Technician can also look for scars or deformities
  - Can use ferromagnetic detectors
  - Can also use plain film radiography to assist in the screening process
Screening Things that Create a Hazard

- Pacemaker (new pacemaker safe one)
- Implantable cardioverter defibrillator (ICD)
- Neurostimulators, tissue expanders, hearing aid
- Aneurysm clip, surgical clips, staples
- Metal implant, artificial limbs, shunts
- Implanted drug infusion device, penile implant
- Foreign metal objects, especially if in or near the eye, artificial heart valve, coils and stents
- Radiation seeds, IUD, pessary, eyelid spring
Screening Things that Create a Hazard

- Shrapnel or bullet wounds, internal electrodes
- Permanent cosmetics or tattoos, tattooed eyeliner
- Dentures/teeth with magnetic keepers
- Other implants that involve magnets
- Medication patch (i.e., transdermal patch) that contains metal foil, cochlear implant, halo vest
- Pillows may contain metal springs
- Sandbags may contain iron pellets
- Wigs, hair implants, body piercing, surgical mesh
Appendix 2

Safety Screening Form for Magnetic Resonance (MR) Procedures

Date: Name (first middle last):

Female [ ] Male [ ] Age: Date of Birth: Height: Weight:

Why are you having this examination (medical problem)?

__________________________________________________________

Have you ever had an MRI examination before and had a problem?
    If yes, please describe:

__________________________________________________________

Have you ever had a surgical operation or procedure of any kind?
    If yes, list all prior surgeries and approximate dates:

__________________________________________________________

Have you ever been injured by a metal object or foreign body (e.g., bullet, BB shrapnel)?
    If yes, please describe:

__________________________________________________________

Have you ever had an injury from a metal object in your eye (metal slivers, metal shavings, other metal object)?
    If yes, did you seek medical attention?
    If yes, describe what was found:

__________________________________________________________

Do you have a history of kidney disease, asthma, or other allergic respiratory disease?
    If yes, please list drugs:

__________________________________________________________
Do you have a history of kidney disease, asthma, or other allergic respiratory disease?
  Do you have any drug allergies?
  If yes, please list drugs________________________

Have you ever received a contrast agent or X-ray dye used for MRI, CT, or other X-ray or study?

Have you ever had an X-ray dye or magnetic resonance imaging (MRI) contrast agent allergic reaction?
  If yes, please describe______________________________________________

Are you pregnant or suspect you may be pregnant?

Are you breast feeding?

Date of last menstrual period_____ Post-menopausal?
ACR 2013  MR Hazard Checklist

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:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any type of electronic, mechanical, or magnetic implant</td>
</tr>
<tr>
<td></td>
<td>Type__________________</td>
</tr>
<tr>
<td></td>
<td>Cardiac pacemaker</td>
</tr>
<tr>
<td></td>
<td>Aneurysm clip</td>
</tr>
</tbody>
</table>
ACR Hazard Checklist  2013

___   ___  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
ACR Guidance on MR Safe Practices

- Any type of metal object (e.g., shrapnel, bullet, BB)
- Artificial heart valve
- Any type of ear implant
- Penile implant
- Artificial eye
- Eyelid spring
- Any type of implant held in place by a magnet
  Type________________
- Any type of surgical clip or staple
- Any IV access port (e.g., Broviac, Port-a-Cath, Hickman, Picc line)
- Medication patch (e.g., Nitroglycerine, nicotine)
- Shunt
- Artificial limb or joint
ACR Hazard Checklist 2013

- ___ Tissue Expander (e.g., breast)
- ___ Removable dentures, false teeth or partial plate
- ___ Diaphragm, IUD, Pessary
  Type________________________
- ___ Surgical mesh
  Location_____________________
- ___ Body piercing
  Location_____________________
- ___ Wig, hair implants
- ___ Tattoos or tattooed eyeliner
- ___ Radiation seeds (e.g., cancer treatment)
- ___ Any implanted items (e.g., pins, rods, screws, nails, plates, wires)
- ___ Any hair accessories (e.g., bobby pins, barrettes, clips)
- ___ Jewelry
Instructions for the Patients

1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination because some patients may find the noise levels unacceptable, and the noise levels may affect your hearing.
2. Remove all jewelry (e.g., necklaces, pins, rings).
3. Remove all hair pins, bobby pins, barrettes, clips, etc.
4. Remove all dentures, false teeth, partial dental plates.
5. Remove hearing aids.
6. Remove eyeglasses.
7. Remove your watch, pager, cell phone, credit and bank cards and all other cards with a magnetic strip.
8. Remove body piercing objects.
9. Use gown, if provided, or remove all clothing with metal fasteners, zippers, etc.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form, and I have had the opportunity to ask questions regarding the information on this form.

Patient signature__________________________________________

MD/RN/RT signature_____________________________________
Date__________

Print name of MD, RN, RT_______________________________

For MRI Office Use Only
MRI Staff Verification  ACR 2013

For MRI Office Use Only

Patient Name______________________________________________

Patient ID Number__________________________________________ Referring Physician_________________________

Procedure__________________________________________________ Diagnosis_________________________

Clinical History________________________________________________

Hazard Checklist for MRI Personnel

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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Endotracheal tube
Swan-Ganz catheter
Extra ventricular device
Arterial line transducer
Foley catheter with temperature sensor and/or metal clamp
Rectal probe

Bare Metal Devices
Ferromagnetic Objects

- It is important to be aware of common ferromagnetic objects
- Buffing machines, janitor buckets, chest tube stands, and clipboards (patient charts), chairs, canes
- Gurneys, hairpins, hearing aids, identification badges, walkers
- Insulin pumps, keys, and medical gas cylinders, mops, IV poles
Ferromagnetic Objects

- Nail clippers and nail files, oxygen cylinders, pulse oximeter, pacemakers, and pagers
- Paper clips, jewelry, pens, and pencils
- Prosthetic limbs, shrapnel, sandbags (with metal filings)
- Steel shoes, stethoscopes, scissors, staples, and tools
- Vacuum cleaners, watches, and wheelchairs
Pregnancy

- No harmful effects on the fetus have been demonstrated—does not use ionizing radiation
  - As precaution, pregnant women should only have MRI when essential
  - If they can wait until the end of pregnancy to have test, that is recommended

- Gadolinium is known to cross the placenta and enter fetal bloodstream, so contrast is not routinely provided if patient is pregnant

- Pregnant staff can work in and around MRI suite but asked not to remain in MRI scanner bore or Zone IV during actual scanning
Pregnancy

- Determine if patient could have an ultrasound instead
- Despite concerns, MRI is growing in importance in diagnosing congenital defects of the fetus and open fetal surgery
- Look at risks versus benefits, give informed consent
- Level 2 MR personnel, designated attending radiologist, can decide the study is warranted
Pregnancy

- Document in the medical record
  - Radiologist should confer with the referring physician
- Include the following information:
  - Cannot be acquired through non-ionizing means such as by an ultrasound
  - Data is needed to affect care of patient or fetus, and
  - Referring physician does not feel it is prudent to wait
Sedation and Monitoring Issues

- Children form the largest group requiring sedation for MRI
  - Many are unable to stay still
- Sedation protocols vary among facilities
- CMS has changes to the anesthesia standards which discuss moderate sedation and deep sedation
  - VA has moderate sedation toolkit at www.patientsafety.gov
- Parent to accompany child must be screened
  - Use hearing protection
Pediatric MR Safety Sedation & Monitoring

- There is a section on pediatric safety that any hospital that does MRIs on pediatric patients should read

- Should be incorporated into P&P

- Need to follow standards from the American Academy of Pediatrics, American Society of Anesthesiologist and TJC

- Fasting requirements, H&P, training and credentialing for staff, monitoring during and after procedure, observe child, charting, protocol for recovery and discharge, etc.
Claustrophobia

- Being in center of long narrow tube can be unpleasant and some patients are claustrophobic
  - Open MRIs and upright MRIs are an option
  - New scan rooms being developed with lighting, sounds and images on wall or ceiling
- Sedation or general anesthesia can be used
- Visualization or imagery techniques may help
- Holding panic button and listening to music on headphones, or watching a movie with head mounted displays while in MRI machine may ease stress
Disadvantages

- If sedation used follow TJC, ASA, and ACR recommendation
- Discuss issue of claustrophobia and hazards
  - Normally 20-30 minutes long but can take 60 minutes
  - Required to stay still and in an enclosed space can be hard for pediatric patients
- Movement can create motion artifact
  - Includes patients with tremors like Parkinson's disease or low back pain
  - Patients with pain can be instructed to take pain medication prior to the procedure
Thermal Issues

- Remove any unnecessary equipment
  - Unplugging unnecessary equipment is not enough
  - Electric current or voltage can be induced in electrically conducting materials
  - Can create heat which can result in a burn
  - MR tech must check all equipment first
Thermal Issues Burns

- If wires or leads have to remain on patient, take care that there are no large caliber conducting loops formed in the scanner.

- Several cases reported of coma and permanent impairment in patients with neurologic stimulators.

- Make sure there is insulation between the patient and the electrically conductive material (pads or air).
Thermal Issues

- Position leads or wires as far as possible from the inner walls of the scanner
  - If leads directly contact the patient, put cold compresses or ice packs to the area
- Make sure patients tissues and skin do not come into contact with the inside (bore) of the MR machine
- Make sure no loop so patient should not cross legs or arms
Thermal Issues

- Skin staples and superficial metallic sutures are okay if not ferromagnetic and not in anatomical volume of RF power deposition
  - Take several precautions if skin staples are ferromagnetic
  - Warn patient about warmth and may experience some burning along staples
  - Can place cold compresses or ice pack along skin staples or superficial metallic sutures
Thermal Issues

- Notify tech immediately of heat
  - Do not wait until end of test
  - Use cold compress or ice bags at site
- Use ice packs for dark tattoos, including permanent eyeliner
- Procedure can smear or smudge edges if new tattoo
- Drug delivery patches and pads with metallic foil can result in a burn
- Ice bag put on patch can affect delivery of medication
Education of Staff

- Provide education during orientation for all staff who will be involved with MRIs
- Consider annual training during skills lab
- Include environmental services (housekeeping) personnel, maintenance, transport, surgical, and emergency response teams for RRT and codes
MR Technologists

- MR technologist should be ARRT (American Registry of Radiologic Technologists)– registered technologist

- All MR tech should be trained as Level 2 MR personnel during orientation

- All MR techs need BLS certification

- Have a minimum of two MR techs, or one MR tech and one other individual, with designation of MR personnel for all zones, except for emergent coverage
SUBJECT: MRI SAFETY  
EFFECTIVE DATE: March 2007  
REVISED DATE: 2008

APPROVED BY: Imaging Director  
DATE: March 2008

POLICY: Access to all MRI sites will be restricted to maintain the safety of the general public and staff.

PURPOSE: To designate appropriately trained MRI staff and the procedure for training and the safe utilization of Magnetic Imaging equipment.

PROCEDURE:


   - Zone I: General public areas. This will be the Waiting Rooms and Business office areas.
   - Zone II: Unscrened MRI patients and personnel. This is the Interview & Education areas.
   - Zone III: Screned MRI patients and personnel This is the entrance or Control Room before entering the scan room.
   - Zone IV: Screned MRI patients and staff under constant direct supervision of trained personnel.
2. MRI patients are requested to complete a questionnaire which the MRI technologist screens and checks for accuracy by reviewing the patient’s history. The MRI technologist performs the interview with all patients. This provides two separate opportunities for patients to answer questions about any metal objects they may have on them, any implanted devices, drug delivery patches, tattoos, and any electrically, magnetically, or mechanically activated devices they may have. If the patient is unconscious or unable to answer questions, the patient’s family member or personal representative is questioned. If this person is unsure, other means are used to determine if the patient has implants or other devices that could be negatively affected by the MRI scan (e.g., look for scars or deformities, scrutinize the patient’s history, use plain-film radiography, use ferromagnetic detectors to assist in the screening process, etc.). The MRI technologist should have the patient’s complete and accurate medical history to ensure that the patient can be safely scanned. All implants should be checked against product labeling or manufacturer literature specific to that implant, or peer-reviewed published data regarding the device or implant in question. Technologists will be provided with ready access to this information by use of the internet. Specially trained staff person who is knowledgeable about the MRI environment will accompany any patients, visitors and other staff who are not familiar with the MRI environment inside the MRI suite at all times.

3. All medical and ancillary staff that may be expected to accompany patients to the MRI suite will have annual safety education about the MRI environment.

4. All staff and patients and their families will be provided with appropriate Education, signage, and information that explain the potential for accidents and adverse events in the MRI environment.
NQF 34 Safe Practices

- Updated list in 2010 and 2011 on 34 Safe Practices for Better Healthcare

- Should be followed in all health care facilities to reduce risk of harm to patients

- Organized into seven sections

- Includes list of **29 never events** that many states require to be reported (2011 NQF changed and updated the list)
Resources on 34 Safe Practices

- NQF has an electronic copy of the book that can be purchased for $29.99\(^1\)
  - NQF, publication unit, 601 Thirteenth Street, NW, Suite 500 North, Washington, DC, 2005\(^2\)
- TMIT has a website and you can listen to past presentations\(^3\)

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1 http://www.nqfstore.org/store/

2 www.qualityforum.org

3 http://www.safetyleaders.org or http://www.tmit1.org/pages/workshopsWebinars.jsp
CHAPTER 8: Condition- or Site-Specific Practices

- Evidence-Based Referrals
- Anticoagulation Therapy
- DVT/VTE Prevention
- Pressure Ulcer Prevention
- Wrong-Site, Wrong Procedure, Wrong Person Surgery Prevention
- Perioperative Myocardial Infarct/Ischemia Prevention
- Contrast Media-Induced Renal Failure Prevention
TJC Standards

- **EC.02.04.01**: The hospital manages medical equipment risks.
  - **EP 3** The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory.
  - Hospitals may use different strategies for different items as appropriate. For example, strategies such as predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance may be selected to ensure reliable performance.
EC.02.04.01 EP5 Hospital must monitor and report any incidents in which medical requirement is suspected or contributed to death or serious injury or illness

- Recent issue of radiation overdose and concern about increased cancer risks

- See TJC SEA 47 on radiation risk of diagnostic imaging

EC.02.04.03 EP 14 Qualified staff inspect, test, and calibrate nuclear medicine equipment annually and document (DS)
Contrast

- No patient should be given contrast without a physician order (ACR 2013)
  - ACR MR Guidelines refer to ACR Contrast Manual-the ACR Committee on Drugs and Contrast Material
- IV injection qualified MR technologists may start a peripheral IV if had the training and are competent
  - Make sure that the state scope of practice is consistent
- IV qualified MR technologists (certified and or licensed) or radiologic nurse may administer gadolinium based contrast in peripheral IV or as bolus
  - Must have and follow the P&P and should be consistent with the ACR policy
Contrast Media-Induced Renal Failure

- Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure.
- Use a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
- Angiography, IVP, and CT scans that use contrast material containing iodine:
  - Can have allergic reaction or kidney damage.
  - Be careful in patients with renal impairment.
  - Do RCA on all cases of contrast media induced renal failure.
Contrast Media-Induced Renal Failure

- Recommendations to prevent contrast media-induced renal failure
  - Make sure patient is adequately hydrated
  - Use low osmolar contrast in patients with renal failure
  - Check serum creatinine level prior to scheduling contrast studies
  - See ACR manual on Contrast Media for the use of intravascular contrast media
ACR PRACTICE GUIDELINE FOR THE USE OF INTRAVASCULAR CONTRAST MEDIA

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed to promote the safe and effective administration of intravascular contrast media used for imaging studies.

Intravascular contrast media are used for a wide variety of imaging studies. The majority of intravascular contrast-enhanced imaging examinations involve iodinated contrast media, but other contrast media may be used for magnetic resonance imaging (MRI), ultrasonic imaging, and angiography.

II. GOAL

The goal of radiologists and other personnel

Contrast Media-Induced Renal Failure

- Recommendations to prevent contrast media-induced renal failure (continued)
  - Need P&P on prevention of contrast media induced nephropathy
  - Document contrast media-induced renal failure assessment regarding its prevention
  - Double check order and make sure most current creatinine level is used
IV Contrast on Diabetic Patients

- Have a process for diabetics on Metformin with abnormal renal function or comorbidity
  - Do you hold the medication temporarily if intravascular iodinated contrast is used in category II patients?
  - Do you order a serum creatinine two days after the CT in category III patients?
  - Do you then notify the attending office to let the patient know to restart their medication?

- ACR also has Manual on Contrast Media
**Category I**

In patients with normal renal function and no known comorbidities (see Table B), there is no need to discontinue metformin prior to intravenously administering iodinated contrast media, nor is there a need to check creatinine following the test or procedure before instructing the patient to resume metformin after 48 hours.

**Category II**

In patients with multiple comorbidities (see Table B) who apparently have normal renal function, metformin should be discontinued at the time of an examination or procedure using IV iodinated contrast media and withheld for 48 hours. Communication between the radiologist, the health care practitioner, and the patient will be necessary to establish the procedure for reassessing renal function and restarting metformin after the contrast-enhanced examination. The exact method (e.g., serum creatinine measurement, clinical observation, hydration) will vary depending on the practice setting. A repeat serum creatinine measurement is not mandatory.\(^1\) If the patient had normal renal function at baseline, was clinically stable, and had no intercurrent risk factors for renal damage (e.g., treatment with aminoglycosides, major surgery, heart failure, sepsis, repeat administration of large amounts of contrast media), metformin can be restarted without repeating the serum creatinine measurement.

**Category III**

In patients taking metformin who are known to have renal dysfunction, metformin should be suspended at the time of contrast injection, and cautious follow-up of renal function should be performed until safe reinstitution of metformin can be assured.
Metformin

Metformin is a biguanide oral anti-hyperglycemic agent used to treat patients with non-insulin-dependent diabetes mellitus. It is available as a generic drug as well as in proprietary formulations, alone and in combination with other drugs (see Table A for some of the brand name formulations). The drug was approved in the United States in December of 1994 for use as monotherapy or combination therapy in patients with non-insulin-dependent diabetes mellitus whose hyperglycemia is not controlled by diet or sulfonylurea therapy alone.

Metformin is thought to act by decreasing hepatic glucose production and enhancing peripheral glucose uptake as a result of increased sensitivity of peripheral tissues to insulin. Only rarely does it cause hypoglycemia.

The most significant adverse effect of metformin therapy is the potential for the development of metformin-associated lactic acidosis in the susceptible patient. This condition is estimated to occur at a rate of 0 to 0.084 cases per 1,000 patient years. Patient mortality in reported cases is about 50%. However, in almost all reported cases, lactic acidosis occurred because one or more patient-associated contraindications for the drug were overlooked. In one extensive 13 year retrospective study of patients in Sweden, 16 cases were found and all patients had several comorbid factors, most often cardiovascular or renal disease. There are no documented cases of metformin-associated lactic acidosis in properly selected patients.
Metformin and Gadolinium

It is not necessary to discontinue metformin prior to gadolinium-enhanced MR studies when the amount of gadolinium administered is in the usual dose range of 0.1 to 0.3 mmol per kg of body weight.

Table A: Medications containing metformin*

<table>
<thead>
<tr>
<th>Generic Ingredients</th>
<th>Trade names</th>
</tr>
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<tbody>
<tr>
<td>Metformin</td>
<td>Glucophage</td>
</tr>
<tr>
<td></td>
<td>Glucophage XR</td>
</tr>
<tr>
<td></td>
<td>Fortamet</td>
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<tr>
<td></td>
<td>Glumetza</td>
</tr>
<tr>
<td></td>
<td>Riomet</td>
</tr>
<tr>
<td>Glyburide/metformin</td>
<td>Glucovance</td>
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<tr>
<td>Glipizide/metformin</td>
<td>Metaglip</td>
</tr>
<tr>
<td>Pioglitazone/metformin</td>
<td>ActoPlus Met</td>
</tr>
<tr>
<td></td>
<td>ActoPlus Met XR</td>
</tr>
<tr>
<td>Repaglinide/metformin</td>
<td>Prandimet</td>
</tr>
<tr>
<td>Rosiglitazone/metformin</td>
<td>Avandamet</td>
</tr>
<tr>
<td>Saxagliptin/metformin</td>
<td>Kombiglyze XR</td>
</tr>
<tr>
<td>Sitagliptin/metformin</td>
<td>Janumet</td>
</tr>
<tr>
<td></td>
<td>Janumet XR</td>
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</tbody>
</table>

(Metformin and several of the combination drugs also available in generic versions)
Contrast Induced Nephropathy CIN

- Kidney failure can occur from iodine dye used for x-rays (70 reports)
  - Hospitals should amend informed consent to include this information
  - 10-12 percent of all renal failure cases from CIN
  - Most common in patients with known history of renal failure or impairment

- Consider doing a FMEA
  - **Toolkit** available¹

¹http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/cin/Pages/home.aspx
Contrast Induced Nephropathy Toolkit

http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/cin/Pages/home.aspx
Toolkit

- Toolkit includes the following:
  - A copy of the advisory
  - Brief informational video on CIN
  - Stand alone algorithm to identify patients at risk for CIN
  - Poster
  - Reference tables for calculating estimated glomerular filtration rate
Discuss with patients the increased risk with:

- Nephrotoxic drugs such as chemo
- Certain antibiotics
- NSAID
- Acyclovir
- Immunosuppressants
- ACE inhibitors
- Lasix
- Lithium
- Oral phosphate bowel cleansing products
Gadolinium Based Contrast

- Gadolinium is a clear, non-radioactive liquid, approved by the FDA as an injectible contrast agent used during MRI
  - Provides better contrast between healthy and unhealthy tissue
  - Can cause nephrogenic systemic fibrosis
- Screen all patients for renal dysfunction
- Gadolinium is a clear, non-radioactive liquid, approved by the FDA as an injectible contrast agent used during MRI
Gadolinium Based Contrast

- Be aware of BUN and creatinine when ordering Magnetic resonance angiography (MRA) that requires IV contrast
  - Use MRI to take pictures of blood vessels
  - Dose for MRA may be 3x higher than dose for MRI
- If patient being dialyzed, do immediately after test
  - Patients with severe renal impairment at risk for NSF
  - Do not exceed recommended dose of GBCA
  - Risk is 4 percent in this population
Gadolinium Based Contrast

- Consider adding to Informed Consent
- FDA says risk for mild to moderate renal insufficiency is unknown but no reported cases
- New box warning now
- Affects mostly middle aged patients
FDA Gadolinium Bases Contrast

www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142882.htm
Gadolinium Based Contrast

- NSF (nephrogenic systemic fibrosis) is a debilitating and sometimes fatal disease affecting skin, muscles, and internal organs.

- Diagnosis is confirmed by skin biopsy (thickened collagen bundles with surrounding clefts, mucin deposition, and proliferation of fibroblasts and elastic fibers).

- Linked to patients with moderate or end-stage kidney disease.

- Note picture characterized by thickening, indurations, and hardening of the skin and distinct nodules can also be seen.
Gadolinium Based Contrast

- Symptoms can include hardening of skin, discoloration, burning, itching, joint pain and stiffness, hip pain, scarring of body organs, muscle weakness, difficult to bend joints, and death
  - Usually develops two to four weeks, but can develop two to three months after MRI
  - No known cure

- Multiple sites for law firms advertising that patients may be entitled to compensation and offering free case review
The International Center for Nephrogenic Systemic Fibrosis Research (ICNSFR)

Last Updated June 27, 2011

Recent updates are indicated in red.

This site can be accessed at the following URL: http://www.icnsfr.org

By Shawn E. Cowper, MD
Associate Professor of Dermatology and Pathology
Yale University

Newly available:

Dr. Cowper's NSF Blog

What is NSF? | Links | Timeline | The "Center" | The NSF Registry at Yale | The NSF Support Group | Gifts of Support for NSF Research | Contact Information |
References | Article Summaries | Citing this webpage | Images | Message from Dr. Cowper | FAQ

Original Case Definition

Patients who have developed large areas of hardened skin with slightly raised plaques, papules, or confluent papules; with or without pigmented alteration and/or with biopsies showing increased numbers of fibroblasts, alteration of the normal pattern of collagen bundles seen in the dermis, and often increased dermal deposits of mucin.

Updated Case Definition

A multidisciplinary team of clinicians and dermatopathologists highly experienced in nephrogenic systemic fibrosis has recently completed a clinicopathological definition of NSF. This definition relies upon a combination of clinical and pathological findings derived from the study of numerous patients, the relevant medical literature, and histological slides and data contained within the Yale NSF Registry to create a reproducible diagnostic and work-up scheme for putative cases of NSF. The definition is currently under peer review, and once published, will be reproduced in some form on this website for the use of clinicians and pathologists.
Summary

- Make sure you have a copy of the ACR MR Guidance Document 2013
- Make sure your P&P is consistent with this document
- Keep door to Magnet room closed and limit and monitor access to MRI suite
- Test all items for ferromagnetic properties before taking them into the MRI room
- **Label** ferrous items that remain in the hospital so everyone knows they cannot be taken into the room
  - Such as sandbags
Summary

- Do pocket check before entering, especially for scissors, hemostats, and pens
- Need to review policy and procedure annually
- Consider education on MRI safety in orientation and during annual skills lab
- Provide formal training for all who enter, including nursing, transport, security, environmental services, maintenance, etc.
- Any nurses or physicians or other staff who enter MRI must be screened
Summary

- Routinely access compliance with these policies and procedures, especially housekeeping and maintenance and security.
- Have special MRI safe equipment for use in MR room such as **IV pole**, oxygen canister, fire extinguishers, monitors, wheelchair, etc. and have them marked for use in MRI room.
- Provide all patients with hearing protection.
Summary

- Don’t make assumptions about equipment such as sand bags and pillows being safe
  - Check them out
- Report all incidents to the FDA MedWatch program
- Never code a patient in the MRI suite
- If you buy a new MRI or upgrade the system make sure the label of “MR Conditional” still applies
Summary

- Always assume MR system’s static magnetic field is on
- Identify 4 zones in the MRI suite and surrounding floors
  - Include adjacent floors where magnetic field exceeds 5 gauss
- Consider doing a FMEA or RCA if event occurs
- Check sedated patients periodically for heating at sensor site
Summary

- Don’t allow equipment and other devices past the 5 G lines unless tested by the device manufactures

- Make sure these devices are labeled “MR safe” (see book at end and website with list of more than objects and implants tested at 3-Tesla or higher)¹

- Audit compliance with policy

¹ http://www.mrisafety.com/list.asp
Summary

- Provide patient information booklet on MRI\(^1\)
  - Explain it is vital to remove all metallic objects in advance of the MRI exam
  - Explain that scanner can dislodge clip from blood vessel, cause heart pacemaker to malfunction, or damage their external hearing aid

\(^1\) http://www.mrisafety.com/safety_article.asp?subject=170
Summary

- Use a MRI screening form to ask about things that might cause a health risk or interfere with imaging
  - Refer MRI screening form on an annual basis for anything that needs to be added or amended
- Remove patches that contain metal before the MRI and if unsure remove patch
Summary

- Make sure MRI procedure is pre-certified if patient has insurance
  - Document information in medical record
- Remember to use an ABN if no medical necessity
  - Check with physician for acceptable ICD code or necessity first
- Patients should wear hospital gown without metallic snaps
Summary

- Have piped medical gases in MR room
  - Will help prevent oxygen tanks from being brought in

- Don’t loop cables or allow cables to cross one another and use MR compatible cables when conducting an MRI

- Don’t let patients touch the wall of the magnetic bore
Summary

- Assign a MR safety officer
  - Review the P&P yearly
  - Ensure staff are trained
- Empower MR technicians to have control over access to MR environment
- Screen all personnel coming into MR environment
### The MRI Suite Safety Score:

A scoring system of many of our recent presentations has been patient management: evaluating and quantifying where you are and determining where you would like to be. This can apply to any number of safety assessment factors for imaging providers, from no-show appointments, to repeat scans, to patient throughput. Today, however, we will help MRI facilities put a score to the safety questionnaires of their practice to help identify how effective your current safety practices are and, most importantly, identify ways to improve safety for your patients and staff.

We start with the safe assumption that your safety score is perfect, not personal, except as modified by the factors below:

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
</table>
| 01. Do your referring physicians frequently order patients with medical implants or patients with infectious medical illnesses? | No: 0  
Yes: 5 |
| 02. Do you pre-screen patients with a telephone appointment confirmation? | No: 0  
Yes: 5 |
| 03. Are the in-room radiographer(s) trained and competent for your institution? | No: 0  
Yes: 5 |
| 04. Do you have a single standard clinical screening form for all patients and visitors, or are only those questions that seem relevant to each person? | No: 0  
Yes: 5 |
| 05. Do you have private screening areas for patient interviews? | No: 0  
Yes: 5 |
| 06. Do you have your patients prior to their MRI exam? | Every Patient: 0  
Every Other: 3  
Stove Clothes: 6 |

**Page Total:**

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**Note:**

- Yes = 5
- No = 0
- Some = 3
- Partial = 1
- None = 0
- n/a = 0
- >n/a = 0

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The End! Questions??

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Board Member
Emergency Medicine Patient Safety Officer www.empsf.org

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Resources

- MRI safety website at www.mrisafety.com
- Cost of MRI accidents at http://www.mri-planning.com/accidents.html
- The Joint Commission Sentinel Event Alert 38, Issued February 14, 2008, Preventing Accidents and injuries in the MRI Suite, at www.jointcommission.org
Resources


Resources (continued)

- “Fatal MRI Accident is First of Its Kind,” www.webmd.com/content/Article/34/1728_85340.htm
“Projectile Cylinder Accidents Resulting from the Presence of Ferromagnetic Nitrous Oxide or Oxygen Tanks in the MR Suite,” AJR:177, July 2001

Radiographic Imaging CEU Source, LLC, Part 6, MRI Safety For Health Care Personnel
Resources (continued)


- CDRH Draft Document: "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems"
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm
"CDRH Guidance for Testing MR Interaction with Aneurysm Clips, Draft Document"
http://www.fda.gov/


Resources (continued)

- IEC 601-2-33 - Medical Electrical Equipment - Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis at www.ansi.org (standards can be purchased)

- To see pictures of things that have flown into the MRI see Danger! Flying Objects! at http://www.simplyphysics.com/flying_objects.html#
Resources (continued)

- MR-Technology information portal at http://www.mr-tip.com/serv1.php?type=welcome and this has links to more than 2100 publications

Resources (continued)


Resources (continued)


- MRI screening form at MRIsafety.com or at www.imrser.org and www.acr.org

- MRI screening tool in ACR 2007 document above

Resources (continued)


- ECRI Hazard Report, Patient Death Illustrates the Importance of Adhering to Safety Precautions in Magnetic Resonance Environments

Resources (continued)

- International Society for Magnetic Resonance in Medicine (ISMRM) at www.ismrm.org
- American College of Radiology at www.acr.org
- FDA Public Health Advisory on Nephrogenic Systemic Fibrosis (NSF) or Nephrogenic Fibrosing Dermopathy (NFD) at http://www.ismrm.org/
Resources (continued)


Resources (continued)


- FDA Public Health advisory on NSF at http://google2.fda.gov/search?q=Gadolinium+based+contrast&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml_no_dtd&getfields=*&x=21&y=14

- FDA information for healthcare professionals at http://www.ismrm.org/special/FDA%20gadolinium%201206.pdf
Resources (continued)


Lenz’s Forces

- Heinrich Lenz formulated this law in 1834.
- Lenz’s law was a physical interpretation of Faraday’s law of induction.
- Lenz’s law states that the induced current in a loop is in the direction that creates a magnetic field that is parallel to the change in magnetic flux through the area enclosed by the loop. That is, the induced current tends to keep the original magnetic flux through the field from changing.
- It is principle of the conservation of energy.
Lenz’s Forces (continued)

- To see why, move a magnet toward the face of a closed loop of wire
- And electric current is induced in the wire because the electrons within it are subject to an increasing magnetic field as the magnet approaches
- This produces an electromagnetic field that acts upon them
- Direction of current depends on whether north or south pole of magnet is approaching (north pole is anti clockwise and south pole is clockwise)
Lenz’s Forces (continued)

- If you take a coil and connect it to make a loop to the permanent magnet like short circuiting the coil
- Basically the coil affects the magnetic field
- For an easy to see video on this go to http://msdaif.googlepages.com/demo_lenz
- The second object basically generated its own magnetic force
Thus, moving a large metallic but non-ferromagnetic electrical conductor toward the magnet bore will result in the induction of a voltage and associated magnetic field.

If, for example, one tries to move a nonferrous oxygen tank into the bore of an MR scanner, as the scanner bore is approached, Lenz’s forces will be sufficiently strong to virtually stop forward progress of the tank.
Lenz’s Forces (continued)

- Further, the faster one moves the tank into the bore, the greater the opposing force that is created to stop this motion, implications for patients with large implants.

- If you move a patient /implant too fast, can result in forces on the implant, slowly move into and out of bore, some light erroneously cancel the procedure.
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1. Press *1 on your touchtone phone. If you are using a speaker phone, please lift the receiver and then press *1.

2. If you would like to withdraw your question, press *1.
The End

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