Update on MRI Safety

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Outline

• American College of Radiology (ACR) guidelines & recommendations
• Considerations for hardware
• Site considerations / zoning
• Personnel considerations
• Device considerations / safety testing
• Patient considerations / screening
• Gadolinium considerations

Objectives

Upon completion of this course, the learner should be able to:

• Describe the importance of safety in Magnetic Resonance Imaging (MRI).
• Recognize the American College of Radiology (ACR) recommendations associates with MRI safety.
• Explain magnetic field considerations with MRI safety.
• Describe static field (known as B0), radiofrequency [RF, a time varied (oscillating) magnetic field known as B1] field and gradient field [a time varied magnetic field (TVMF)] considerations.
• Demonstrate appropriate patient screening techniques in MRI.
• Identify safety considerations associated with contrast media (CM), typically gadolinium (Gd)) in MRI.

MRI Safety Update – ACR Guidelines

• History of MRI safety
• ACR white paper 2002
• ACR update
• ACR white paper 2004
• ACR white paper 2007
• Contrast media update 2010
• Up-to-the-minute updates!

From Very Bad to Better!

• In 2001, a child was killed in New York
  – Oxygen tank flew into an MRI scanner!
  – Boy was hit in the head by the O2 Tank!
• ACR develops a “Blue Ribbon” panel of MRI experts
  – Review existing MRI safety practices & guidelines
  – Establish recommendations for MRI safety training
• 2002 – White Paper on MR Safety
• 2002 – Commentary – ACR White Paper
• 2004 – Combined papers 2002 & 2004
• 2010 – Contrast Media update
Blue Ribbon Panel

- MRI experts
- Radiologists
- Physicians
- PhDs
- Technologists
- Representatives from corporate
- FDA
- Lawyers

MRI Safety Resources

- Institute for Magnetic Resonance Safety, Education & Research
  [www.imrser.org]
- Frank Shellock, PhD, MRI Safety Page
  [www.mrisafety.com]
- American College of Radiology
  [www.acr.org]


ACR Recommendations

- Establish, implement & maintain safety policies & procedures
  - Develop current MRI safety policies & practices
  - Update with upgrades of equipment and protocols
- "Name" MRI medical director
  - Develop safety training program
  - Ensure that safe policies are established & maintained
  - Appropriate to site (equipment & practice)
  - Implemented and adhered to at all times
- Report incidents
  - Actual events & "near misses"
  - Within 24 hours of the event
  - "Med-watch" program

Magnetic Moment...

The first ACR white paper on MRI Safety was published in:

a. 1895
b. 1975
c. 2002
d. 2009

If you had difficulty answering this "Magnetic Moment" question correctly, or if you would like to re-review this concept: Click back to slide 5 & 6 on the table of contents. Remember, you are NOW on slide 12. Click slide 12 to continue with this lecture.
The main objectives for the production of the ACR white paper is to accomplish all of the following EXCEPT:

a. Establish, implement & maintain safety policies & procedures
b. “Name” MRI medical director
c. Report incidents
d. Optimize scan protocols

If you had difficulty answering this “Magnetic Moment” question correctly, or if you would like to re-review this concept: Click back to slide 9 on the table of contents. Remember, you are NOW on slide 14. Click slide 14 to continue with this lecture.

MRI Safety Update – Hardware

- Magnetic fields
  - Time varied magnetic fields (TVMF)
  - Radiowave Fields (RF)
  - Gradient fields
- Static magnetic field
- Fringe field

RF Field Safety

- RF
  - Power
  - Wavelength
- Bio-effects
  - RF Heating
    - More problematic when dealing with metallic materials within the imaging volume of the magnet
    - Different issues with higher field strengths
    - Varies with system
      - SAR
    - FDA Regulations

Bio-effects of RF

- Most of the RF power used in MRI imaging
  - Is transformed into heat
  - Is absorbed in the patient's tissues
- Bio-effect of RF absorption is heating of tissue
  - FDA limits to an increase in core body temperature of 1 degree...Centigrade (°C)
  - FDA limits the absorption of RF
    - To 4.0 watts/kilogram (w/kg) for whole body absorption
    - Averaged over 15 minutes for clinical imaging

SAR Limits for RF Fields

<table>
<thead>
<tr>
<th>Site</th>
<th>Dose (W/kg)</th>
<th>Time (min)</th>
<th>SAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>Averaged Over</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Head</td>
<td>Averaged Over</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Head or Torso</td>
<td>Per Gram of Tissue</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Extremities</td>
<td>Per Gram of Tissue</td>
<td>5</td>
<td>12</td>
</tr>
</tbody>
</table>
Increased … RF Effects

- Scans & options
  - Magnetic Transfer (MTI)
  - Fast Spin Echo (FSE)
    - More heat / more RF pulses
    - Double the flip, 4X the power
  - Patients with compromised thermoregulatory systems
    - Higher risk for RF effects
  - More heat / more RF pulses
  - Double the flip, 4X the power
  - Patients who are more sensitive to heat

Bio-effects of TVMF

- Acoustic noise
  - Hearing protection
- Peripheral nerve stimulation
  - No loops
  - Do not cross hands or legs
  - Magnetophosphenes
    - Stimulate the retinal phosphenes
    - Stars in your eyes!

“According to the FDA, special consideration should be given to certain patient populations (pediatric patients, seriously ill) when performing certain MRI procedures that may produce peripheral nerve stimulation. Patients should be instructed to report any painful sensations that occur during the procedure.”

Gradient Field / TVMF Safety

- Gradient units
  - 1 mT/m = 10 g/cm (strength / amplitude)
  - Microseconds (speed / rise time)
  - m/s (speed – strength & speed)
- Gradient switching
  - Higher slew rates increase possibility of current induction
  - Time varied magnetic fields
  - Bio-effects
  - FDA regulations

Gradient Magnetic Fields

United States (US) Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)

Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices, issued on 07/14/03

“Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation.”

Increased … TVMF Effects

- Scans & options
  - High speed gradients
  - EPI (Echo Planar Imaging) diffusion / perfusion
  - No loops within the magnet
  - Patients for increased risk of anxiety due to acoustic noise:
    - Head trauma, elderly, pediatric
    - Psychiatric disorders
  - Time-varying gradient magnetic field-related issues:
    - Induced voltages in head trauma, elderly, pediatric
    - Patients with implanted or retained wires in anatomically or functionally sensitive areas (e.g. myocardium or epicardium)
    - Such patients should be reviewed by the level 2 MRI personnel-designated attending radiologist supervising the case or patient.

**Static Magnetic Field – Fringe Field**

- **Main magnetic field strength**
  - Low field 0.2 – 0.35T
  - Mid field 0.5T
  - High field 1.0T – 2.0T
  - Ultra high field 3.0T
- **Fringe field**
  - Limit to 5 gauss
  - Shielding
- "**Missile effects**"
  - Occur when the fringe field draws ferromagnetic materials rapidly into the magnetic field
  - Terminal velocity of a projectile, determined by the mass of the object (and its material) and distance from the magnet

**To date, there are no long-term biological affects associated with exposure to static magnetic fields!**

**Static Magnetic Field**

- FDA limit for exposure to static magnetic field
  - 4.0 T < 1 month of age or less
  - 8.0 T > 1 month

**Safety Considerations for the Static Magnetic Field**

- **Main magnetic field strength (T)**
  - Within the bore
  - Direction
    - Vertical
    - Horizontal
- **Fringe field (g)**
  - Outside the imager
  - Projectiles
- **Forces**
  - Translational
  - Rotational
- **Bio-effects**
- **FDA regulations**
- **Screening**

**Siting Issues Magnetic Field Shielding**

- **Passive**
  - Metal in scan room walls
  - Steel
- **Active**
  - Implies current
  - Other magnets within
- **5 g within the wall**
  - General public
  - De-activates pacer

**Active Shielding – Tennis Anyone?**

- **Active shield**
  - 1/4 of a doubles tennis court
- **Passive shield**
  - Steel within scan room walls
- **Non-shielded**
  - The entire tennis court

**Magnet Configurations**

- **Permanent Magnet**
  - Ferromagnetic material
  - Magnetized
  - Low cost (purchase)
  - Low cost (operation)
  - Heavy in weight
  - Low field strength
- **Resistive Magnet**
  - Coils of wire
  - Current creates magnet
  - Low cost (purchase)
  - High current cost (operation)
  - Light in weight
- **Superconducting Magnet**
  - Coils of wire
  - Superconducting
  - Low cost (purchase)
  - Zero current cost (operation)
  - Cryogen cost
  - Medium in weight
  - High field strength

**Images courtesy of Hitachi Medical**

**Images courtesy of Philips Medical**

**Images courtesy of Siemens Medical**
**Quench: Superconducting Magnets**

- Uses cryogens
  - Liquid helium
- Helium stable as gas
  - Helium 750 liter (gas) to 1 liquid liter
  - 1,000 liquid liters per magnet
  - 750,000 liters of gas inside the magnet!
- Quench
  - Boil off of cryogen
- Quench hazards in the MRI scan room
  - Increased pressure, can't open door
  - Reduced room temperature – frostbite
  - Reduced oxygen – asphyxia

**Ramp Down vs. Quench**

- Ramp down
  - Controlled removal of cryogens
  - Controlled reduction of magnetic field
- Quench
  - Uncontrolled removal of cryogens
  - Cryogens are designed to vent into the ceiling through a venting system.
  - Quench hazards in the MRI scan room
    - Note that the ceiling tiles have fallen out
    - The increased pressure from the quench moved the scan room walls. As a result, the ceiling tiles fell out.

**To Quench or not to Quench?**

- During cardiac arrest
- Remove patient from the bore – field
- Begin CPR
- No need to quench!
- ACR Guidance Document for Safe MR Practices / quench
  - Not routinely advised for cardiac or respiratory arrest or other medical emergency
  - Quench can be hazardous
  - Ideally one should evacuate the magnet room
  - One should initiate life support measures while removing the patient from Zone IV

**Magnetic Moment...**

- The FDA limit for RF exposure is:
  a. 0.4 w/kg
  b. 4.0 w/kg
  c. 8.0 T
  d. Until the patient feels discomfort

**Magnetic Moment...**

- The FDA limit for RF exposure is:
  a. 0.4 w/kg
  b. 4.0 w/kg
  c. 8.0 T
  d. Until the patient feels discomfort

*If you had difficulty answering this “Magnetic Moment” question correctly, or if you would like to re-review this concept, click back to slide 17 & 18 on the table of contents. Remember, you are now on slide 36. Click slide 36 to continue with this lecture.*
The FDA limit for static magnetic field strength is:

a. 2.0 T for all patients
b. 4.0 T for all patients
c. 6.0 T for infants
d. Until the patient feels discomfort

If you had difficulty answering this “Magnetic Moment” question correctly, or if you would like to re-review this concept: Click back to slide 26 on the table of contents. Remember, you are NOW on slide 38. Click slide 38 to continue with this lecture.

MRI Safety Update – Levels, Siting & Zones

- Magnetic fields
  - Static field
    - Within the bore
    - Outside the bore
  - TVMF
    - RF
    - Gradients
- Site considerations
  - Zones
  - Shielding
  - Signs

Levels & Zones - According to ACR

<table>
<thead>
<tr>
<th>Personnel In the MRI Environment</th>
<th>Locations In the MRI Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-MRI Personnel – No MRI Training</td>
<td>Zone I – Level 1 or 2 Non-MRI Personnel</td>
</tr>
<tr>
<td>Level 1 – Limited MRI Training</td>
<td>Zone II – Level 1 or 2 Non-MRI Personnel</td>
</tr>
<tr>
<td>Level 2 – Extensive MRI Training</td>
<td>Zone III – Only level 2</td>
</tr>
<tr>
<td></td>
<td>Zone IV – Only level 2</td>
</tr>
</tbody>
</table>

ACR Recommendations – Zones

- Zoning 2002
  - Zone I
  - Zone II
  - Zone III
  - Zone IV
- Zoning 2004 & 2007
  - Zone I
  - Zone II
  - Zone III – Modified
  - Zone IV

Imager Considerations – Zoning

- Zone I:
  - This includes all areas that are freely accessible to the general public.
- Zone II:
  - This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III.
- Zone III:
  - This area is the region in which free access by unscreened non-MRI personnel and/or ferromagnetic objects and equipment can result in serious injury or death. All access to at least Zone III is to be strictly restricted, with access.
- Zone IV:
  - This area is synonymous with the MRI scanner magnet room itself.

* Based on the ACR white paper. The concept of designating various zones to help control site access relative to the static magnetic field of the MRI system.
Levels of MR Personnel – Who Goes Where?

- **Non-MRI Personnel**
  - Patients, visitors or facility staff who do not meet the criteria of level 1 or level 2 MRI personnel.
  - Examples of non-MRI personnel
- **Level 1 Personnel**
  - Individuals / minimal safety educational efforts to ensure their own safety as they work within Zone III regions (e.g., MRI department office staff, patient aides)
  - Examples of Level 1 personnel
- **Level 2 Personnel**
  - Individuals / more extensively trained and educated in the broader aspects of MRI safety issues including issues related to the potential for thermal loading/burns, direct neuromuscular excitation from rapidly changing gradients, etc., (e.g., MRI technologists, radiologists, radiology department nursing staff)
  - Examples of Level 2 personnel

Note the locations of various categories of personnel relative to MR imager.

Annual MRI Safety Training for Everyone!

- Who needs MRI safety training?
  - Level 2 – Extensive training
    - Technologists
    - Radiologists
  - ALL healthcare professionals
    - Level 2 or level 1
    - Nurses
    - Doctors
    - Level 1 – Limited training
      - Ancillary staff (aides, clerical)
      - Transporters
    - Others
      - Non-MRI personnel
      - Fireman
      - Police
      - Visitors

From the ACR Guidance Document for Safe MRI Practices 2007

Non-MRI Personnel - Who Goes Where?

"Non-MRI personnel should be…

- Accompanied by, or under the immediate supervision of, and in visual or verbal contact with, one specifically identified level 2 MRI person for the entirety of their duration within Zone III or Zone IV restricted regions.
- However, it is acceptable
  - To have non-MRI personnel in a changing room or restroom in Zone III without visual contact
  - As long as the personnel and the patient can communicate verbally with each other."

Level 1 Personnel

**Level 1 MRI Personnel**: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III.

Level 1 personnel can include ancillary MR staff such as transporters, technologist aides, clerical staff, nurses, physicians and even technologists from radiography – to name a few.

Zone I – Accessibility

"Zone I: This region includes all areas that are freely accessible to the general public. This area is typically outside the MRI environment itself and is the area through which patients, health care personnel, and other employees of the MRI site access the MRI environment."

It is acceptable for Non-MRI personnel to be within Zone I without escort from Level 2 personnel.

Zone II – Patients Greeted

"Zone II: This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MRI personnel. It is in Zone II that the answers to MRI screening questions, patient histories, medical insurance questions, etc. are typically obtained.

It is acceptable for Level 1 personnel to ‘greet’ Non-MRI personnel within Zone II."
**Level 1 Personnel - Who Goes Where?**

Level 1 MRI Personnel are permitted unaccompanied access throughout Zones III and IV. Level 1 MRI personnel are also explicitly permitted to be responsible for accompanying non-MRI personnel into and throughout Zone III, excluding Zone IV. However, level 1 MRI personnel are not permitted to directly admit or be designated responsible for non-MRI personnel in Zone IV.

In the event of a shift change, lunch break, etc., no Level 2 MRI personnel shall relinquish their responsibility to supervise non-MRI personnel still within Zone III or Zone IV until such supervision has been formally transferred to another of the site’s level 2 MRI personnel.

**Level 2 Personnel - Training**

Level 2 MRI Personnel:
- Those who have been more extensively trained and educated in the broader aspects of MRI safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients.
- It is the responsibility of the MRI medical director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MRI personnel.
- It is understood that the medical director will have the necessary education and experience in MRI safety to qualify as level 2 MRI personnel.

**Level III – Accompanying Personnel**

“Zone III: This area is the region in which free access by Unscrenced non-MRI personnel or ferromagnetic objects or equipment can result in serious injury or death.

- These interactions include, but are not limited to, those involving the MRI scanner’s static and TVMF.
- All access to Zone III is to be strictly restricted.
- With access to regions within it (including Zone IV) controlled by, and entirely under the supervision of, Level 2 MRI personnel.
- Specifically identified MRI personnel (typically, but not necessarily only, the MRI technologists) are to be charged with ensuring that this MRI safe practice guideline is strictly adhered to for the safety of the patients and other non-MRI personnel, the health care personnel and the equipment itself. This function of the MRI personnel is directly under the authority and responsibility of the MRI medical director or the level 2 MRI personnel-designated physician of the day for the MRI site.”

**Level III – Locked Access**

Zone III regions should be physically restricted from general public access by

- Key locks, passkey locking systems, or any other reliable, physically restricting method that can differentiate between MRI personnel and non-MRI personnel.
- The use of combination locks is discouraged as combinations often become more widely distributed than initially intended.
- Only MRI personnel shall be provided free access, such as the access keys or passkeys, to Zone III.

*There should be no exceptions to this guideline. Specifically, this includes hospital or site administration, physician, security, and other non-MRI personnel. Non-MRI personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MRI personnel themselves.*

**Zone III – Signs**

Signs should be posted outside the MR imager room. Bear in mind that:

- Magnetic fields are three-dimensional volumes.
- Zone III controlled access areas may project through floors and ceilings of MRI suites, posing magnetic-field hazards on persons on floors other than that of the MRI scanner.
- Zones of magnetic field hazard should be clearly delineated (with signs) even in typically non-occupied areas such as rooftops or storage rooms, and access to these Zone III areas should be similarly restricted from non-MRI personnel as they would be inside any other Zone III region associated with the MRI suite.
- Magnetic field strength plots for all MRI systems should be analyzed in vertical section as well as in horizontal plan, identifying areas above or below...

**Warning vs. Danger Signs**

Warning or Danger signs should be prepared and posted outside Zone III and/or Zone IV.

- Location of lock outside Zone III and/or Zone IV.
- Location of signs posted outside Zone IV - May be recommended to post in 3 dimensions.

*From the ACR Guidance Document for Safe MRI Practices 2007*
Warning vs. Danger vs. Hazard Signs

**Zone IV – Lighted Signs**

*Zone IV should be clearly marked*

- with a red light and lighted sign stating, "The Magnet is On."
- Except for resistive systems, this light and sign should be illuminated at all times and
- should be provided with a backup energy source to continue to remain illuminated for at least 24 hours in the event of a loss of power to the site.*

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Zone IV – Keep an eye on the Patient!

* Zone IV = the MRI scanner magnet room itself
- The physical confines of the room within which the MRI scanner is located.
- Zone IV, by definition, will always be located within Zone III.
- The MRI magnet and its associated magnetic field of Zone IV.
- Zone IV should also be
  - Demarcated and clearly marked as being hazardous due to very strong magnetic fields.
- Zone IV site restriction, all MRI installations
  - should provide
    - Direct visual observation by level 2 personnel to pathways to Zone IV.
    - By means of illustration only, the MRI technologists would be able to directly observe and control, via line of sight or via video monitors,
      - The entrances or access corridors to Zone IV from their normal positions when stationed at their desks (at the console) in the scan control room.*

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MRI Technologists

"MRI Technologists should be American Registry of Radiologic Technologists (ARRT)–registered technologists (RTs)."

- All MRI technologists must be trained as level 2 MRI personnel prior to being permitted free access to Zone III.
- All MRI technologists will maintain current certification in American Heart Association basic life support.
- Except for emergent coverage, there will be a minimum of 2 MRI technologists or one MRI technologist and one other individual with the designation of MRI personnel in Zone II through Zone IV.
- For emergent coverage, the MRI technologist can scan with no other individuals in their Zone II through Zone IV.
- As long as there is in-house, ready emergent coverage by designated department of radiology MRI personnel (e.g., radiology house staff or attending radiologist)."

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Pregnant Healthcare Workers

"Healthcare Practitioner Pregnancies"

- Pregnant healthcare practitioners are permitted to work in and around the MRI environment.
- Throughout all stages of their pregnancy.
- Acceptable activities include, but are not limited to,
  - positioning patients, scanning, archiving,
  - injecting contrast material,
  - and entering the MRI scan room in response to an emergency.
- Although permitted to work in and around the MRI environment, pregnant healthcare practitioners are requested
  - Not to remain within the MRI scanner bore or Zone IV
  - During actual data acquisition or scanning."
**MRI & Pregnancy – Patients (ACR)**

- To date, no conclusive documentation of any deleterious effects of MRI exposure on the developing fetus.
  - Pregnant patients can be accepted to undergo MRI scans at any stage of pregnancy.
  - No special consideration is recommended for the first, versus any other, trimester in pregnancy.
  - The information requested from the MRI study cannot be acquired via non-ionizing means (e.g., ultrasonography).
  - The data are needed to potentially affect the care of the patient or fetus during the pregnancy.
  - The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.
- It is prudent to screen women of reproductive age for pregnancy prior to permitting them access to MRI imaging environments.
- Risks versus benefits of the pending study
- The risk–benefit ratio to the patient
- The radiologist should confer with the referring physician.

**MRI & Pregnancy – Gadolinium (ACR)**

- MRI contrast agents should not be routinely provided to pregnant patients. However, the decision to administer Gd...
  - Case-by-case basis by the level 2 MRI personnel-designated attending radiologist who assesses the risk–benefit ratio for that particular patient.
  - A well-documented and thoughtful risk–benefit analysis.
  - This analysis should be able to defend a decision to administer the contrast agent based on...
    - Overwhelming potential benefit to the patient or fetus
    - Outweighing the theoretic, but potentially real, risks of long term exposure of the developing fetus to free gadolinium ions.
- Studies have demonstrated that gadolinium-based MRI contrast agents pass through the placental barrier and enter the fetal circulation.
  - From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid, and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated.

**Magnetic Moment…**

The ACR recognizes the “level” of training for MRI personnel, whereby:

a. Level 1 is extensively trained
b. Level 1 is not trained
c. Level 2 is minimally trained
d. Level 2 is extensively trained

**Magnetic Moment…**

The ACR designates “Zones” whereby:

a. Zone I is the location within the scan room
b. Zone II is the location within the scan room
c. Zone III is the location within the scan room
d. Zone IV is the location within the scan room
The ACR designates “Zones” whereby:

a. Zone I is the location within the scan room
b. Zone II is the location within the scan room
c. Zone III is the location within the scan room
d. Zone IV is the location within the scan room

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ACR Recommendations – Compatibility

- MRI safe
- MRI unsafe
- MRI conditional

“With the increasing advent and use of 3.0-Tesla and higher strength magnets, users need to recognize that one should never assume MRI compatibility or safety information about a device if it is not clearly documented in writing.

Decisions based on published MRI safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields.”

From the American Society for Testing and Materials (ASTM)

MRI “Compatibility”

- MRI Safe
- MRI Conditional
  - “an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the specified MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), RF, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.”

- MRI Unsafe
  - “an item that is known to pose hazards in all MRI environments.”

- NOT … MRI Compatible
  - devices that have been previously tested and deemed “MRI Compatible” will not be re-tested/changed. New devices will be deemed MRI Safe, MRI Unsafe or MRI Conditional, since 2005.

Ancillary Equipment - Testing & Marking

- If MRI safety data are not prospectively available for a given device, initial testing for the purpose of this labeling is to be accomplished by the site’s MRI personnel by exposing the metallic object to a handheld magnet (≥ 1500 gauss).
- If grossly detectable attractive forces are observed between the object being tested or any of its components and the handheld magnet, it is to be labeled with a circular red “not MRI safe” label.
- If no or negligible attractive forces are observed, a triangular yellow “MRI conditional” label is to be attached to the object. It is only when the composition of an object and its components are known to be nonmetallic that the green “MRI safe” label is to be affixed to a device or object.

Non-MRI – Clinical Equipment

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as “non-magnetic,” or outdated classifications such as “MRI-compatible,” should not be presumed to conform to a particular current ASTM classification. Similarly, any product marketed as “MRI safe” but with metallic construction or components should be treated with suspicion.
Why should screening be performed?

To determine…

• MRI unsafe
  - Pacemaker
  - Metal in the eyes
  - Aneurysm clip

• MRI safe

• MRI conditional

Contraindications for MRI Imaging

• Cardiac pacemaker
  - Dependent pacer patient
  - Non-dependent pacer patients
  - New cardiac pacemakers?

• Intra-ocular ferrous foreign bodies
  - Metal in the eyes
  - X-rays or removal

• Intracranial vascular clips
  - Aneurysm clips (head)
  - Torque

Cardiac Pacemaker

Some facilities will scan pacemakers ONLY IF …

• The patient has a non-dependent pacer
• The patient meets the clinical criteria
• The cardiologist, radiologist, company that makes the pacer are present during and after the exam & assess the patient
• They follow strict criteria, listed on www.mrisafety.com

MRI Conditional Pacemaker - February 8, 2011

Revo MRI™ SureScan® Pacing System

MR Conditional Labeling

- Revo MRI Pacemaker – 5086 MRI CapSureFix
- MRI Pacing Lead – SureScan Software

MRI Conditions for MR Conditional Pacer

• Brand name - Revo™ System
• Scanned with (and ONLY with)...
  - Cylindrical bore MR (solenoid electromagnet)
  - 1.5 T only
  - Whole body SAR not more than 2 W/Kg (normal mode)
  - Head SAR not more than 3.2 W/Kg
  - Maximum gradient slew rate ≤ 200 T/m/s
  - Isocenter (center of bore) superior to C1 or inferior to T12
  - Patient monitoring
    - Verbal and visual
    - Pulse Ox
    - ECG

Additional Conditions for Revo™ System

• Must be programmed by cardiology personnel trained in operation of the SureScan™ component of the system.

SureScan™ component confirms the system is a complete system and ensures the patient is ready for the MRI procedure.
Intraocular Ferrous Foreign Bodies (IFFB)

- All such patients should also undergo plain film imaging of the skull or orbits and chest to exclude metallic foreign objects (if recently obtained plain films or CT or MRI studies of such areas are not already available).
- Should it be determined that non-MRI personnel wishing to accompany a patient into an MRI scan room require their orbits to be cleared by plain-film radiography, a radiologist must first discuss with the non-MRI personnel that plain X-ray films of their orbits are required prior to permitting them access to the MRI scan room.

Intracranial Aneurysm Clip

- Radiologist is responsible for the decision to scan.
- Risk vs. benefit
- Just because they have been scanned before, does not automatically make them safe this time!

Implants in MRI

- Medical risk vs. benefit decision
- Be sure to check field strength that the device / implant has been tested
- Up-to-date information is crucial
- Beware of blanket statements! Example: All stents are not safe
  - www.mrisafety.com
  - www.imrsor.org
  - www.drkanal.com
- Concerns for implants & devices
  - Torque / movement (translational forces)
  - Electrical current induction (burns)
  - Tissue heating (burns)
  - Device failure

Deep Brain Stimulators (DBS)

- Less Ferrous
- More Ferrous

Bone Growth Stimulator with Broken Leads

From the ACR Guidance Document for Safe MRI Practices 2007
**Burn Possibilities**

- Report of permanent brain injury from DBS probe (burn during MRI exam) at 1.0 T
  - Some can only be scanned with transmit/receive head coil.
  - Before scanning, be sure the coil is not receive only!
  - Be sure that a device/implant is safe before scanning.

- Report of 3rd degree burn (1.5 T) with Intracrania pressure (ICP) catheter

*For patients with tattoos or dark tattoos, including tattooed eyelids; in order to decrease the potential for RF heating of the tattooed tissue, it is RECOMMENDED that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process. If these tattoos are in the volume in which the body coil is being used for RF transmission, then these precautions should be followed. Additionally, patients with tattoos that have been placed within 48 hours prior to the pending MRI examination should be advised of the potential for smudging of the edges of the freshly placed tattoo.*

**Burn Possibilities – Config. & Field Strength**

- It is possible to introduce resonant circuitry between the transmitted RF power & the lead (depending upon lead length, field strength and parameter settings)

- This can also occur with implanted leads or wires, even when they are not connected to any other device at either end.

- The FDA has noted several reports of serious injury, including coma and permanent neurologic impairment, in patients with implanted neurologic stimulators who underwent MRI imaging examinations. The injuries in these instances resulted from heating of the electrode tips.

- It is entirely possible for a lead or wire to demonstrate no significant heating while undergoing MRI imaging examinations at 1.5 Tesla (T), yet demonstrate clinically significant and potentially harmful degrees of heating within seconds at, for example, 3T. It has also been demonstrated that leads may show no significant heating at 3T, yet may rapidly heat to hazardous levels when undergoing MRI imaging at, for example, 1.5T.

- What is being used to scan the patient?
- How long has the bullet been in?
- What material are the bullets made of?
- Where is the bullet?

*Correspondence to Mark E. Schweitzer, Department of Radiology, Thomas Jefferson University Hospital, Philadelphia, PA. From the ACR Guidance Document for Safe MRI Practices 2007*

**Other Burn Possibilities**

- Tattoos
- Metal in trans-dermal patches
- Metallic leads/probes
  - ECG leads
  - Risk increases with field strength

**Burns**

- **Risk increases with field strength**

**Ballistics**

- **What material are the bullets made of?**
  - The ferromagnetism of various bullets and shotgun pellets was tested in vitro
  - Ferromagnetic bullets readily rotated within a gelatin phantom in response to magnetic torque. Non-ferromagnetic bullets and pellets demonstrated only mild to moderate metal artifact during spin-echo and gradient-echo magnetic resonance (MRI) imaging.

- **Where is the bullet?**
  - “Caution should be exercised with MRI imaging in the presence of metallic foreign bodies, particularly if they are located near vital neural, vascular, or soft-tissue structures.”

- “Patients with retained bullets and shotgun pellets were imaged safely.”

*From the ACR Guidance Document for Safe MRI Practices 2007*

**Wires in the Magnet – No Loops**

- “When electrically conductive materials are required to be within the bore of the MRI scanner with the patient during imaging, care should be taken to:
  - Place thermal insulation (including air, pads, etc.) between the patient and the electrically conductive material, while simultaneously attempting (as much as feasible) to:
    - Keep the electrical conductor from directly contacting the patient during imaging. It is also appropriate to try to:
    - Position the leads or wires as far as possible from the inner walls of the MRI scanner if the body coil is being used for RF transmission.
  - When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of:
    - Cold compresses or ice packs to such areas.
  - Depending on specific magnet designs, care may be needed to ensure that the patient’s tissues do not directly come into contact with the inner bore of the MRI imager during the imaging process.”

*From the ACR Guidance Document for Safe MRI Practices 2007*

**Metallic ballistic fragments: MRI imaging safety and artifacts**

Steven S. Smugar, MD, Mark E. Schweitzer, MD, Eric Hume, MD
Department of Radiology, Thomas Jefferson University Hospital, Philadelphia, PA.
*Correspondence to Mark E. Schweitzer, Department of Radiology* 4/19/2011

**No Loops!**

- It is important to ensure the patient’s tissues do not form large conductive loops.

- Care should be taken to ensure that the patient’s arms or legs are not positioned in such a way as to form a large-cable loop within the bore of the MRI imager during the imaging process.

- It is preferable that patients be instructed not to cross their arms or legs in the MRI scanner.

- Unpublished reports of thermal injuries that seem to have been associated with skin folds, such as in the region of the inner thighs.

- While the cause of this is not yet fully understood, it might be prudent to:

*From the ACR Guidance Document for Safe MRI Practices 2007*
Post Operative Patients

“Skin staples and superficial metallic sutures:
- Patients may be permitted to undergo the MRI examination if the skin staples or SMS are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed.
- If the non-ferromagnetic skin staples or SMS are within the volume to be RF-irradiated for the requested MRI study, several precautions are recommended.
- Warn the patient and make sure that they are especially aware of the possibility that they may experience warmth or even burning along the skin staple or SMS distribution.
- The patient should be instructed to report immediately if they experience warmth or burning sensations during the study (and not, for example, wait until the “end of the knocking noise”).
- It is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely clinically accomplished during the MRI examination.”

Medication Patches – ACR

Drug Delivery Patches and Pads
- Metallic drug delivery patches
  - Some drug delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury.
  - Remove
    - Since removal or repositioning can result in altering of patient dose, consultation with the patient’s prescribing physician would be indicated in assessing how to best manage the patient.
    - If the patch is removed, a specific staff member should be given responsibility for ensuring that it is replaced or repositioned.
  - Ice pack
    - Alternative options may include placing an ice pack directly on the patch.
    - This solution may still substantially alter the rate of delivery or absorption of the medication to the patient.

Placement of Drug Delivery Patches and Pads

Magnetic Moment...

Terminology with respect to MRI devices, includes all of the following EXCEPT:
- MRI compatible
- MRI safe
- MRI unsafe
- MRI conditional
Magnetic Moment...

Contraindications for MRI imaging, may include any of the following EXCEPT:

a. Patients with certain types of intracranial vascular clips
b. Patients with claustrophobia
c. Patients with certain types of cardiac pacemakers
d. Patients with intra-ocular ferrous foreign bodies

Who Needs Patient Screening?

Everyone who wants to enter the MRI environment, including:

• Patient
• Family / visitors
• Ancillary staff education
  – Transport personnel
  – Construction / maintenance
  – Nursing
  – Patient support
• Emergency response
  – Security
  – Fire department

Recommended Screening Forms – ACR

Forms available at www.acr.com

Recommended Screening Forms

Forms available at www.mrisafety.com

Who performs the screening?

• Screened by level 2 personnel
• More than once
• Verbally & visually
• Written
  – or –
• X-rays
Non-MRI Personnel

All non-MRI personnel wishing to enter Zone III must first pass an MRI safety screening process. Only MRI personnel are authorized to perform an MRI safety screen before permitting non-MRI personnel into Zone III.

Metal Detectors

“The usage in MRI environments of conventional metal detectors which do not differentiate between ferrous and non-ferromagnetic materials is not recommended. Reasons for this recommendation against conventional metal detector usage include, among others:

1. They have varied – and variable – sensitivity settings.
2. The skills of the operators can vary.
3. Today’s conventional metal detectors cannot detect, for example, a 2 × 3 mm, potentially dangerous ferromagnetic metal fragment in the orbit or near the spinal cord or heart.
4. Today’s conventional metal detectors do not differentiate between ferromagnetic and non-ferromagnetic metallic objects, implants, or foreign bodies.
5. Metal detectors should not be necessary for the detection of large metallic objects, such as oxygen tanks on the gurney with the patients. These objects are fully expected to be detected – and physically excluded – during the routine patient screening process.”

Hand-Held Magnets

- Ferromagnetic detection systems are currently available that are simple to operate, capable of detecting even very small ferromagnetic objects external to the patient, and now, for the first time, differentiating between ferromagnetic and non-ferromagnetic materials.
- While the use of conventional metal detectors is not recommended, the use of ferromagnetic detection systems is recommended as an adjunct to thorough and conscientious screening of persons and devices approaching Zone IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage.

Patient Preparation for MRI

- Any individual undergoing an MRI procedure…
- …must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches, jewelry, pagers, cell phones, body piercings [if removable], contraceptive diaphragms, metallic drug delivery patches, cosmetics containing metallic particles [such as eye make-up], and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads).
- “It is therefore advisable to require that the patients or research subjects wear a site-supplied gown with no metal fasteners when feasible.”

Patient Considerations

- Emergency care
- Claustrophobia
- Sedation
- Monitoring
- Pregnancy
- Contrast agents
ACR Recommendations for Claustrophobic Patients

1. Prepare the patient (explain the exam)
2. Allow a family member to accompany
3. Maintain verbal/visual contact
4. Headphones
5. Monitor – distraction
6. Virtual reality
7. Feet-first
8. Prone
9. Mirrors or prism glasses
10. Blindfold
11. Lights
12. Fan
13. Lemon or vanilla scent
14. Relaxation techniques
15. Systematic desensitization
16. Hypnosis

Patient Monitoring

Who should be monitored?

- All patients should be monitored verbally & visually.

Who would require additional monitoring?

1. Patients who cannot communicate
2. Patients with weak voices
3. Patients who do not speak English
4. Patients who are sedated
5. Patients with diminished mental capacity
6. Patients at risk for contrast reaction

Monitoring Devices

MRI compatible monitors & devices
- ECG
- Pulse oximeters
- Blood pressure
- Respiratory & apnea
- Temperature
- Multi-parameter monitoring systems
  - The potential for thermal injury from excessive RF power deposition exists.
  - Sedated, anesthetized, or unconscious patients may not be able to express symptoms of such injury.
  - This potential for injury is greater on especially higher-field whole-body scanners (e.g., 1 Tesla and above).
  - Patients who require ECG monitoring and who are unconscious, sedated, or anesthetized should be examined after each imaging sequence, with potential repositioning of the ECG leads and any other electrically conductive material with which the patient is in contact.
  - Cold compresses or ice packs could be placed upon all necessary electrically conductive material that touches the patient during scanning.

Magnet – Hemodynamic Effect

Distortion of the electrocardiogram within the magnetic field makes interpretation of the ECG complex unreliable, even with filtering used by contemporary monitoring systems. However, routine monitoring of heart rate and rhythm may be accomplished using pulse oximetry, which also eliminates the risks of thermal injury from electrocardiography.

Emergency Treatment

All MRI personnel should be familiar with the procedure for removing a patient from the MRI scan room in the event of a medical emergency.
- MRI “safe” supplies for imaging
- Non-ferrous IV poles
- Non-ferrous wheel chairs
- Non-ferrous IV poles
- Stretchers
- Non-ferrous IV poles
- MRI “safe” monitoring devices & more!

According to the ACR white paper on MRI Safety, “Zone III & Zone IV site access restriction must be maintained during resuscitation and / or other emergencies.”
The following patients MUST be screened prior to entering the MRI environment:

- Patients with implants
- Patients without implants
- Parents of pediatric patients
- Anyone who intends to enter the scan room

When hand-held magnets are used in MRI for screening patients:

- The screening is more efficient
- The screening is less efficient
- There can be a false sense of security
- The implant is undetectable

MRI Safety Update – Contrast Media

- Contrast Media in MRI
- Venipuncture
- Safety associated with CM
- Contraindications for Gadolinium

Contrast Administration – ACR White Paper

- No patient is to be administered prescription MRI contrast agents without orders from a duly licensed physician.
- Intravenous injection-qualified MRI technologists may start and attend to peripheral IV access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area.
- IV-qualified MRI technologists may administer FDA-approved gadolinium-based MRI contrast agents via peripheral IV routes as a bolus or as a slow or continuous injection as directed by the orders of a duly licensed site physician.
- Administration of these agents is to be performed according to the ACR policy.
- The ACR approves of the injection of contrast material and diagnostic levels of radiopharmaceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations.
- There must also be prior written approval by the medical director of the radiology department or service of such individuals.
- Such approval process must follow established policies and procedures, and the radiologic technologists and nurses who have been so approved must maintain documentation of continuing medical education related to materials injected and to the procedures being performed.

From the ACR Guidance Document for Safe MRI Practices 2007
Avoid Extravasation

• Animal studies do show moderate necrosis
• Osmolality a consideration
  – More problematic with ionic agents

Investigative Radiology 2002 July;37(7):393-8

Gadolinium Toxicity

• Rare earth metal ion (as a contrast agent)
• Heavy metal (toxic) – as an element
• To remove toxicity – chelate "claw"
  – Non toxic!
  – Ligand
  – Ionic vs. non-ionic
  – Can be excreted

Gadolinium Chelates

Gadoteridol
  (Gd HP-DO3A
  ProHance by Bracco)

Gadopentetate Dimeglumine
  (Gd DTPA
  Magnevist by Bayer / Berlex)

Gadodiamide
  (Gd DTPA-BMA
  Omniscan by GE / Nycomed)

Gadoversetamide
  Optimark by Covidien / Malinkrodt

Adverse Reactions

• Minor reactions occur with all agents in a low percentage of cases.
  – The current 5 agents have similar safety profiles.
• Anaphylactoid reactions are rare.
  – Have occurred with all agents
• Sites should be prepared to treat a reaction.


Adverse Reactions

• Mild transitory headaches (HA)
• Slight increase bilirubin & blood iron
• Nausea / vomiting
• Urticaria / rash
• Less than 1% anaphylaxis or death

Gd Side Effects - Signs vs. Symptoms

• Standard IV use/doses
  – Not nephrotoxic (usually)
• Iodinated contrast equivalent doses or intra-arterial (IA) use for digital subtraction angiography (DSA)
  – Nephrotoxicity has been reported
  – Debatable if gadolinium performs better than low osmolar iodinated agents
• Patients in renal failure ... 1998
  – Nephrogenic fibrosing dermopathy
  – Nephrogenic systemic fibrosis
New Disease – What is it?

Scleromyxoedema-like cutaneous diseases in renal-dialysis patients


1998

What’s in a name? What is it called?

• First described in 1997, in 15 dialyzed patients
• Resembled scleromyxedema
• So … mislabeled at first
• First named…
  – NFD – nephrogenic fibrosing dermopathy (skin)
• Then…
  – NSF – nephrogenic systemic fibrosis
  • Circulating fibrocytes
  • Systemic nature
• Should be diagnosed by skin biopsy
  – Generally is not

NFD / NSF

• NFD – nephrogenic fibrosing dermopathy
• NSF – nephrogenic systemic fibrosis

“... It has been recently noted that over a 4-year period, 20 patients in Denmark and five in Austria developed a very rare disease that is seen only in patients with severely impaired renal function [32, 33]. Each of these patients had been administered Omniscan (gadodiamide, GE Healthcare), a gadolinium-based MRI contrast agent (GBCA), for an MRI imaging or angiographic examination within a few weeks or months prior to the onset of the disease. Roughly 17,500 patients are examined using Omniscan in Denmark each year. Since January 2002, about 400 patients with severely impaired renal function had been examined, of which 20, or 5%, to whom Omniscan had been administered, eventually were diagnosed with this disease in that country.”

ACR Manual on Contrast Media

Version 7, 2010

Risk Factors

• Chronic kidney disease
• Acute kidney injury
• High dose
• Multiple exposures
Identifying Patients at Risk

- eGFR within 6 weeks of procedure in patients with suspected kidney disease
- > 60 years of age
- Hx of renal disease
- Diabetes, hypertension

If possible, avoid administration in patients with eGFR 30 < mL/min/1.73 m².

If possible, avoid administration in patients with eGFR 30 < mL/min/1.73 m²:

a. True
b. False

Upon completion of this course, the learner should be able to:

- Describe the importance of safety in Magnetic Resonance Imaging (MRI).
- Recognize the American College of Radiology (ACR) recommendations associated with MRI safety.
- Explain magnetic field considerations with MRI safety.
- Describe static field (known as B₀), radiofrequency (RF, a time varied oscillating) magnetic field known as B₁ field and gradient field [a time varied magnetic field (TVMF)] considerations.
- Demonstrate appropriate patient screening techniques in MRI.
- Identify safety considerations associated with contrast media (CM), typically gadolinium (Gd)) in MRI.