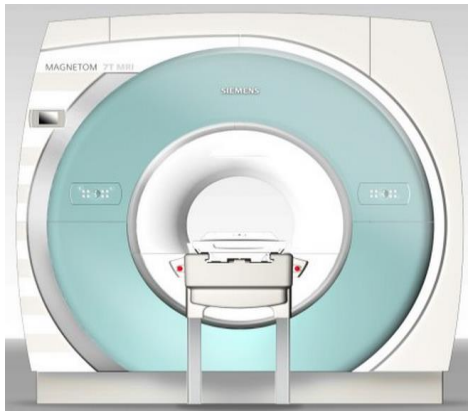
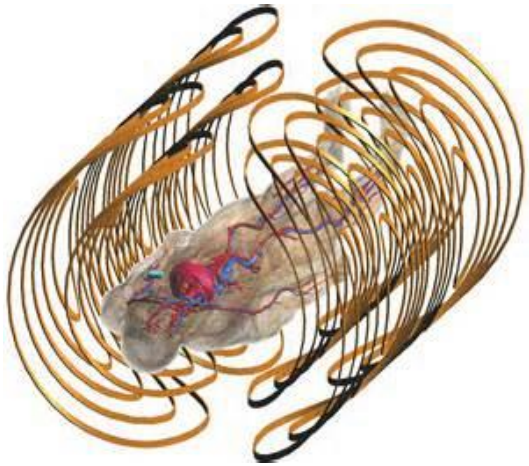




MR Safety Site Management and Policies

Vera Kimbrell
BSRT MR R

Brigham and Women's Hospital
Presenter Disclosure Slide

Nothing to disclose

Outline and Objectives

- Magnet and room design
- Policy and Procedure creation and Implementation
- Screening workflow
- Clearing of Implants and Devices
- Adverse Event Reporting
- Education and training

Areas for Concern

- Projectiles
- RF Burns
- Hearing damage
- Peripheral Nerve stimulation
- Implant or device malfunction/damage
- Cryogen Safety

What really works?

- Most of us practice some combination of these safety measures
  - Ferrous Metal Detectors
  - MR Safety officers/MD/Expert
  - Screening and Implant research

Do these measure keep us safe?

- Under reporting of accidents makes meaningful statistics difficult
  - Accidents however seem to be increasing, by how much depends on whose statistics you review
- MR Safety IS our most important task and maintaining a safe environment for staff and patients the basis of all Safety workflow and policies
- In a busy MR clinic or hospital, safe practices and adherence to those safety policies is vital to your mission

The Perfect MR Site

- Site planning that involves:
  - Careful attention to the surrounding physical setting
    - Neighboring department or traffic
    - Future building plans
      - What is planned around you?
      - What if you need to upgrade or add on?
    - Compliance with Regulations
  - Designing for optimal workflow
    - Decide your plan for daily work BEFORE you design a room/suite

In an ideal world

- MR Medical Director/MD in charge of MR Safety
  - Makes and Implements MR Safety policy
  - Directs Radiologist in protocoling and clearing implanted devices
  - Is accessible for questions concerning safety and protocols
- Physicist
  - Aides in Policy creation and implementation
  - Evaluates equipment for safety and technical issues
  - Is accessible for Questions concerning MR safety
- MR Technologist in charge of reviewing, researching and sending issues forward for Safety clearance
- Clerical Staff to screen/review and prepare the Patient

Reality in many sites

How do we prevent accidents?

Managers can control

- ***Room design and restricted access***
- Policy in place, known and followed consistently
- ***Education***
  - Staff, patient, and all who need access to Zone 3
- ***Labeling all equipment and testing anything that might enter Zone 4***

Controlled by "staff on the floor" during the workday

- Screening and changing Patients and staff
- Positioning pts without loops, wires, and metal
  - All metal removed-If it can't be removed-does not touch anything else
  - Patients have and know how to use emergency call buttons
- Hearing protection-Used correctly

MR Regulatory Bodies

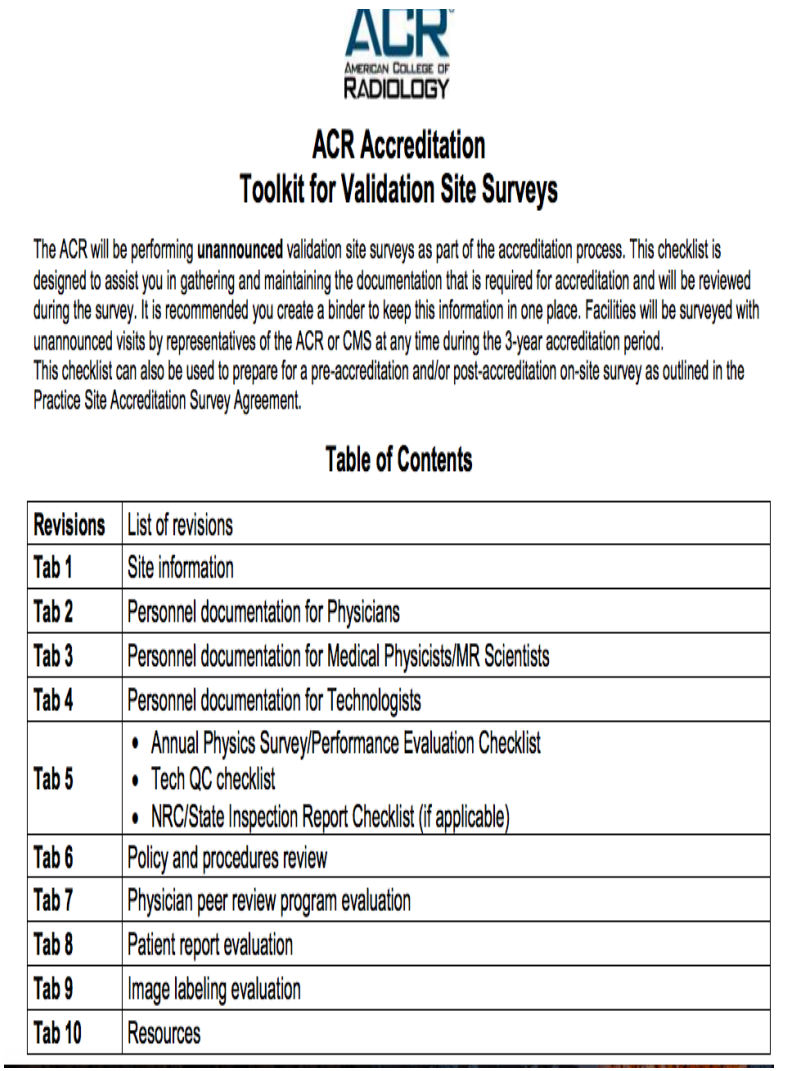
- Regulatory Bodies in USA for MR
  - **ACR**
    - Site certification
    - Radiologist Organization for education and guidelines
  - **JC**
    - Certifies Hospitals including Radiology
  - **Department of Public Health**
    - Governs mostly building codes and pharmaceuticals
  - **ARRT**
    - Technologist certification
  - **FDA**
    - Government clearance for scanners and implanted devices

Specific Safety Documents

- IEC- 60601-2-33 -Requirements for the Safety of MR Equipment for Medical Diagnosis
- FDA-Guidelines for Premarket Notifications for MR Diagnostic Devices NEMA MS 1 through 9 Safety and Performance Standards
- ASTM -Test Methods for MR Safety of Implanted Medical Devices
- ACR -Site Safety Guidelines and White Paper on Safety

ACR Requirements for Sites

- Policies addressing:
  - Site Access
    - Zone 4 specific
  - Incident reporting
  - Training and Education
    - Credentials
      - MR technologists, Rads, Physicist
    - Orientation and Updates
  - Images and Reports
    - Turn around time, critical results
  - Emergency Response
    - Quench
    - Medical Emergency
    - Contrast reaction
    - Unsuspected metal in Zone 4
    - Crash Cart



ACR
American College of Radiology

ACR Accreditation
Toolkit for Validation Site Surveys

The ACR will be performing **unannounced** validation site surveys as part of the accreditation process. This checklist is designed to assist you in gathering and maintaining the documentation that is required for accreditation and will be reviewed during the survey. It is recommended you create a binder to keep this information in one place. Facilities will be surveyed with unannounced visits by representatives of the ACR or CMS at any time during the 3-year accreditation period.
This checklist can also be used to prepare for a pre-accreditation and/or post-accreditation on-site survey as outlined in the Practice Site Accreditation Survey Agreement.

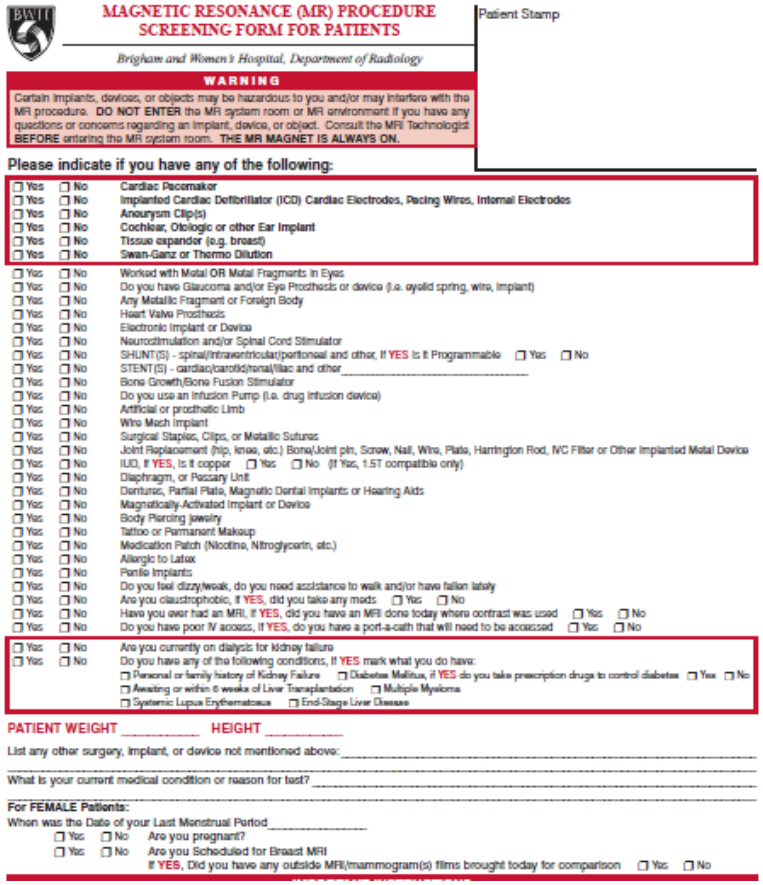
Table of Contents

Revisions	List of revisions
Tab 1	Site information
Tab 2	Personnel documentation for Physicians
Tab 3	Personnel documentation for Medical Physicists/MR Scientists
Tab 4	Personnel documentation for Technologists
Tab 5	• Annual Physics Survey/Performance Evaluation Checklist • Tech QC checklist • NRC/State Inspection Report Checklist (if applicable)
Tab 6	Policy and procedures review
Tab 7	Physician peer review program evaluation
Tab 8	Patient report evaluation
Tab 9	Image labeling evaluation
Tab 10	Resources

ACR Tool kit cont.

- Screening
- Contrast, sedation
  - Who injects?
  - Renal Screening
  - Rad on site
- Claustrophobia
- Signage
  - Zones
  - Pt. complaints
- MR Director and MR Safety Officer
- QA-Weekly and yearly
  - Tech
  - Physicist
- Peer to Peer Rads
- Image and Report labeling

Screening Workflow and Implant policy



MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM FOR PATIENTS

Brigham and Women's Hospital, Department of Radiology

Patient Stamp

WARNING

Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure. **DO NOT ENTER** the MR system room or MR environment if you have any questions or concerns regarding an implant, device, or object. Consult the MRI Technologist **BEFORE** entering the MR system room. **THE MR MAGNET IS ALWAYS ON.**

Please indicate if you have any of the following:

- ☐ Yes ☐ No **Cardiac Pacemaker**
- ☐ Yes ☐ No **Implanted Cardiac Defibrillator (ICD) Cardiac Electrodes, Pacing Wires, Internal Electrodes**
- ☐ Yes ☐ No **Aneurysm Clip(s)**
- ☐ Yes ☐ No **Cochlear, Otologic or other Ear Implant**
- ☐ Yes ☐ No **Tissue expander (e.g. breast)**
- ☐ Yes ☐ No **Swan-Ganz or Thermo Dilution**

- ☐ Yes ☐ No Worked with Metal OR Metal Fragments in Eyes
- ☐ Yes ☐ No Do you have Glaucoma and/or Eye Prosthesis or device (i.e. eyelid spring, wire, implant)
- ☐ Yes ☐ No Any Metallic Fragment or Foreign Body
- ☐ Yes ☐ No Heart Valve Prosthesis
- ☐ Yes ☐ No Electronic Implant or Device
- ☐ Yes ☐ No Neurostimulation and/or Spinal Cord Stimulator
- ☐ Yes ☐ No SHUNT(S) - spinal/intraventricular/peritoneal and other, If YES Is it Programmable ☐ Yes ☐ No
- ☐ Yes ☐ No STENT(S) - cardiac/carotid/renal/iliac and other _____
- ☐ Yes ☐ No Bone Growth/Bone Fusion Stimulator
- ☐ Yes ☐ No Do you use an Infusion Pump (i.e. drug infusion device)
- ☐ Yes ☐ No Artificial or prosthetic Limb
- ☐ Yes ☐ No Wire Mesh Implant
- ☐ Yes ☐ No Surgical Staples, Clips, or Metallic Sutures
- ☐ Yes ☐ No Joint Replacement (hip, knee, etc.) Bone/Joint pin, Screw, Nail, Wire, Plate, Harrington Rod, IVC Filter or Other Implanted Metal Device
- ☐ Yes ☐ No IUD, If YES, Is it copper ☐ Yes ☐ No (If Yes, 1.5T compatible only)
- ☐ Yes ☐ No Diaphragm, or Pessary Unit
- ☐ Yes ☐ No Dentures, Partial Plate, Magnetic Dental Implants or Hearing Aids
- ☐ Yes ☐ No Magnetically-Activated Implant or Device
- ☐ Yes ☐ No Body Piercing Jewelry
- ☐ Yes ☐ No Tattoo or Permanent Makeup
- ☐ Yes ☐ No Medication Patch (Nicotine, Nitroglycerin, etc.)
- ☐ Yes ☐ No Allergic to Latex
- ☐ Yes ☐ No Penile Implants
- ☐ Yes ☐ No Do you feel dizzy/weak, do you need assistance to walk and/or have fallen lately
- ☐ Yes ☐ No Are you claustrophobic, If YES, did you take any meds ☐ Yes ☐ No
- ☐ Yes ☐ No Have you ever had an MRI, If YES, did you have an MRI done today where contrast was used ☐ Yes ☐ No
- ☐ Yes ☐ No Do you have poor IV access, If YES, do you have a port-a-cath that will need to be accessed ☐ Yes ☐ No

- ☐ Yes ☐ No Are you currently on dialysis for kidney failure
- ☐ Yes ☐ No Do you have any of the following conditions, If YES mark what you do have:
  - ☐ Personal or family history of Kidney Failure ☐ Diabetes Mellitus, if YES do you take prescription drugs to control diabetes ☐ Yes ☐ No
  - ☐ Awaiting or within 6 weeks of Liver Transplantation ☐ Multiple Myeloma
  - ☐ Systemic Lupus Erythematosus ☐ End-Stage Liver Disease

PATIENT WEIGHT _____ **HEIGHT** _____

List any other surgery, implant, or device not mentioned above: _____

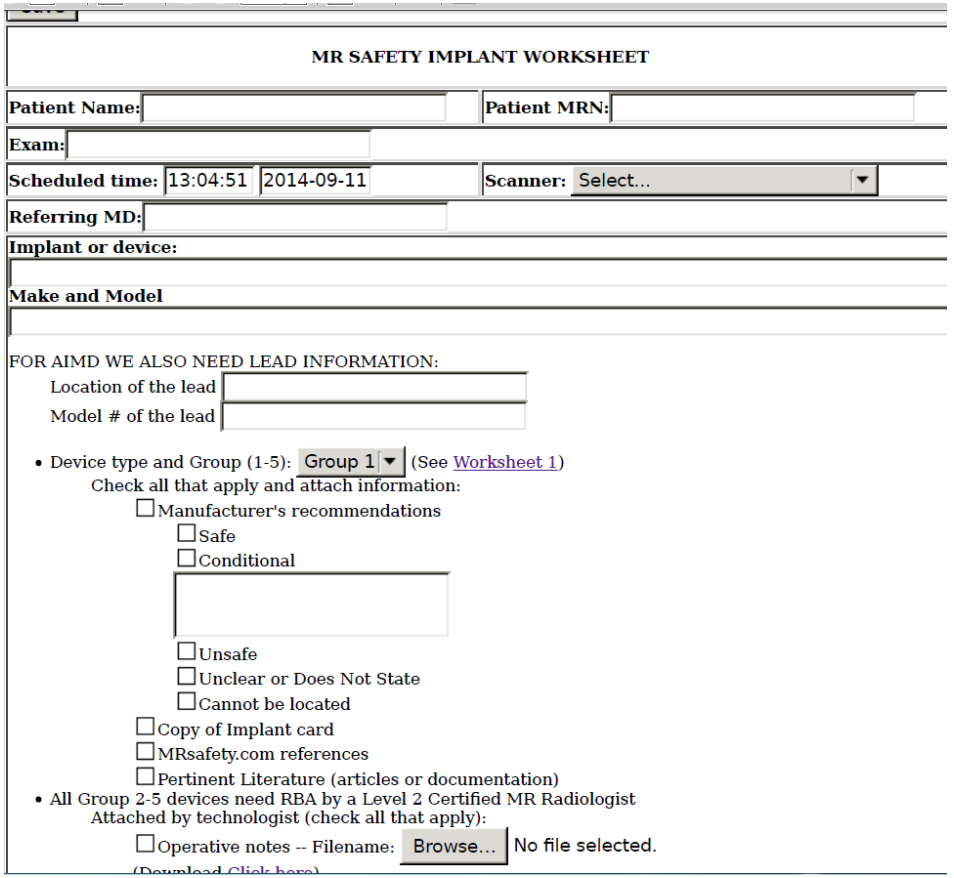
What is your current medical condition or reason for test? _____

For FEMALE Patients:

When was the Date of your Last Menstrual Period _____

- ☐ Yes ☐ No Are you pregnant?
- ☐ Yes ☐ No Are you Scheduled for Breast MRI

If YES, Did you have any outside MRI/mammogram(s) films brought today for comparison ☐ Yes ☐ No



MR SAFETY IMPLANT WORKSHEET

Patient Name: **Patient MRN:**

Exam:

Scheduled time: 13:04:51 2014-09-11 **Scanner:** Select...

Referring MD:

Implant or device:

Make and Model

FOR AIMD WE ALSO NEED LEAD INFORMATION:

Location of the lead

Model # of the lead

- Device type and Group (1-5): Group 1 (See Worksheet 1)

  Check all that apply and attach information:

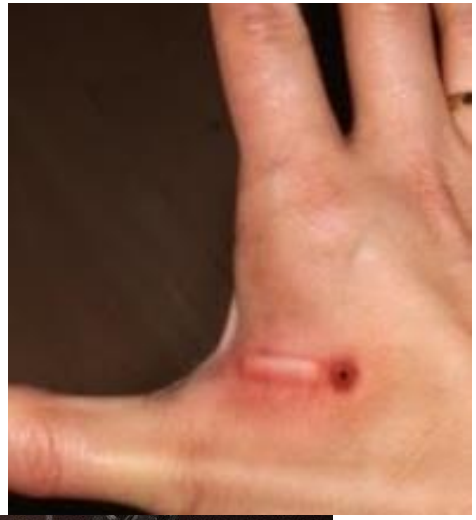
  - ☐ Manufacturer's recommendations
    - ☐ Safe
    - ☐ Conditional
    - ☐ Unsafe
    - ☐ Unclear or Does Not State
    - ☐ Cannot be located
  - ☐ Copy of Implant card
  - ☐ MRsafety.com references
  - ☐ Pertinent Literature (articles or documentation)
- All Group 2-5 devices need RBA by a Level 2 Certified MR Radiologist

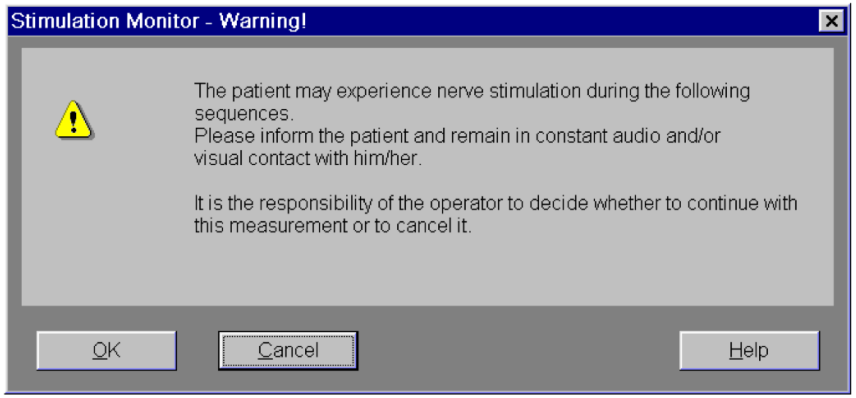
  Attached by technologist (check all that apply):

  - ☐ Operative notes -- Filename: Browse... No file selected.

  (Download Click here)

http://newjersey.news12.com/news/mri-explosion-at-oradell-animal-hospital-injures-3-1.10026427?firstfree=yes





http://www.dailymail.co.uk/news/article-2890088/Two-hospital-workers-spend-FOUR-HOURS-pinned-MRI-machine-metal-oxygen-tank-catapulted-room-device-s-giant-magnet-turned-on.html

Zone 4 Planning

- Siting the magnet
  - Decision on vendor
    - Field Strength
    - Coils
  - Doors and line of site for technologists
    - Technologist should be able to see the pt. in the magnet while they are scanning
    - Cameras can be a nice adjunct but not the primary visual monitoring
    - Doors that open in? Out?
      - Pressure release valves/hatches
    - How many doors?
  - Venting for cryogens
    - Marked and checked at least annually
    - O2 sensors
    - Vent fans
    - Quench button(s)

Incorporating safety in your design

- Ferrous Metal Detectors
- Staff Education and access
- Equipment in Zone 3 and 4
- Vendor sourcing for non-ferrous equipment
- Ancillary planning and education for maintaining the environment
  - Service
  - Cleaning

Magnetic Shielding

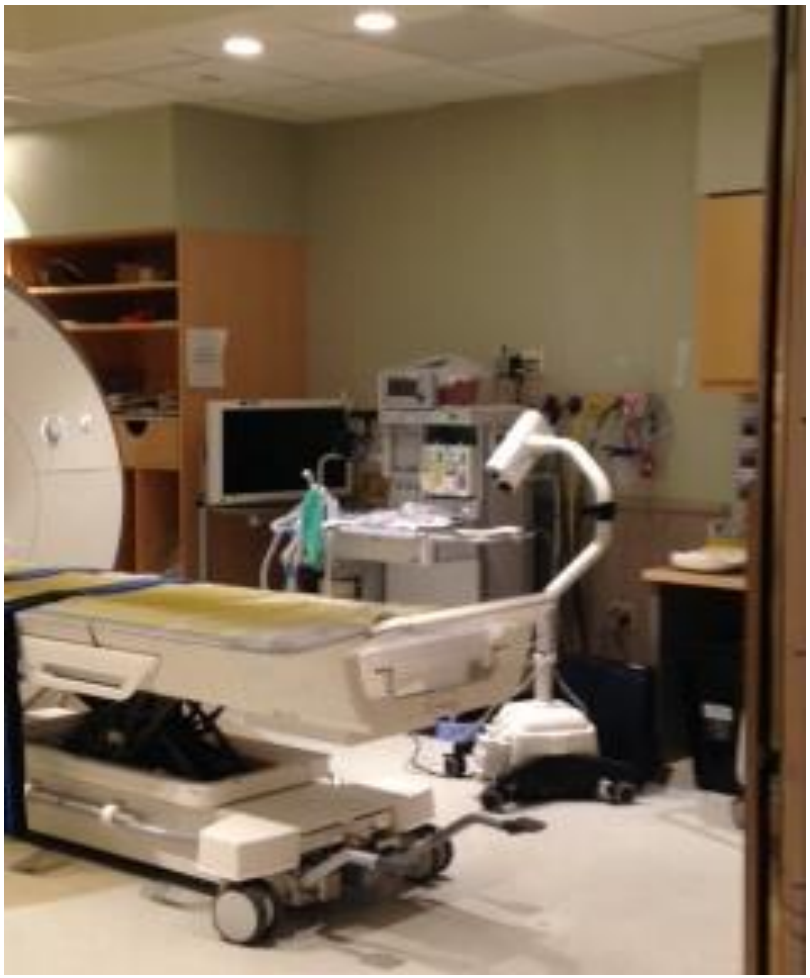
Silicon Steel Shielding

Steel Plate Shielding

Courtesy of Lingren

Scan Room doors

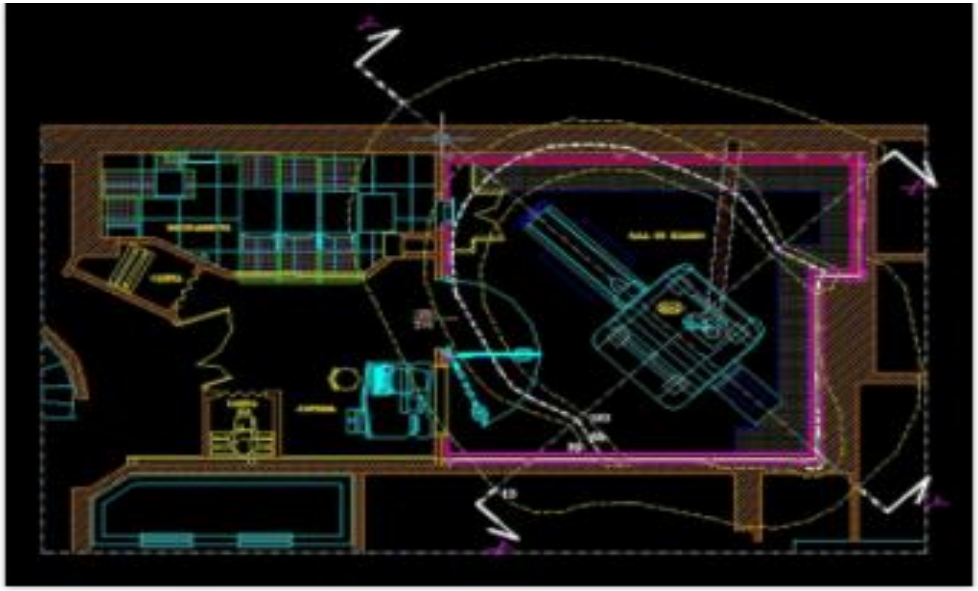
Inside the Scan Room



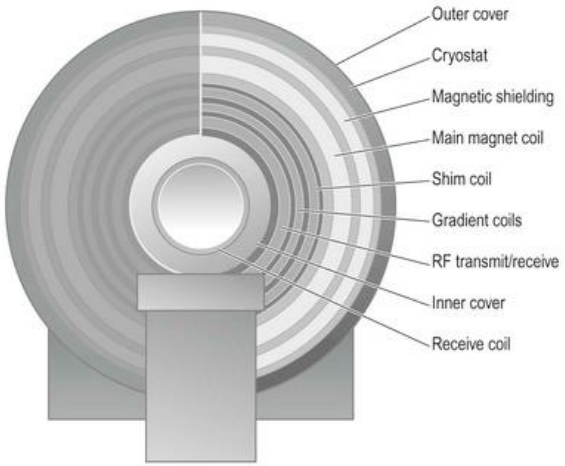
- Cabinets and supplies
  - Storing contrast and meds
  - Needles and sharps
  - Coils
  - Phantoms
- Infection Control
- Linen, trash, etc.…
- Furniture (chairs, tables)

Magnetic Field Shielding

- Passive
  - Usually ferromagnetic material in walls and floor
- Active
  - superconducting windings in the scanner that opposes (contains) the magnetic field

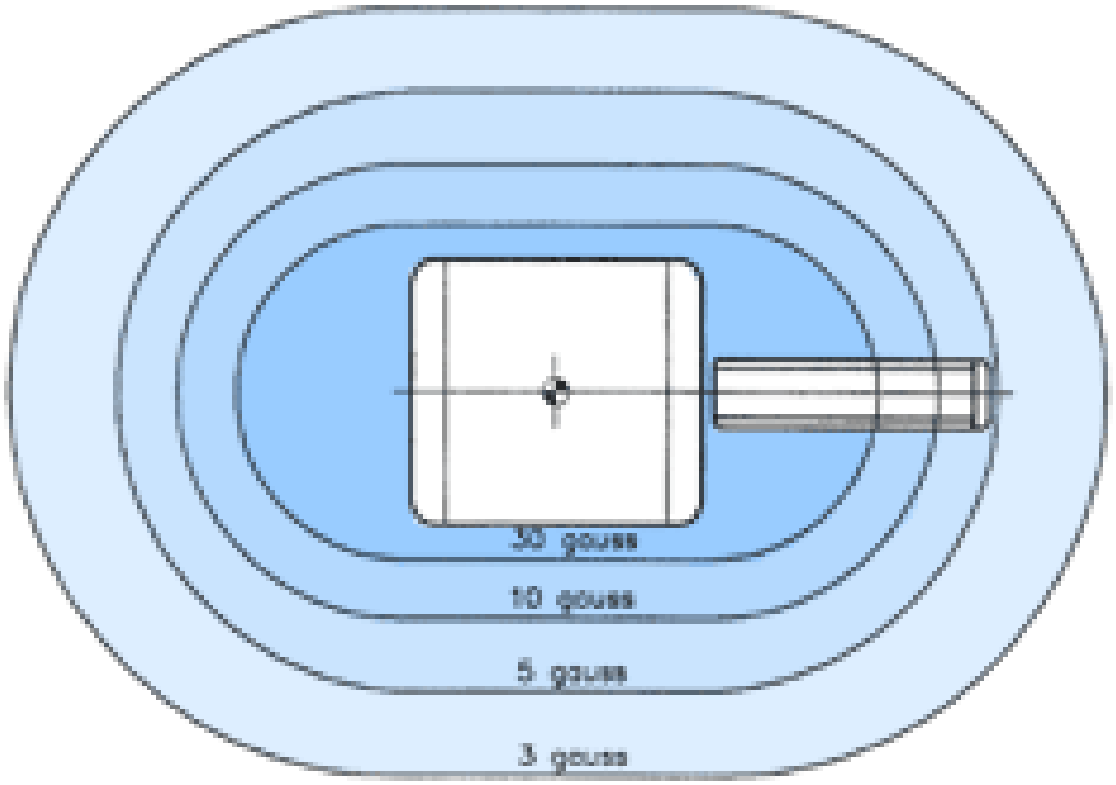


http://www.itelte.it/en/cnt/passive-shielding



http://radiologykey.com/magnetic-resonance-imaging-8/

Gauss lines in the scan room



https://www.studyblue.com/notes/note/n/mri-415-420-lab-2014-study-guide-2013-14-davies/deck/9580566

Equipment in Zone 4

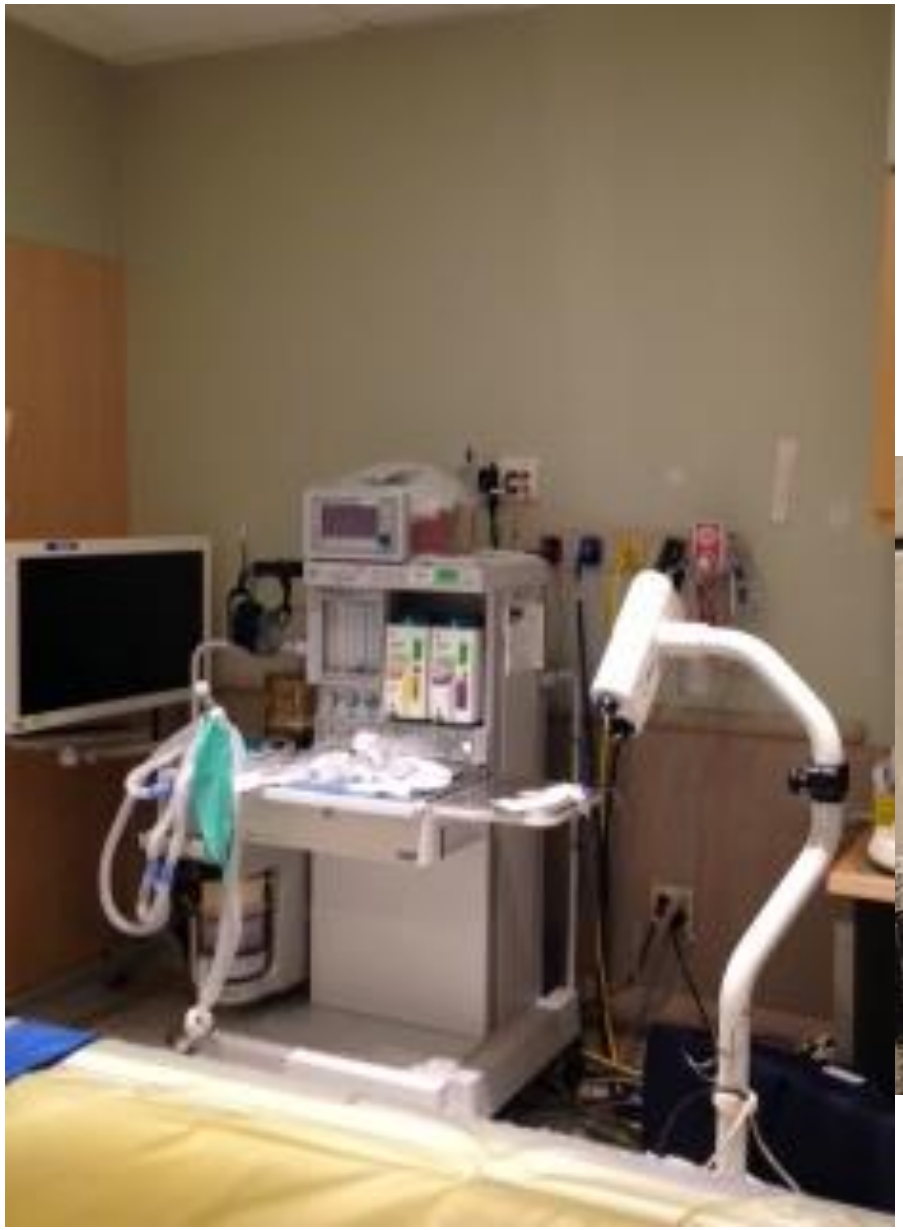
Before you try this…

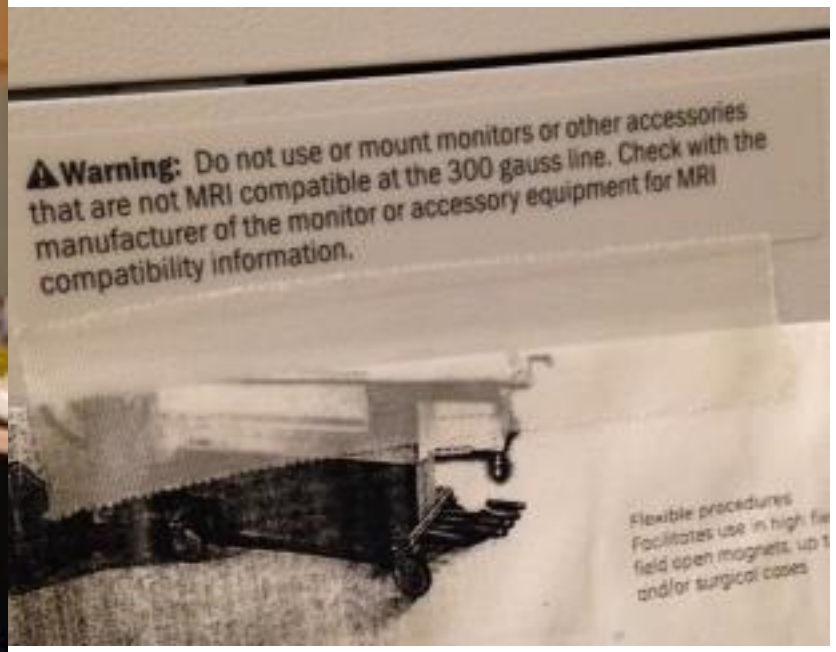
https://www.draeger.com/Products/Image/fabius-mri-mt-0753-2008-us.jpg

Guidelines for Zone 4 equipment

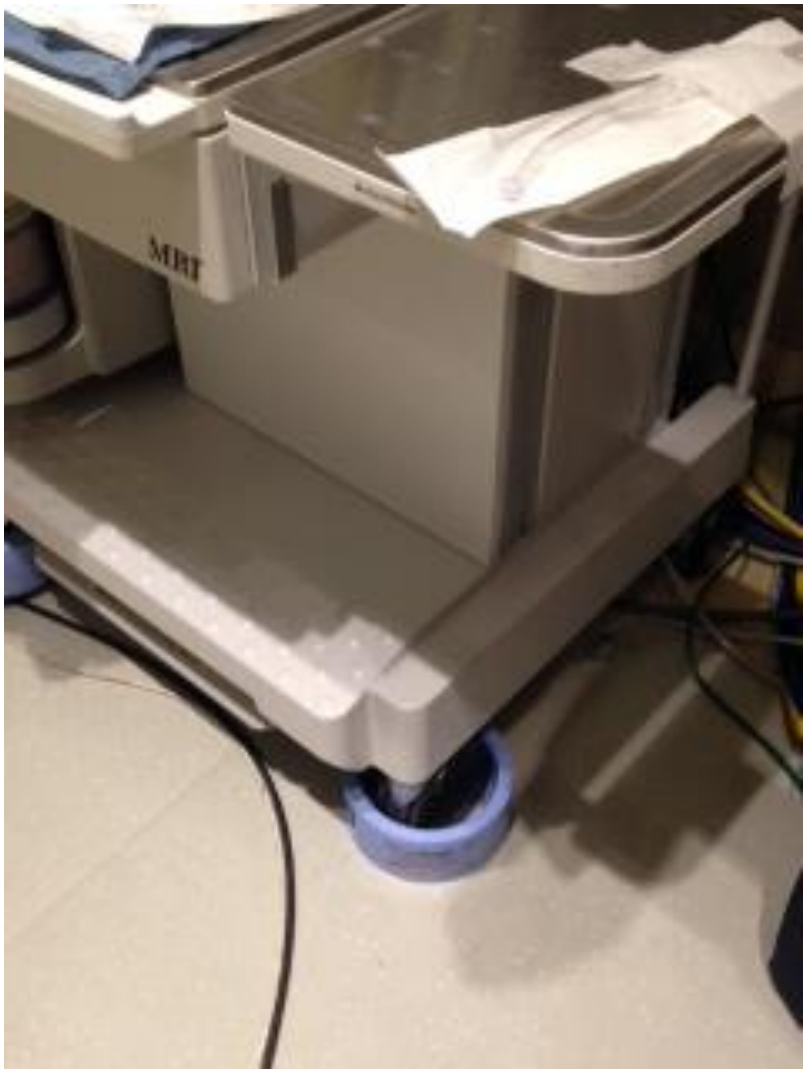
- Test it! Does it have any ferrous components
- Read the labeling-Follow the conditions
- Label EVERYTHING
- Mark your floor-gauss lines
- Plan workflow and educate ALL staff who use the equipment AND function in the site

Zone 4 Equipment planning






DANGER!


MRI

Planning for your Faraday Cage

- RF interference/Noise can be caused by many influences

Walls

Doors

Music system for pts

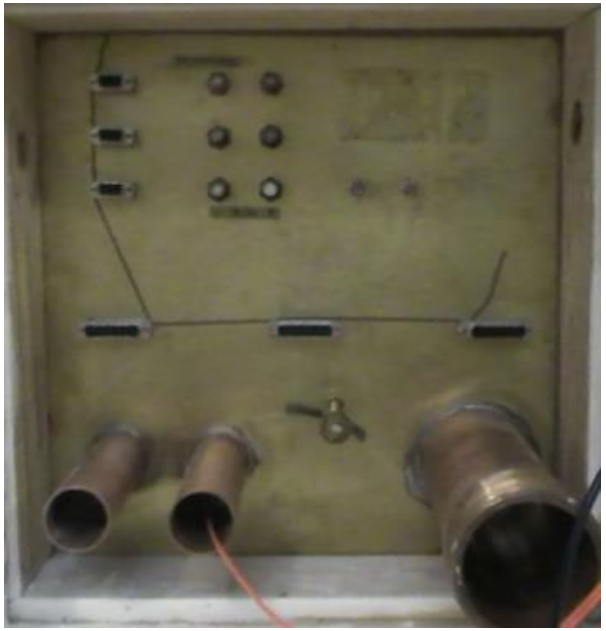
Equipment living in Zone 4

Outside Noise –phones, radio, etc.

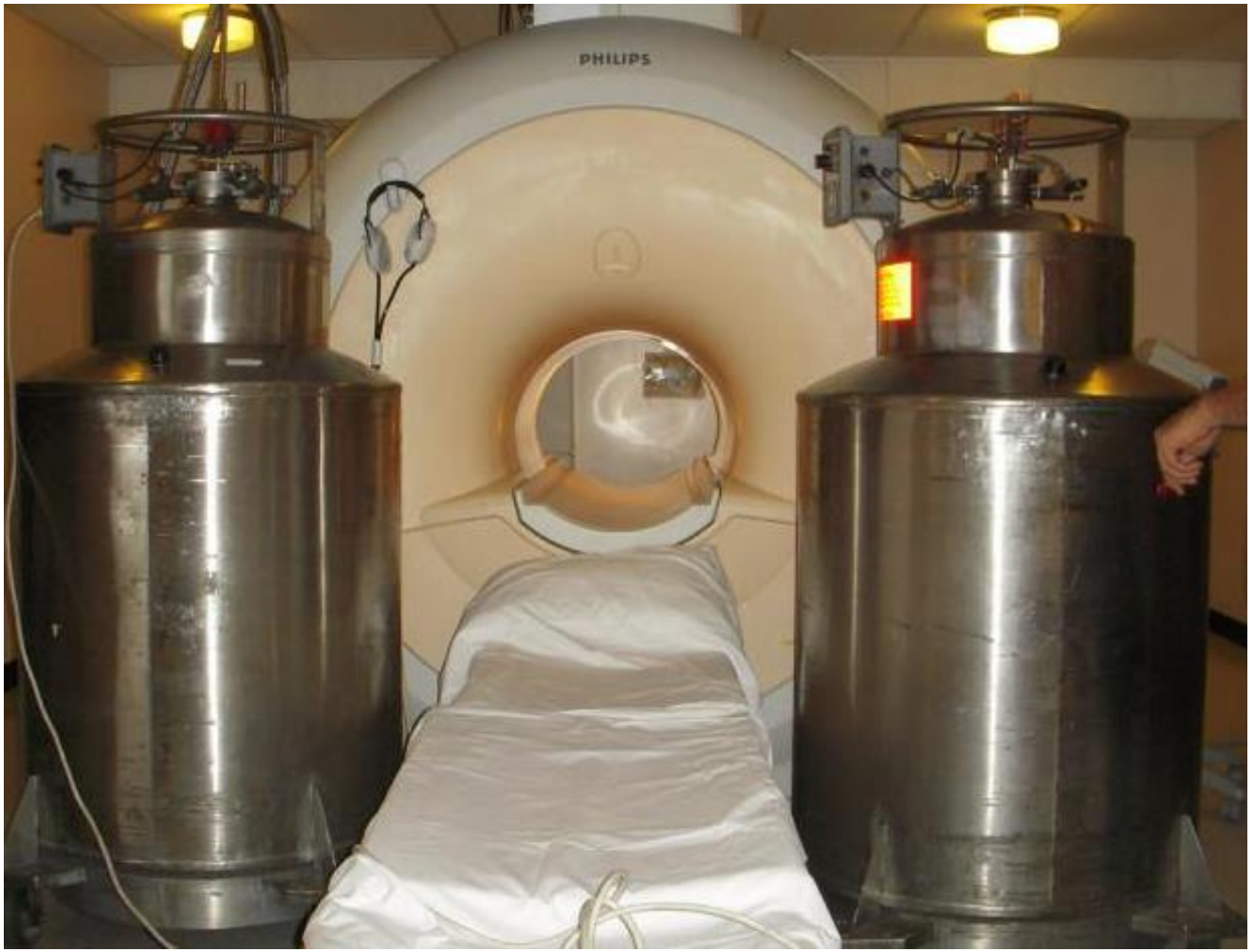
Lights, vent fans and occasionally the MR itself

Wave guides for external use-fMRI, IV's, etc.

Cooper lined Scan room



Cryogens



Cryogen Safety

- Helium
  - Liquid Helium
    - Most commonly used element in superconductive magnets today
  - Boils at -437’F
  - Expands 737 to 1 when converting liquid to gaseous state
  - Natural resource
    - Expensive
    - Limited supply

Quench video (from Jim Stuppino)

Training and Planning for Emergencies

- Education
  - Yearly reminders
  - Practice and mock drills
  - Posters and signs
  - Keep up with changes
    - In your physical space
    - Equipment, upgrades
- Policies
  - Fire
  - Natural Disaster
  - Projectile incident
  - Burns
  - Contrast reactions and codes
  - Reporting and follow-up

Reporting Adverse Events

- Requirement for Joint Commission and ACR
  - Most facilities have something in place
    - Policy detailing what, when and where to report
    - Training with staff
      - Writing a detailed report
      - Understanding that it is a “discoverable” document
    - Follow up and remediation
      - Careful scrutiny of the event
      - Retraining, new or updated policies
      - Occasionally disciplinary action
        - » Culture of staff support and freely reporting is important

Resource list

The Safe Medical Devices Act of 1990

The Joint Commission: Sentinel Event Alert, Issue 38, Feb. 14, 2008

Medicare Improvements for Patients and Providers Act (MIPPA) of 2008

http://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm135362.htm

http://www.fda.gov/radiationemittingproducts/radiationemittingproductsandprocedures/medicalimaging/mri/ucm482765.htm