MRI Safety:
Medical Implants and Other Concerns

Nathan Yanasak, PhD
Assistant Professor, Dept of Radiology
Georgia Regents University

Basic Safety concerns:
Foreign Objects (metals)
Projectile Hazards (ferrous materials)
Screening:
Patients, Devices
Medical Implants:
What to do? – a reality check
What should be your concerns?

Note: NO DISCUSSION OF CONTRAST AGENT SAFETY TODAY

Here's the way that we summarize MR safety to the GRU community at large:

The MRI environment can be a fairly safe place to work …
… if you follow a few IMPORTANT rules.

Rule #0: Giving yourself an extra 1-2 seconds to consider a situation, for MR safety sake, is rarely ever a problem (even during a code).

What am I about to do? What does this involve?

What do I have on my person?

Stop, consider, then act.

GRU GEORGIA REGENTS UNIVERSITY

Ten Basic GRU MR Safety Rules

Rule #1: NEVER ENTER THE MRI ROOM WITHOUT PERMISSION FROM AN MRI TECHNOLOGIST

Rule #2: THE MRI MAGNET IS ALWAYS ON (24 hrs a day, 365 days a year).

Rule #3: MRI ZONES INDICATE AREAS OF ACCESS.

GRU GEORGIA REGENTS UNIVERSITY

Ten Basic GRU MR Safety Rules

Rule #4: DEVICES THAT ARE NOT LABELED AS "MR SAFE" SHOULD BE CONSIDERED *UNSAFE UNDER SOME OR ALL CIRCUMSTANCES* IN THE MR SCANNER ROOM.

Rule #5: FERROUS OBJECTS CAN BE ATTRACTED TO AN MR MAGNET

Ten Basic GRU MR Safety Rules

Rule #6: BEFORE ENTERING THE SCAN ROOM, PAY ATTENTION TO *OBJECTS IN YOUR POSSESSION.*

Rule #7: FOREIGN OBJECTS *WITHIN* THE BODY CAN POSE A HAZARD WITHIN THE SCAN ROOM.

Rule #8: MEDICAL IMPLANTS DESERVE SPECIAL ATTENTION.

GRU GEORGIA REGENTS UNIVERSITY

Ten Basic GRU MR Safety Rules

Rule #9: PATIENTS WITH ANEURYSM CLIPS ARE ONLY ALLOWED IN THE MR SCAN ENVIRONMENT IF THEIR PRIMARY PHYSICIAN SIGNS AN ATTESTATION TO THE SAFETY OF THE CLIP.

Rule #10: BEFORE ATTEMPTING CRITICAL CARE, MEDICAL STAFF MUST REMOVE A PATIENT FROM THE MR SCAN ROOM DURING A CODE.

GRU GEORGIA REGENTS UNIVERSITY

Metals & MR Safety

Metals and MR Environment

In the MR environment in general…metals are NOT your friends.

- All metals are good electrical conductors.
- Conductor = mobile electrons (e.g., wires)
- Why do electrons want to move around?
  - Electric fields = 0 inside conductor
  - Magnetic fields = constant inside conductor.

In the MR environment in general…metals are NOT your friends.

- Outside conductor: Oscillating EM field(i.e., RF excitation)

→Inside conductor: stimulated oscillating b-field

→Electrons move inside the conductor to balance non-constant b-field

Moving charges= current

Current → heat (P=IV) **(Problem #1 with metals)**

Heat or current may be bad/extreme under certain conditions.

When is heat/current bad (metal or otherwise)?

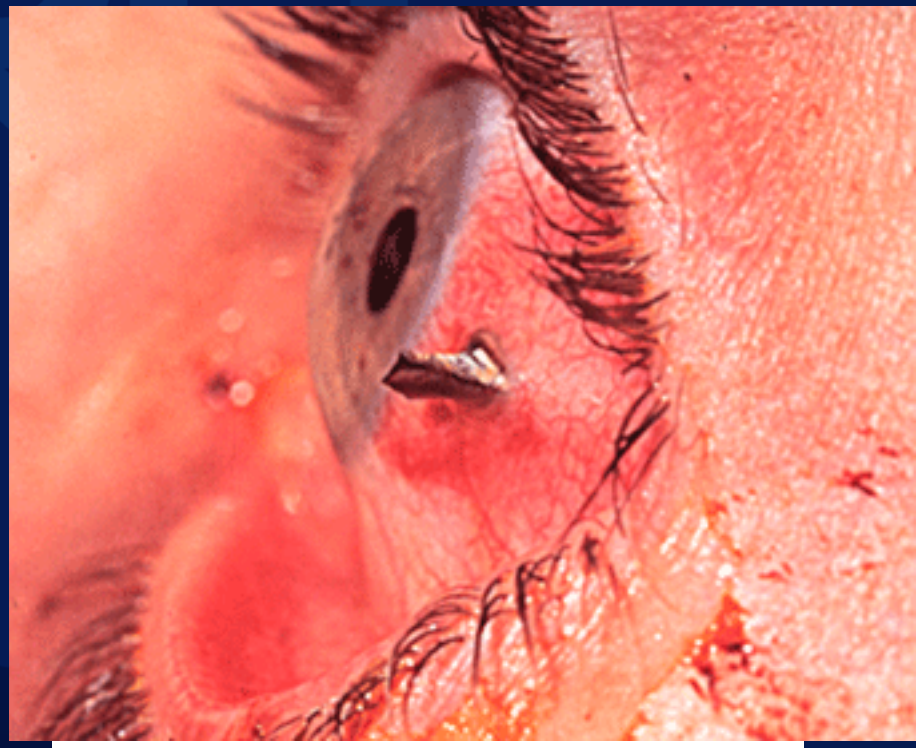
- Tissue conduction of heat away from metal is poor (large patients)
- Close proximity of current/heat to nerves (pain).
- Patient forms current loops using body.
- Proximity to RF transmit coils (sides of bore).

  Double whammy(current/heat) – arm touching side of bore and forming a body loop.
- Medical devices

In the MR environment in general…metals are NOT your friends.

When should we worry about heat/current?

- Dimensions of metal object “tune” it to the oscillating frequency.



GRU GEORGIA REGENTS UNIVERSITY

So, what can we do about it?

Shouldn't allow wires/cables to touch skin→ avoid thermal burns. Use pads/thick blanket.

Padding between arms and body/legs.

Non-MR-compatible leads in scanner are bad.

No loops in wire → avoid antennas!

No touching the side of bore – pads.

Projectile Hazards and MR Safety

FERROUS OBJECTS CAN FLY INTO THE MAGNET WITH GREAT SPEED AND FORCE. (Problem #2 with metals)

Some metals are not ferrous… but can YOU tell the difference by eye?

GRU GEORGIA REGENTS UNIVERSITY

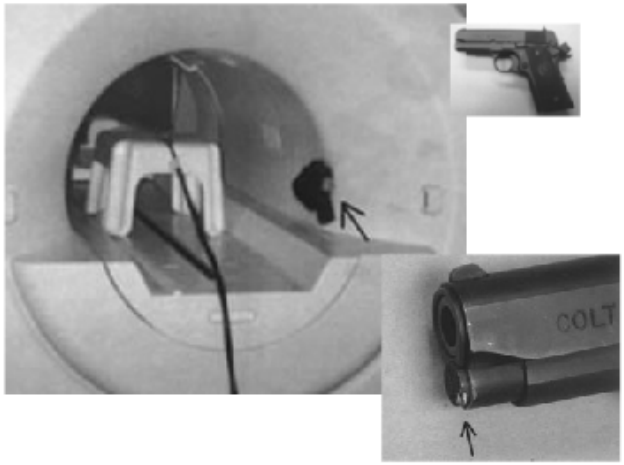
Flying metal can be deadly

A child was killed in New York (2001) by a flying oxygen cylinder, similar to the gas tank shown here.

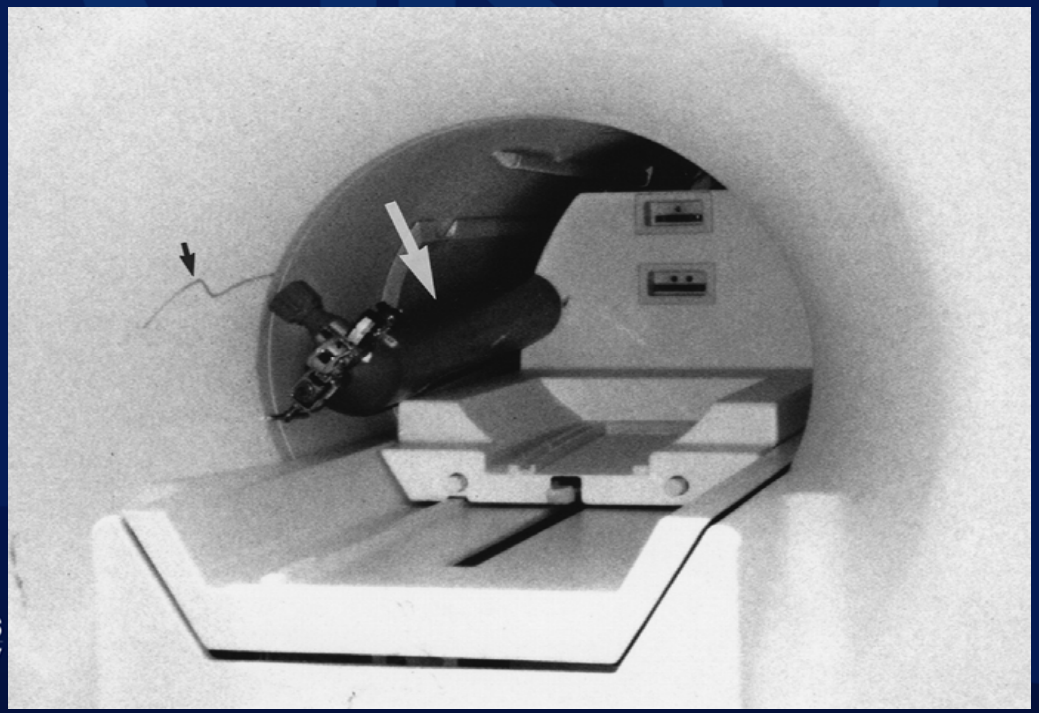
http://simplyphysics.com/fl
ing_objects.html#


YUGO

Hospital Bed pulled into 3T Magnet



An incident recently occurred at an outpatient imaging center in western New York State, in which a firearm spontaneously discharged in a 1.5-T MR imaging environment with active shielding.

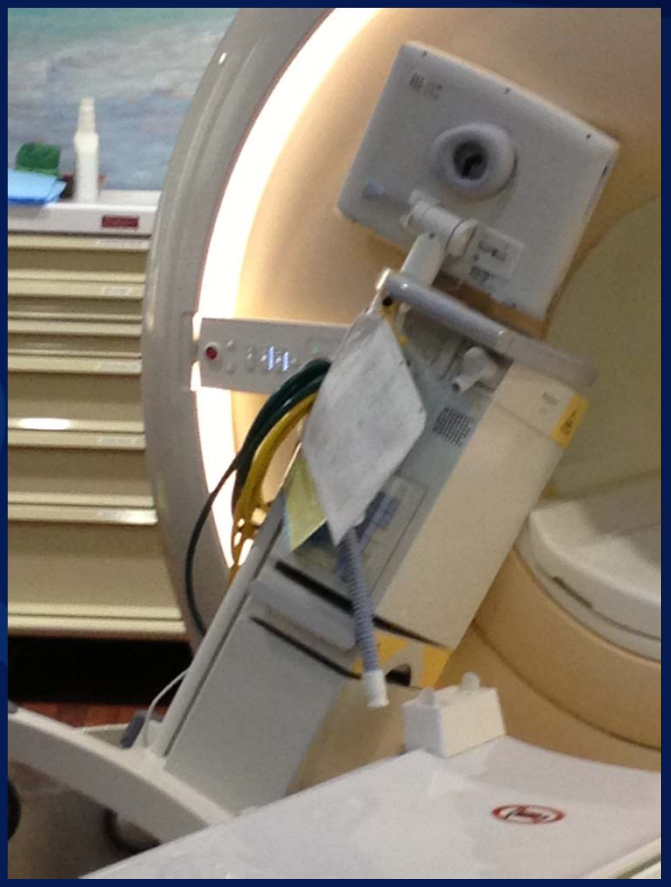


GRU GEORGIA REGENTS UNIVERSITY

Other Projectile Accidents at Other Places

- Scissors from a physician assistant in scan room flew into MR tech's forehead (trip to the OR).
- Patient thrown into magnet with gurney (foot, ankle fractures).
- Flat-screen monitor (research) was brought into scan room...flew into volunteer's face.

Accidents have occurred on our site.



These two incidents were preventable. Fortunately, no one was hurt.

GRU GEORGIA REGENTS UNIVERSITY

Code carts NEVER go into MRI room!

Carts can become projectile objects. Bringing a cart into the room with a patient in the MR scanner could harm or kill the patient and staff.

GRU GEORGIA REGENTS UNIVERSITY

All of

ot the MR C

How

Why

bring →

they

DO NOT TRUST UNLABELED ITEMS AS MR SAFE!

GRU GEORGIA REGENTS UNIVERSITY

Screening: Mechanisms

Why should we screen devices or people?

MR Safe – Item poses NO KNOWN HAZARDS in all MR environments.

Absolutely no metal present in device.

MR Conditional – Item poses no known hazards IN A SPECIFIED MR ENVIRONMENT WITH SPECIFIED CONDITIONS OF USE.

May contain some steel or conductive materials.

MR Unsafe – ITEM POSES A HAZARD IN ALL MR ENVIRONMENTS.

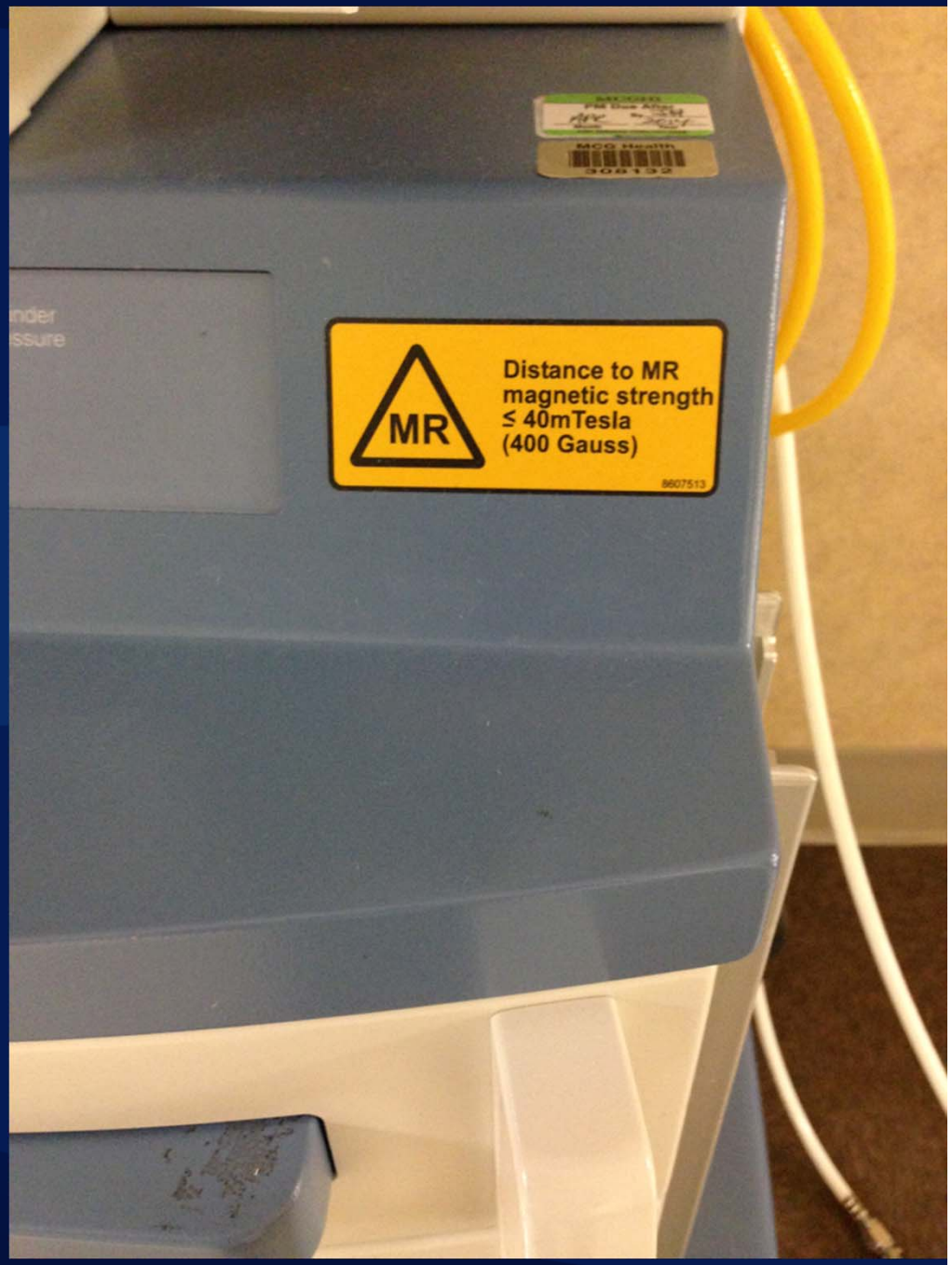
Ferromagnetic ("steel") substances.

"MR Conditional" devices are safe only under certain conditions.

Conditions can vary widely for each device.

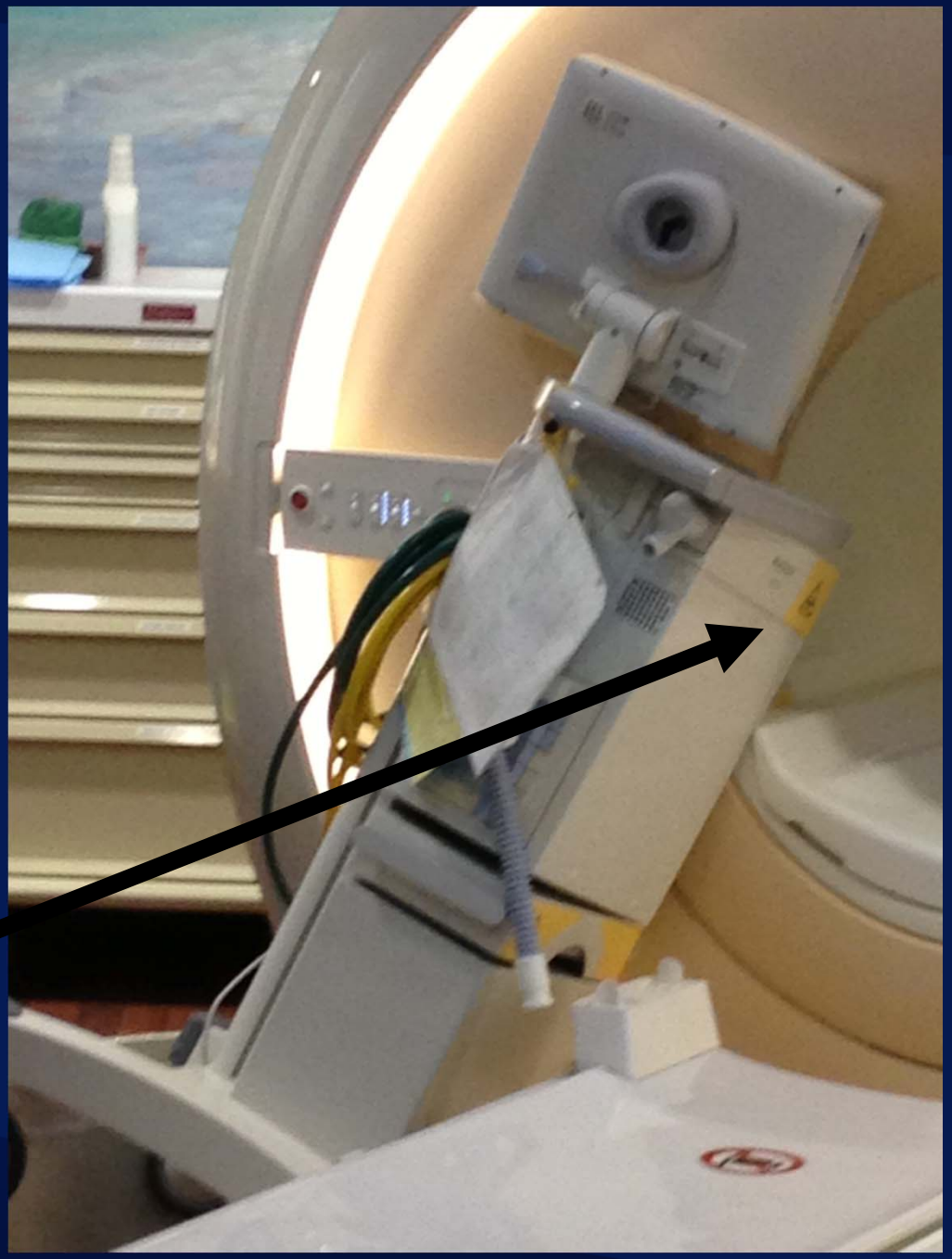
If you do not know what the conditions are for a particular device, ASK FOR HELP, and DO NOT ASSUME!

GRU GEORGIA REGENTS UNIVERSITY



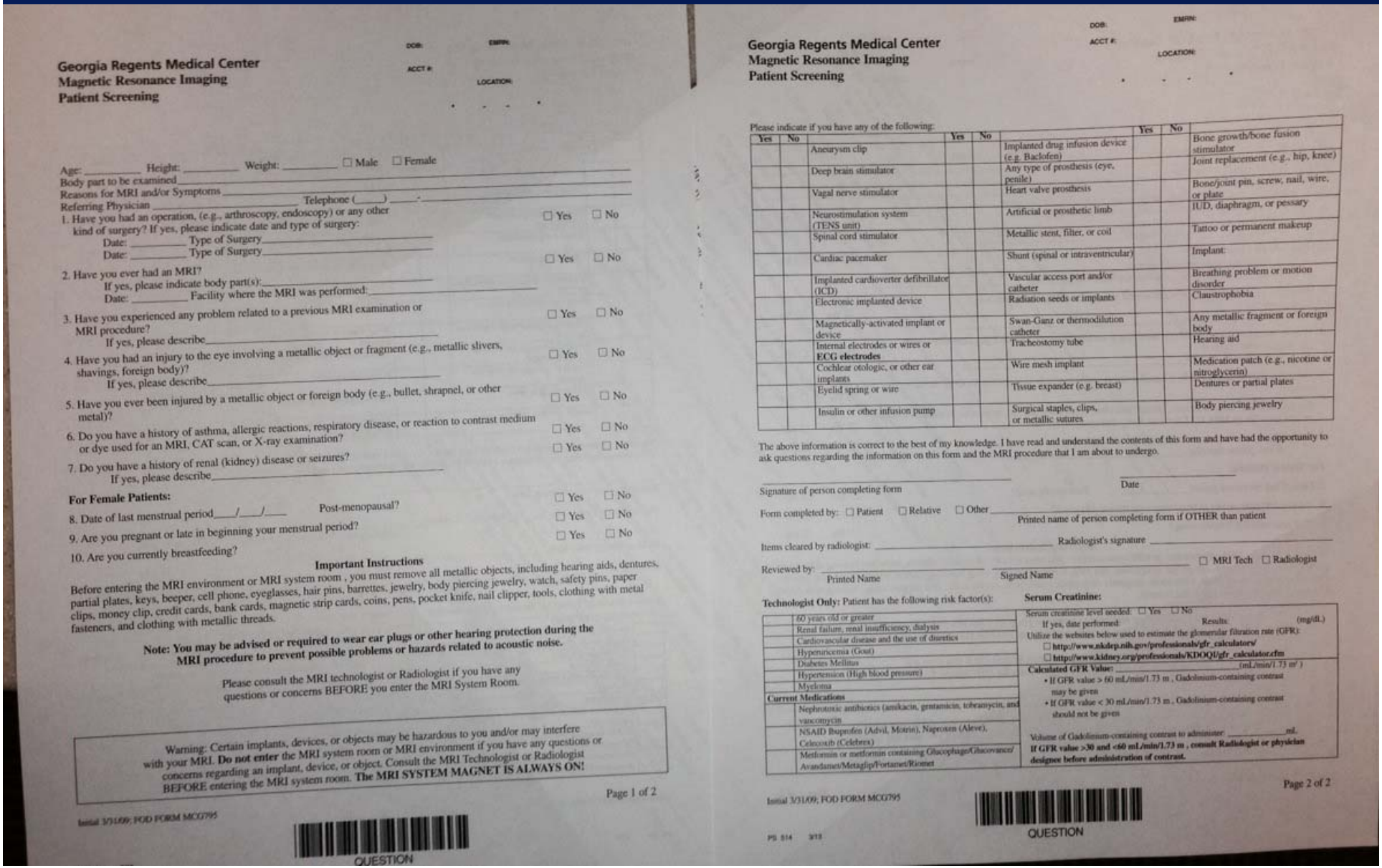
Notice the “MR Conditional” sticker on the ventilator.

Clearly, the conditions for safety were NOT MET.



GRU UNIVERSITY

Screening tool #0: Screening form



Georgia Regents Medical Center
Magnetic Resonance Imaging
Patient Screening

DOB: EMPN:
ACCT #: LOCATION:

Age: _____ Height: _____ Weight: _____ ☐ Male ☐ Female
Body part to be examined _____
Reasons for MRI and/or Symptoms _____
Referring Physician _____ Telephone (____) ____-____

1. Have you had an operation, (e.g., arthroscopy, endoscopy) or any other kind of surgery? If yes, please indicate date and type of surgery: ☐ Yes ☐ No
   Date: _____ Type of Surgery _____
   Date: _____ Type of Surgery _____
2. Have you ever had an MRI? ☐ Yes ☐ No
   If yes, please indicate body part(s): _____
   Date: _____ Facility where the MRI was performed: _____
3. Have you experienced any problem related to a previous MRI examination or MRI procedure? ☐ Yes ☐ No
   If yes, please describe _____
4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body)? ☐ Yes ☐ No
   If yes, please describe _____
5. Have you ever been injured by a metallic object or foreign body (e.g., bullet, shrapnel, or other metal)? ☐ Yes ☐ No
6. Do you have a history of asthma, allergic reactions, respiratory disease, or reaction to contrast medium or dye used for an MRI, CAT scan, or X-ray examination? ☐ Yes ☐ No
7. Do you have a history of renal (kidney) disease or seizures? ☐ Yes ☐ No
   If yes, please describe _____

For Female Patients:

8. Date of last menstrual period___/___/___ Post-menopausal? ☐ Yes ☐ No
9. Are you pregnant or late in beginning your menstrual period? ☐ Yes ☐ No
10. Are you currently breastfeeding? ☐ Yes ☐ No

Important Instructions

Before entering the MRI environment or MRI system room , you must remove all metallic objects, including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paper clips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, and clothing with metallic threads.

Note: You may be advised or required to wear ear plugs or other hearing protection during the MRI procedure to prevent possible problems or hazards related to acoustic noise.

Please consult the MRI technologist or Radiologist if you have any questions or concerns BEFORE you enter the MRI System Room.

Warning: Certain implants, devices, or objects may be hazardous to you and/or may interfere with your MRI. **Do not enter** the MRI system room or MRI environment if you have any questions or concerns regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MRI system room. **The MRI SYSTEM MAGNET IS ALWAYS ON!**

Initial 3/31/09; FOD FORM MCG795

QUESTION

Georgia Regents Medical Center
Magnetic Resonance Imaging
Patient Screening

DOB: EMPN:
ACCT #: LOCATION:

Please indicate if you have any of the following:

Yes	No		Yes	No		Yes	No	
		Aneurysm clip			Implanted drug infusion device (e.g. Baclofen)			Bone growth/bone fusion stimulator
		Deep brain stimulator			Any type of prosthesis (eye, penile)			Joint replacement (e.g., hip, knee)
		Vagal nerve stimulator			Heart valve prosthesis			Bone/joint pin, screw, nail, wire, or plate
		Neurostimulation system (TENS unit)			Artificial or prosthetic limb			IUD, diaphragm, or pessary
		Spinal cord stimulator			Metallic stent, filter, or coil			Tattoo or permanent makeup
		Cardiac pacemaker			Shunt (spinal or intraventricular)			Implant:
		Implanted cardioverter defibrillator (ICD)			Vascular access port and/or catheter			Breathing problem or motion disorder
		Electronic implanted device			Radiation seeds or implants			Claustrophobia
		Magnetically-activated implant or device			Swan-Ganz or thermodilution catheter			Any metallic fragment or foreign body
		Internal electrodes or wires or **ECG electrodes**			Tracheostomy tube			Hearing aid
		Cochlear otologic, or other ear implants			Wire mesh implant			Medication patch (e.g., nicotine or nitroglycerin)
		Eyelid spring or wire			Tissue expander (e.g. breast)			Dentures or partial plates
		Insulin or other infusion pump			Surgical staples, clips, or metallic sutures			Body piercing jewelry

The above information is correct to the best of my knowledge. I have read and understand the contents of this form and have had the opportunity to ask questions regarding the information on this form and the MRI procedure that I am about to undergo.

_____ _____
Signature of person completing form Date

Form completed by: ☐ Patient ☐ Relative ☐ Other _____
Printed name of person completing form if OTHER than patient

Items cleared by radiologist: _____ Radiologist's signature _____

Reviewed by: _____ _____ ☐ MRI Tech ☐ Radiologist
Printed Name Signed Name

Technologist Only: Patient has the following risk factor(s):

	60 years old or greater
	Renal failure, renal insufficiency, dialysis
	Cardiovascular disease and the use of diuretics
	Hyperuricemia (Gout)
	Diabetes Mellitus
	Hypertension (High blood pressure)
	Myeloma
Current Medications	
	Nephrotoxic antibiotics (amikacin, gentamicin, tobramycin, and vancomycin
	NSAID Ibuprofen (Advil, Motrin), Naproxen (Aleve), Celecoxib (Celebrex)
	Metformin or metformin containing Glucophage/Glucovance/ Avandamet/Metaglip/Fortamet/Riomet

Serum Creatinine:

Serum creatinine level needed: ☐ Yes ☐ No
If yes, date performed: Results: (mg/dL)
Utilize the websites below used to estimate the glomerular filtration rate (GFR):
☐ **http://www.nkdep.nih.gov/professionals/gfr_calculators/**
☐ **http://www.kidney.org/professionals/KDOQI/gfr_calculator.cfm**

Calculated GFR Value: _____ (mL/min/1.73 m²)
- If GFR value > 60 mL/min/1.73 m , Gadolinium-containing contrast may be given
- If GFR value < 30 mL/min/1.73 m , Gadolinium-containing contrast should not be given

Volume of Gadolinium-containing contrast to administer: _____ mL
If GFR value >30 and <60 mL/min/1.73 m , consult Radiologist or physician designee before administration of contrast.

Initial 3/31/09; FOD FORM MCG795

PS 514 3/13

QUESTION

Screening tool #1: Ferroguard Detectors

First line of defense:

Pros: everything is screened

Cons: immunity to the sound

GRU GEORGIA REGENTS UNIVERSITY

Screening tool #2: Hand-held Metal Detectors

Second line of defense:

Pros: MR techs will pay attention to it.

Cons: takes a bit of time…and, detects ALL metals.

GRU GEORGIA REGENTS UNIVERSITY

Screening tool #3: Survey Magnet

MR Techs and the relevant personnel in a service can and will survey equipment with a magnet before taking it in the room.

MR Techs also bring the equipment into the room, *exclusively.*

When is a “sandbag” not a sandbag?

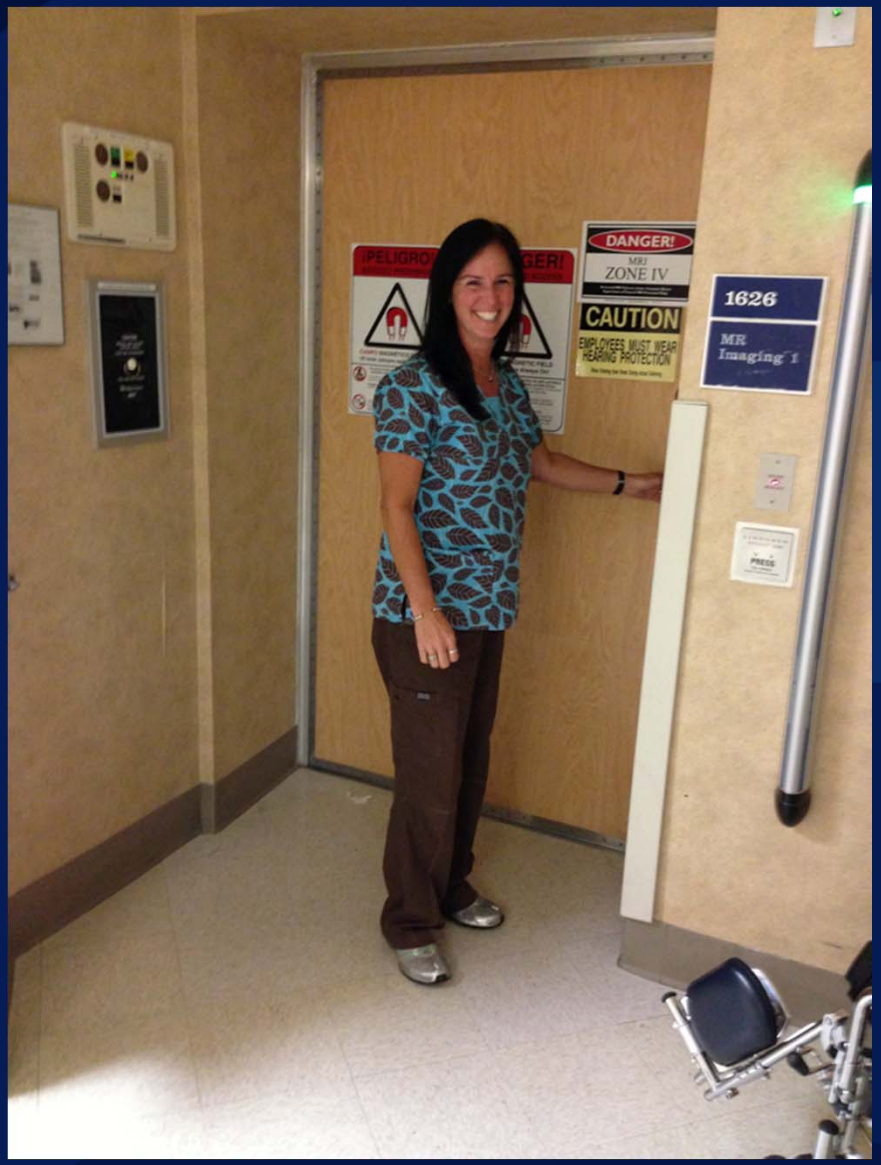
This innocent-looking “sandbag” was not surveyed (name says it all, right?)

Flew towards magnet, knocked top of coil off patient and hit him in the face

Moral of the story? Vigilance in surveying unlabeled objects is not silly.

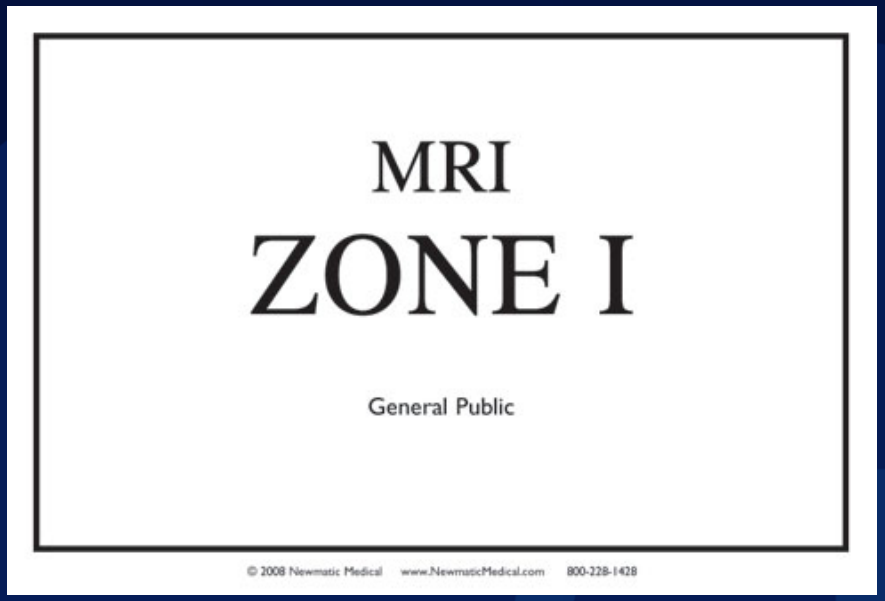
He was O.K., but…this was preventable by survey.

Other precautions at our institute:



MR technologists are the *MR gatekeepers* and the local resource for safety.

GRU GEORGIA REGENTS UNIVERSITY



GRU GEORGIA REGENTS UNIVERSITY

Signage indicates the different zones.

Other precautions at our institute:

Every patient puts on a gown.

Every patient is wanded at this point.

Equipment taken in by techs, to specified places.

Equipment Placement in the Room

Infusion pumps
MR Conditional: B<150 gauss
They can fly.

Anesthesia Carts and Ventilators–
Drager: B<400 gauss
Datex-Ohmeda: B<300 gauss
Gas cylinders, too

Marking multiple gauss lines could lead to confusion and potential accidents.

GRU GEORGIA REGENTS UNIVERSITY

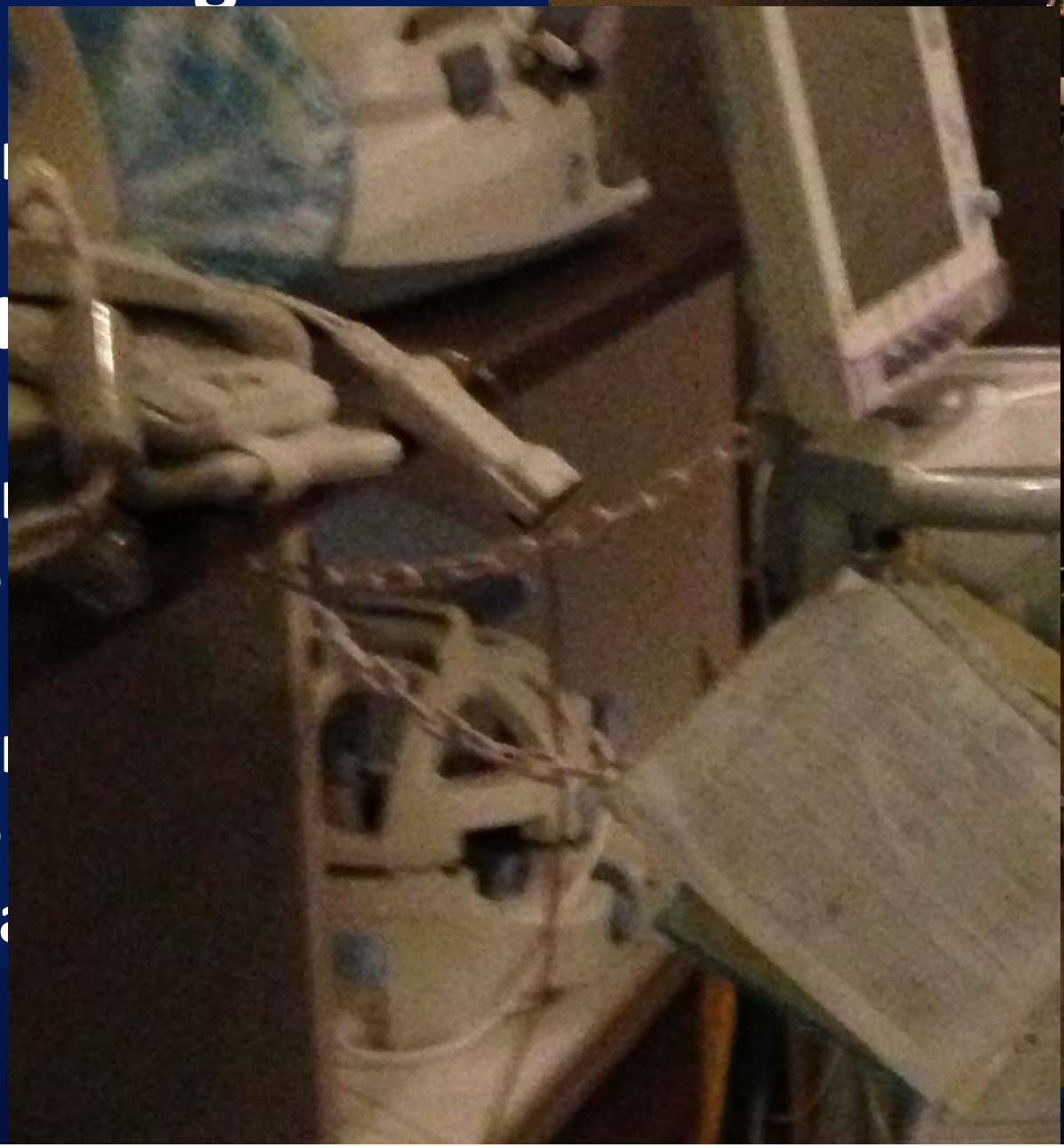
Tethering

Tether

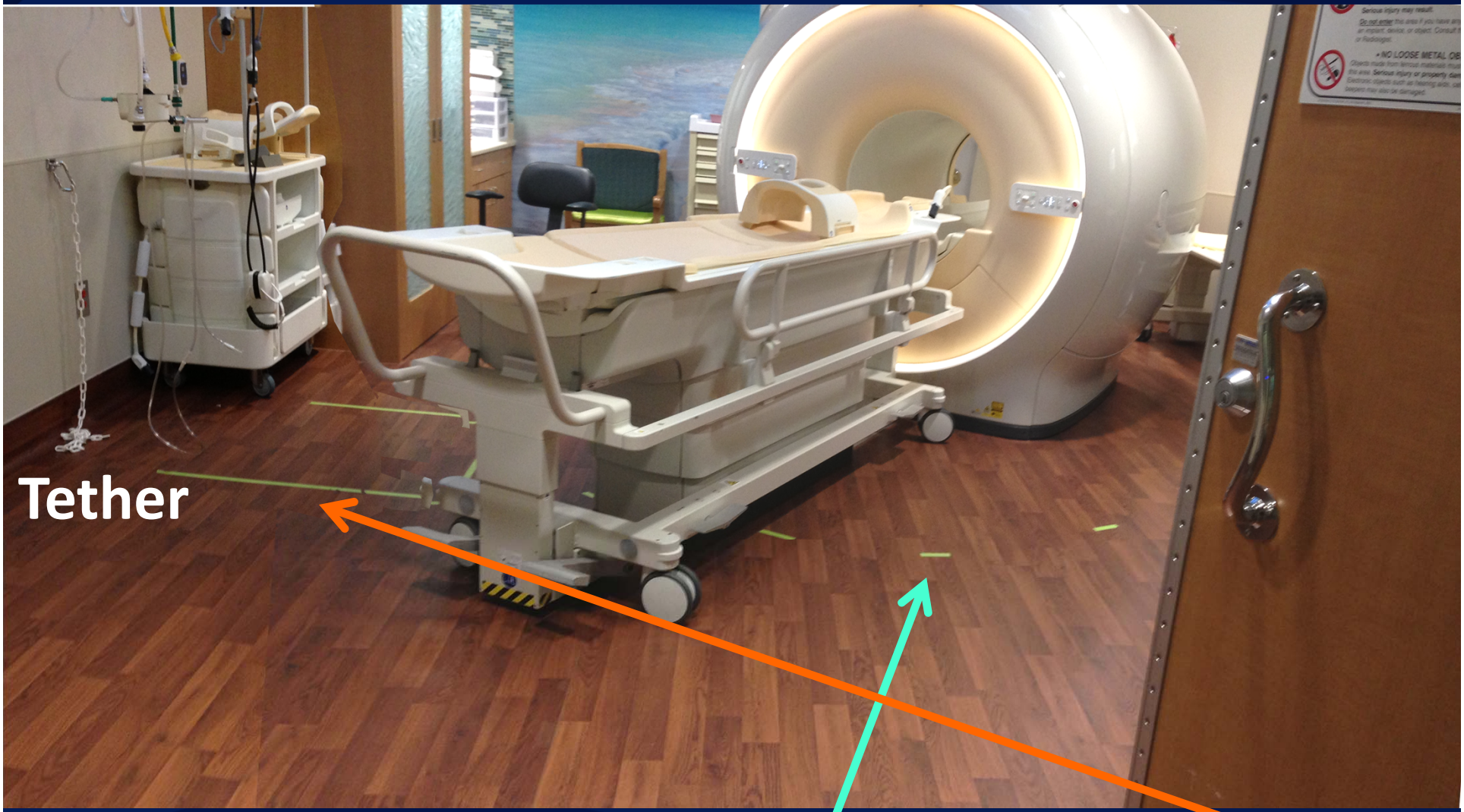
→Tetl

Tether
preve

Tether
preve
mecha



Two markers: 100 Ga line and “the box”



Patient Screening “Anecdotes”

On the worth of se

- **Tale 1: hidden k**
- **Tale 2: Aneurysr**

GRU GEORGIA REGENTS UNIVERSITY

Medical Implants

What role can/does the Medical Physicist play?

What role am *I* expected to play?

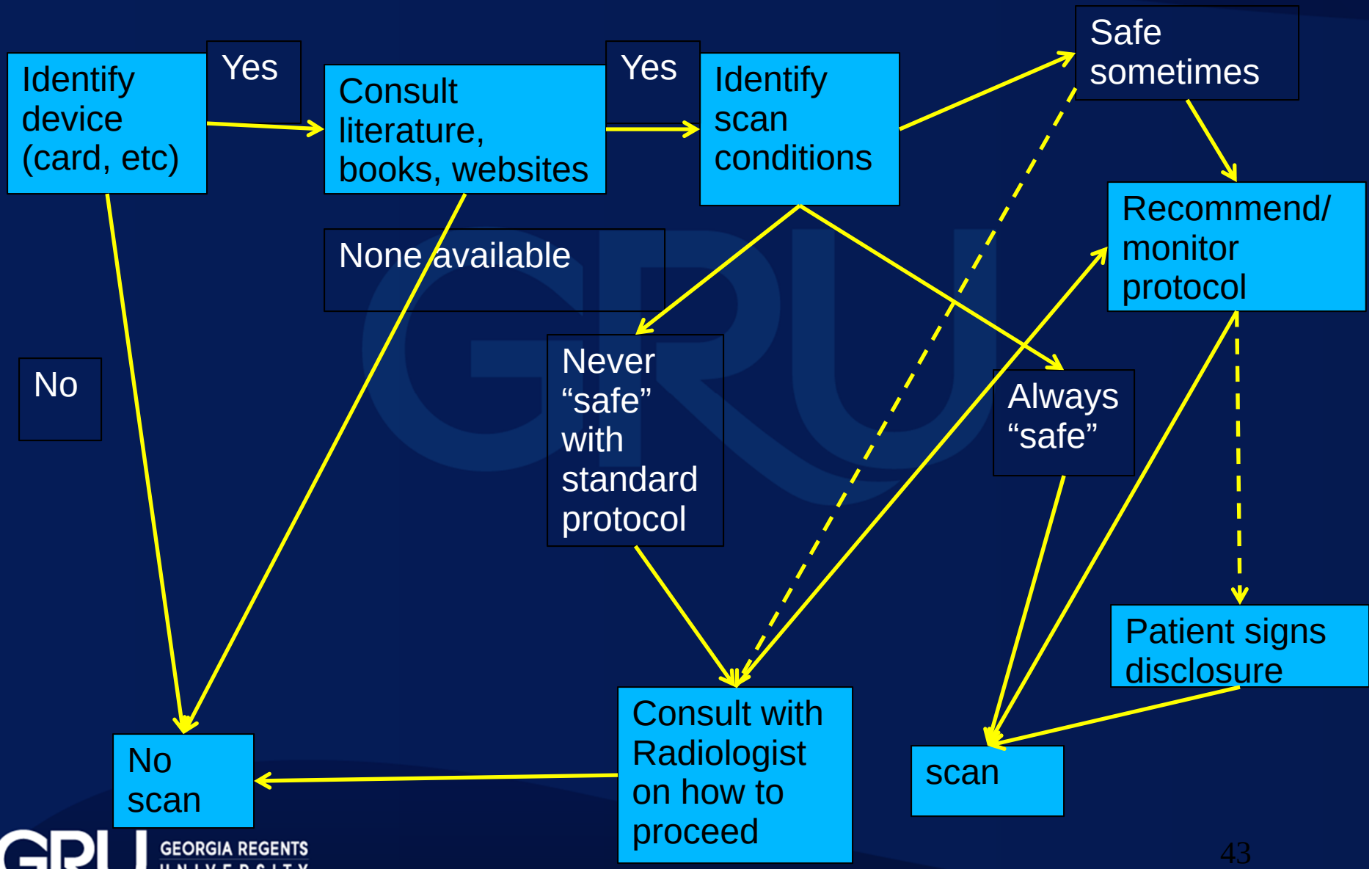
Determine safety of devices day-to-day (boots on the ground)

Monitor safety during MR scans

Develop protocols

Suggest/draft policies

Practical steps for determining safety



What concerns exist with medical implants?MR Unsafe (e.g., defibrillators, some aneurysm clips)

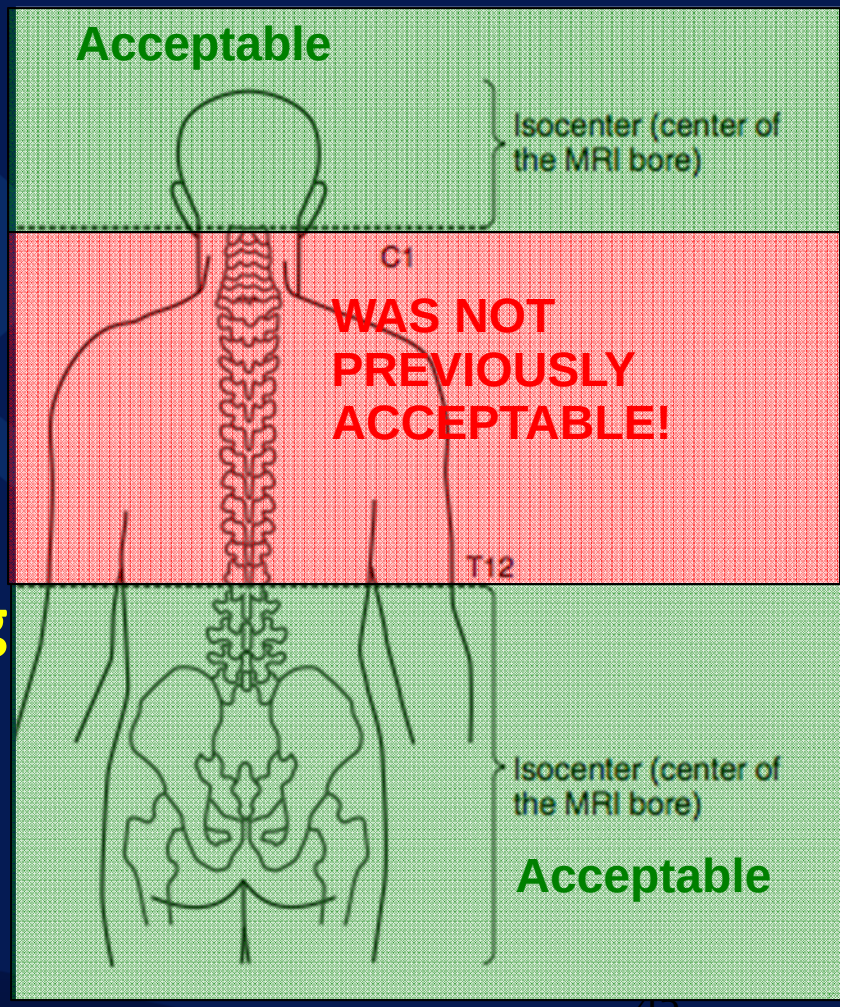
MR Conditional issues (management) --
Movement within the body – B0, dB/dx
(e.g., pumps)
Heating – RF
(e.g., leads)
Malfunction – B0, RF, dB/dt
(e.g., stimulators)
Device destruction –B0, RF, dB/dt, dB/dx
(e.g., Baclofen pumps)

Many Medical Implants are safe ONLY for a given set of conditions → MR CONDITIONAL.

Example: Medtronics SureScan Pacemaker System (Revo and Advisa models) can be scanned under certain conditions.

However, MR exam of the chest before 2013 was unsafe…including the HEART!

That's changed now, but …



GRU GEORGIA REGENTS UNIVERSITY

Many Medical Implants device requirements change dramatically over time.

Medtronics Pacemakers:
pre-2011: None
2011: Surescan – Revo,
1.5T, but no body Tx over chest
2013: Surescan – Revo, Advisa,
chest requirements ok now

Ensura surescan, not approved for scanning in US (so get docs from proper website: .com, vs. .eu)

Many Medical Implants device requirements change dramatically over time.

Cyberonics Vagal Nerve Stimulators:

Dec. 2008 -- Only 1.5T, only head Tx/Rx, <1.3 W/kg for a 154.5 lb patient, dB/dt < 10 T/sec

Oct. 2011 -- 1.5T and 3T, head or extremity Tx/Rx only, <3.2 W/kg head averaged (non-human), dB/dx<720 Ga/cm

Physics Concerns: B0

Biological effects of static magnetic fields

"In general, there is no conclusive evidence for irreversible or significant biological effects related to acute, short-term exposure of humans to static magnetic field strengths up to 2.0 T."

FDA Guidance

Main Static Magnetic Field

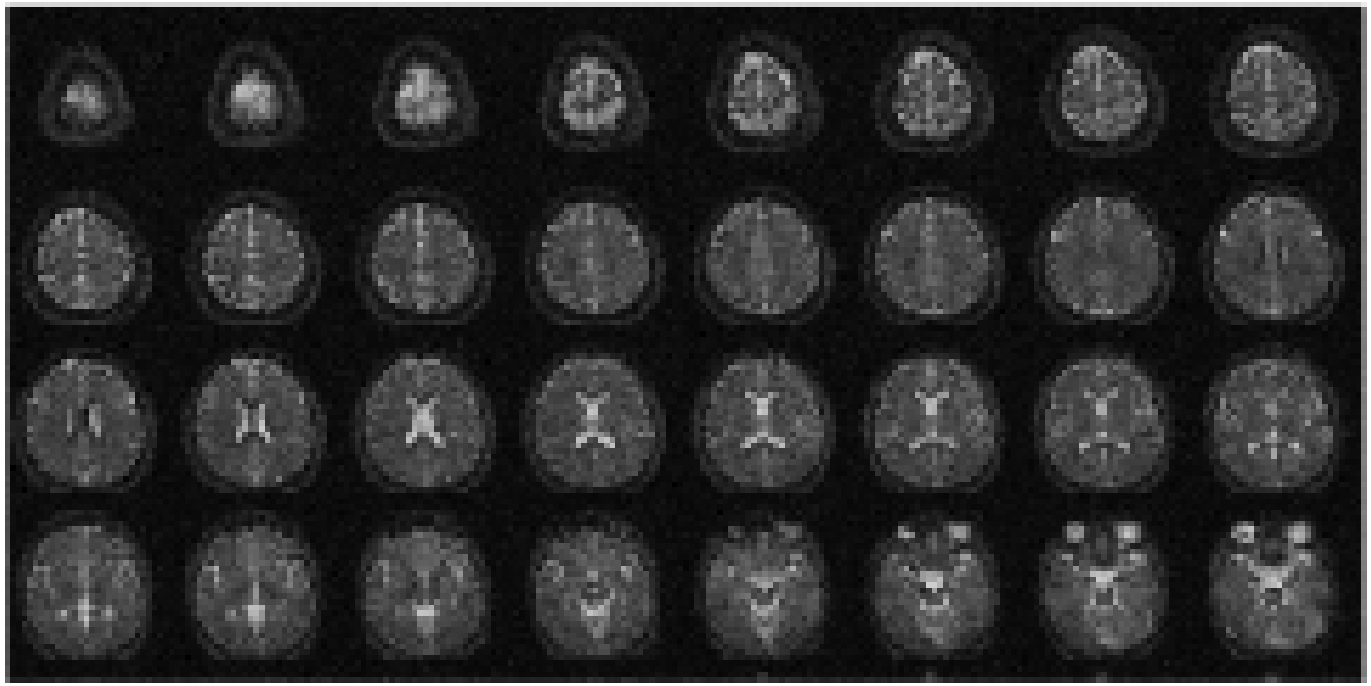
Population	Main static magnetic field greater than (tesla)
adults, children, and infants aged > 1 month	8
neonates i.e., infants aged 1 month or less	4

B0 – where we're going?

Atkinson, et al, JMRI, 26: 1222-7, 2007 (9.4T)

"No statistically significant changes in heart rate, systolic ...diastolic BP, end-tidal CO_2, respiratory rate, peripheral arterial O_2 sat, or skin temperature were observed..."

Below: 6 min acquisition for 3mm isotropic Na images.



Physics Concerns: B0

For implants, issues include torque and force on ferrous parts, and induced magnetism →

- Malfunction (reed switches)
- Destruction
- Motion (3T vs. 1.5T)

If it is safe at 1.5T, IT IS NOT NECESSARILY SAFE AT 3T (Field issues)

If it is safe at 3T, IT IS NOT NECESSARILY SAFE AT 1.5T (RF Resonance issues)

Aneurysm Clips …

In 1992, a patient *suffered a hemorrhage and died* after an aneurysm clip in her brain shifted while she was on a table preparing for an MRI procedure.

If a clip is safe at 1.5T, IT IS NOT NECESSARILY SAFE AT 3T.

Physics Concerns: B1 (RF)

Biological effects of RF magnetic fields

-RF magnetic fields are oscillating magnetic fields

-These fields produce heating of tissue

-Energy deposited (degree of heating) is measured by the Specific Absorption Rate (SAR) in units of Watts/kilogram

Specific Absorption Rate (SAR)

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	4
head	averaged over	10	3
head or torso	per gram of tissue	5	8
extremities	per gram of tissue	5	12

Overall FDA SAR Safety Guidance for MR Devices

Physics Concerns: B1 (RF)

For implants, issues include

induction of current (dB/dt)

→ **heating**

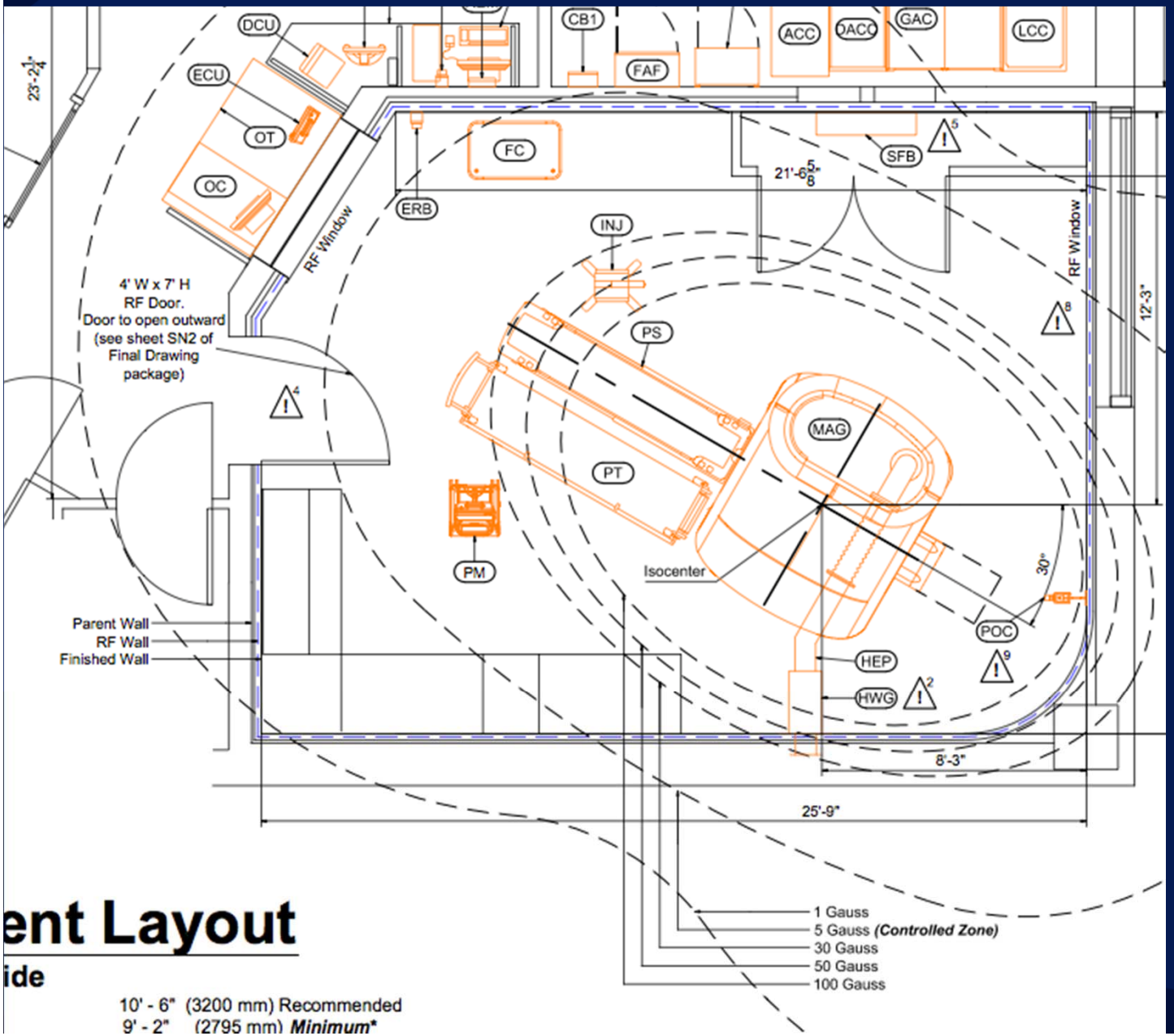
Burning of tissue

Heating of leads

Device damage

→ **stimulation of leads**

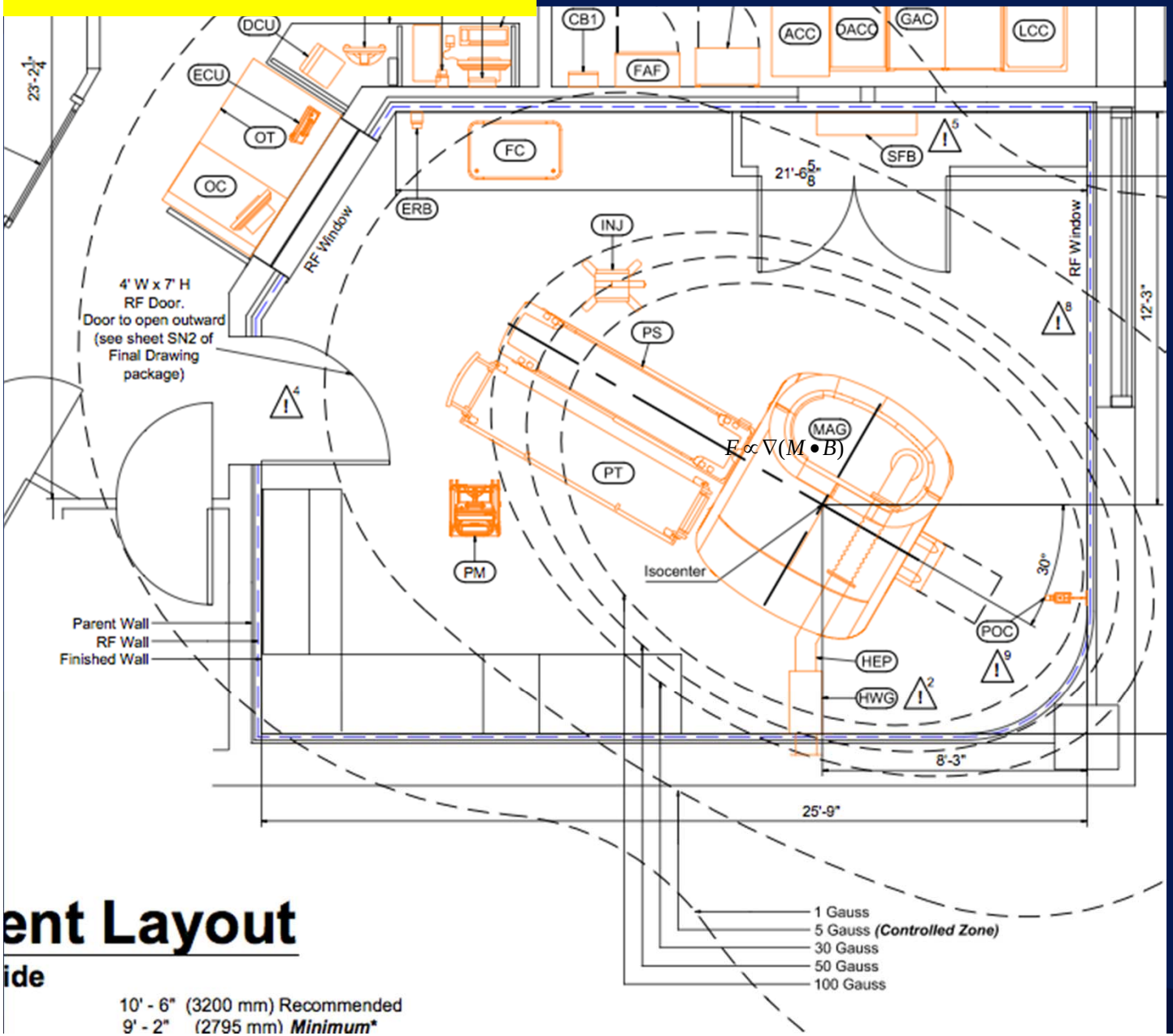
Physics Concerns: dB/dx



How do we gauge safe distance from a scanner?

We have a fringe field map on site for each magnet.

$$F \propto \nabla(M \bullet B)$$



B = local B-field
M=stimulated field in metal object

Faster changes in fringe field, stronger force.

Even worse (m increases in increasing field) … but …

Physics Concerns: dB/dx

Force ~ d/dx (M•B)

What does all of this mean for us?

Old 1.5T – large fringe field/lower field – less force per change in distance.

New 3Ts – small fringe field/higher field – small changes in distance lead to large changes in force.

So, if some piece of equipment gets too close, you will know this only when it's too late.

Physics Concerns: dB/dx

For implants, issues include

- Pulling of device (<6 wks, or in general)
- Big issue – dB/dx maps not readily available.
- In theory, scanning of foot with a stimulator near the MR opening could ALSO allow for significant dB/dx via gradient coils.
- D. Jordan, J. Och, AAPM(WG on magnetic resonance testing and quality assurance) are working on this.
- We use our old, passively-shielded 1.5T when we have dB/dx concerns.

Physics and Concern: dB/dt

Biological effects of time varying (gradient) magnetic fields

Nerve stimulation

Gradient Fields Rate of Change

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

Table 2-5 Threshold Limit Operating Actions

Operating Mode	STL% or T/s Limit
Clinical	US: 66% of STL IEC: 20 T/s (unless you accept message prompt)
First Level (controlled mode)	Requires you to click the **[Accept]** button to proceed when the Clinical mode dB/dt or SAR limits are exceeded, but Second Level mode has not yet been reached.
Second Level (controlled mode)	Requires research key and IRB or Human Ethical Committee approval of the research to be conducted

Example GE dB/dt levels

Stimulation Threshold Levels

Mean Cardiac
Stimulation Threshold

Mean Respiratory
Stimulation Threshold

Mean Painful Nerve
Stimulation Threshold

Mean Peripheral Nerve
Stimulation Threshold

Typical Operating Range

T/s = Tesla per second

0 - 20 T/s = clinical mode

>20 T/s = First or Second Controlled Modes*

* Limited by IRB or Human Ethical Committee

Physics Concerns: dB/dt

For implants, issues include:

- Stimulation of leads
  - Damage to device
  - Overstimulation of patient
- For reference, 200 T/m/sec is high-performance today → 200mT/msec over a meter
- 50 mT/m maximum strength is high-performance.
- When we are concerned (e.g., neurostimulators), we remove these sequences from the protocols:
  1. EPI → No DWI nor PWI
  2. MRA

JOURNAL OF MAGNETIC RESONANCE IMAGING 000:000–000 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

Expert Panel on MR Safety: Emanuel Kanal, MD,[1*] A. James Barkovich, MD,[2] Charlotte Bell, MD,[3] James P. Borgstede, MD,[4] William G. Bradley Jr, MD, PhD,[5] Jerry W. Froelich, MD,[6] J. Rod Gimbel, MD,[7] John W. Gosbee, MD,[8] Ellisa Kuhni-Kaminski, RT,[1] Paul A. Larson, MD,[9] James W. Lester Jr, MD,[10] John Nyenhuis, PhD,[11] Daniel Joe Schaefer, PhD,[12] Elizabeth A. Sebek, RN, BSN,[1] Jeffrey Weinreb, MD,[13] Bruce L. Wilkoff, MD,[14] Terry O. Woods, PhD,[15] Leonard Lucey, MD,[16] and Dina Hernandez, BSRT[16]

Because there are many potential risks in the MR environment and reports of adverse incidents involving patients, equipment and personnel, the need for a guidance document on MR safe practices emerged. Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. As the MR industry changes the document is reviewed, modified and updated. The most recent version will reflect these changes.

Key Words: MR safety; MR; MR safe practices
J. Magn. Reson. Imaging 2013; 000:000–000.

THERE ARE POTENTIAL risks in the MR environment, not only for the patient (1,2) but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. (3–6). There have been reports in the medical literature and print-media detailing Magnetic Resonance Imaging (MRI) adverse incidents involving patients, equipment and personnel that spotlighted the need for a safety review by an expert panel. To this end, the American College of Radiology originally formed the Blue Ribbon Panel on MR Safety. First constituted in 2001, the panel was charged with reviewing existing MR safe practices and

Questions?

Nathan Yanasak
Dept of Radiology, GRU

706-721-3602
nyanasak@gru.edu

GRU GEORGIA REGENTS UNIVERSITY