MRI Safety Manual

University of Texas Rio Grande Valley
Institute of Neuroscience

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SECTION ONE - GENERAL INFORMATION

PURPOSE:

- The Institute of Neuroscience is committed to the safety of customers and employees and has established these guidelines for maintaining safety, surveillance of potential and actual safety issues, and research into the newest MRI technology.

- To establish the policies and procedures to maintain safe clinical and laboratory practice involving magnetic resonance imaging (MRI) devices at UT Health RGV facilities.

- To implement a MRI safety program that models the recommendations given by ACR Guidance Document for Safe MR Practices: 2013 that are applicable to University Health System.

SCOPE:

- This manual establishes requirements that are applicable to all persons who receive, possess, acquire, transfer or use MRI devices in either clinical or laboratory settings at UT Health RGV facilities; or who operate UT Health RGV owned MRI devices at temporary sites for limited time periods.

- The contents of this manual have been developed by the UT Health RGVMRI Safety Committee.

- In situations where there is a conflict with the policies and procedures contained in this manual and those contained in local policies and procedures, such as "UT Health RGV Nursing Practice Standards", those contained in this manual shall take precedence.

PROHIBITIONS:

- MRI devices **shall not** be used in any manner that creates a threat or danger to UT Health RGVfaculty, staff, patients and/or the general public.

- Exposure of an individual for training is prohibited unless under the direct supervision of a MRI practitioner.

    - Exposure of an individual for the purpose of healing arts screening is prohibited without a written doctor's order or any other proper language.

    - Exposure of an individual for the purpose of research on humans is prohibited unless prior authorization is received from the institutional review board (IRB).

DEFINITIONS:

- **Absolute Contraindications:** Anything that will definitely prevent a patient from undergoing an MRI.

- **Biological Effect**: It is generally accepted that static magnetic fields under 4 Tesla produce no adverse biological effects.

- **Claustrophobia:** Is an anxiety disorder that involves the fear of enclosed or confined spaces. It may be categorized as mild, moderate, severe, or panic level. Patients with claustrophobia will often require treatment with an anti-anxiety medication or general anesthesia for MRI procedures.

- **Ferromagnetic:** Items composed of a substance which will experience a force of attraction in the presence of a magnetic field.

- **GAUSS (G):** The unit of measure of magnetic induction or flux density; 10,000 G = 1 Tesla (T). *(The Earth's magnetic field = .5 to 1 gauss)

- **Helium:** An inert gas frequently used to cool superconductive magnets like those used in MRI equipment. In its gaseous state helium is lighter than air and will rise.

- **Individuals:** Within this document, individuals are employees, staff, PIs or other personnel who are working and /or conducting studies in the MRI environment.

- **Medical Event:** Any adverse patient health effect that is a result of failure or misuse of MRI equipment.

- **Magnetic Resonance Imaging (MRI)**: The enhanced absorption of energy occurring when nuclei of atoms or molecules within an external magnetic field are exposed to radio-frequency energy, and Larmor or resonance frequency energy is emitted.

- **MRI Compatible**: Equipment that is designed and manufactured without the use of ferromagnetic materials and has been determined safe for the use in MRI scanning rooms (item will not be attracted to the magnetic field).

- **MRI Conditional**: Equipment that has been demonstrated to pose no known hazards in a Specified MR environment with specified conditions of use. MR conditional label is used to alert the user that there are certain limitations to the usability of the item. As an example, an item may have been tested for a 1.5Tesla but not a 3Tesla. Before using Equipment that is marked MRI Conditional know what the conditionality of use is, such as a gauss-line restriction or SAR level limitation.

- **MRI Device Operator:** The MRI scanner operator is an individual who is an UT Health RGVemployee, has completed the MRI safety training and is specially trained in the operation of one or more of the MRI scanners. There are two levels of device operators:

- Individuals who are allowed to operate the device for phantom studies

- Individuals who are allowed to operate the device for patients and/or research participant studies

- **MRI Environment:** The MRI environment is that area within the scanner room where the magnetic field strength exceeds 3 gauss.

- **MRI Practitioner (practitioner)**: a person licensed to practice the healing arts by either the Texas State Board of Medical Examiners as a physician; the Texas State Board of Dental Examiners; the Texas Board of Chiropractic Examiners; the Texas Board of Nursing; the American Osteopathic Association or the Texas State Board of Podiatry Examiners. A practitioner's use of a MRI device is limited to his/her scope of professional practice as determined by the appropriate licensing agency.

- **MRI Unsafe**: Is any item that is known to pose a hazard in all MRI environments containing ferrous material that would be attracted to the MRI magnetic field.

- **Nitrogen**: An inert gas sometimes used to cool MRI magnets. It is a relatively heavy component of air, therefore, it will mix evenly making it more dangerous to use.

- **Patient:** A patient is a human subject who is placed into the bore of the MRI device for clinical purposes. The patient must be treated and cared for within all institutional and federal guidelines and regulations.

- **Projectile**: Any ferromagnetic object brought within close proximity of the magnetic field of the MRI scan room can be launched into the air and travel through space at a rapid rate of speed causing severe injury or death to anyone between the object and the magnet.

- **Quenching:** A condition that occurs when a superconductive magnet loses its superconductivity (magnetic field); caused by the rapid release of a large volume of liquid helium from the magnet. During quenching, if built in safety measures malfunction, anyone in the scanning room will be in extreme danger of frostbite, loss of consciousness and asphyxiation within a few minutes.

- **Radio Frequency (RF):** An electromagnetic wave frequency between audio and infrared; RF are always produced during MRI scanning; certain RF can produce heat and place the patient at risk for burns.

- **Relative Contraindications**: Anything that may prevent a patient from undergoing an MRI (i.e. pregnancy, dehydration)

- **Research Participant:** is a human subject who is placed into the bore of the MRI device for research purposes. The research participant must be treated and cared for within all institutional

and federal guidelines and regulations.

- **Scanning Room**: The restricted room where the active magnet is located and the place where all MR scanning is performed. All persons must be screened for safety before entering.

- **Specific Absorption Rate (SAR)**: The SAR is the mass normalized rate at which RF power is coupled to biological tissue and is typically indicated in units of watts per kilogram (W/kg). The relative amount of RF radiation that an individual encounters during an MR procedure is usually characterized with respect to the whole-body averaged and peak SAR levels. It is the thermoregulatory and physiologic changes that a human subject exhibits in response to exposure to RF radiation and are dependent on the amount of energy that is absorbed.

- **Technical Staff:** Non-faculty who have met certain training and experience requirements as set forth in this manual and whose MRI use is under the general supervision of an MRI Practitioner.

- **Tesla (T):** The unit of measure for a magnetic field created by electric currents; the unit used to express magnetic field strength, for example - 1.5 T (Tesla) magnet = 15,000 GAUSS.

RESPONSIBILITIES OF MRI PRACTITIONER:

- Notify the UT Health RGVMRI Medical Director of any acquisition, transfer or disposal of a MRI device.

- Ensure that MRI devices are properly maintained, aligned, calibrated and repaired by qualified persons.

    - MRI Practitioner shall not allow non-UT Health RGV employees to provide such services without first obtaining a copy of documents indicating that the vendor/person is qualified to provide MRI services. A copy of these documents shall be sent to the Radiation Safety Office.

- Verify that the annual physics report is completed for each MRI unit per Joint Commission Standards. This physics report also serves as an annual inventory of the unit.

- Ensure that only appropriately trained and authorized individuals use the MRI devices.

- Maintain a current list of individuals authorized to use the MRI devices.

- Ensure all individuals who work with or in the vicinity of MRI devices shall be knowledgeable about the devices in their work area and the potential health hazards associated with the use of these devices.

- Confirm that all ACR accredited MRI magnets follow ACR mandated QC requirements.

TRAINING/QUALIFICATIONS:

- All individuals (Technical and Non-Technical staff) shall have MRI safety training applicable to their job functions for the hazards encountered working within all zones of the MRI environment.

- All individuals (Technical and Non-Technical staff) shall complete an applicable job function MRI safety training refresher course annually.

- Documentation of training shall be in a manner approved by the MRI Medical Director.

- Exemptions from attending UT Health RGVMRI training classes (this exemption does not apply to annual refresher training):

    - Individuals who have documentation of comparable training received prior to arriving at University Health System.

    - Individuals who have documentation of comparable training received outside of University Health System.

    - Faculty members whose training and experience history has been accepted by the Radiation Safety Office in the course of becoming an MRI Practitioner.

    - Individuals who have been granted exemption by the MRI Medical Director

- Documentation of hands-on training shall be signed by the preceptor or vendor.

- Non-Technical Staff shall have MRI safety training applicable to their job function for the hazards encountered working within all zones of the MRI environment

STATIC MAGNETIC FIELD:

The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field.

- ***Field Strength***

    - The strength of the static field is regulated by the federal government. As of July 14, 2003 the U.S. Department of Health and Human Services (DHHS) Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) determined that there is a significant risk scanning adults, children, and infants older than one month at a main static field greater than 8 T. The limit for neonates and infants younger than one month

is 4 T. Currently the maximum magnetic field strength for clinical use and research use at UT Health RGV is 3.0T and 1.5T respectively.

- ***Projectile Effect***

    - Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field.

    - Projectiles have the potential of causing serious injury including death, to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet. Equipment may be irreparably damaged by becoming a projectile or by being struck by one.

    - All patients will be screened for possible projectile objects (e.g. pens, coins, bobby pins, and keys) prior to admission to the scan room.

    - Nurses and physicians from outside of the Radiology department will be screened through the ferrous metal detector prior to entering the scan room. All stethoscopes, pen lights, pens, name badges, scissors, and other ferromagnetic objects will be removed.

    - Patients coming to Radiology from other patient care areas will not be taken into Zone IV area in wheel chairs, on stretchers, with portable ferrous air cylinders or with IV poles from those areas.

    - Patient's belongings will be stored in lockers located in the patient dressing rooms (Zone II).

    - In the setting of an immobile patient that requires wheelchair or stretcher carriage, all patient transfers to MRI compatible transportation will occur in the nursing bay (Zone III).

- ***Torsion and Translation Forces***

    - Ferromagnetic objects or devices, including those within the human body will be attracted to the magnet.

EQUIPMENT SCREENING:

All equipment used for research studies or patient MRI scans, including projectors and stimulus producing apparatus, must be tested for MRI safety BEFORE entering the fringe field. Individuals are cautioned to NEVER take equipment into the magnet room without prior testing for magnetic attraction

- ***MRI Safety Label Terminology***

    - MR Safe: An item that poses no known hazards in all MRI environments. Items include

non-conducting, nonmetallic, nonmagnetic items such as a plastic container or a cotton sheet. An item may be determined to be *MR Safe* by providing a scientifically based rationale rather than test data. The *MR Safe* icon consists of the letters 'MR' in green in a white square with a green border or the letters 'MR' in white within a green square.

- MR Conditional: An item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. For *MR Conditional* items, the labeling includes results of testing sufficient to characterize the behavior of the item in the MRI environment. Any parameter that affects the safety of the item should be listed, and any condition that is known to produce an unsafe condition must be described. The *MR Conditional* icon consists of the letters 'MR' in black inside a yellow triangle with a black border.

- MR Unsafe: An item that is known to pose hazards in all MRI environments. This includes magnetic items such as a pair of ferromagnetic scissors. The *MR Unsafe* icon consists of the letters 'MR' in black on a white field inside a red circle with a diagonal red band.

- ***Patient Equipment***
  - **Patient monitor.** MRI compatible patient monitors are available in the MRI department and will be used on:
    - Critically ill patients

- Patients under general anesthesia
- Patients receiving procedural sedation
- Physically or mentally unstable patients
- Neonatal and pediatric patients
- Patients with compromised physiologic functions

- **IV infusion pumps**. MRI compatible infusion pumps are maintained in the MRI department and will be used as required. It is recommended that the radiology nurse, when possible, take the infusion pumps to the critical patient to make the change from a non-MRI compatible infusion pump to the MRI compatible infusion pump in the ICU.

PERSONAL PROTECTIVE EQUIPMENT:

- ***Hearing protection***
  - Hearing loss can occur if the ears are not protected during MRI scanning.
    - Ear protection will be provided for all patients during the MRI scanning.
    - Ear protection will be provided for the employees and patient sponsors when monitoring the patient during an MRI scan.

SECTION TWO – CLINICAL USE OF MRI DEVICES

ACCESS SAFETY:

Access to the MRI suites will be limited.

- Doors will have badge access locks and monitored via security cameras.
  - Badge access will be given to essential personnel only.
  - Persons requiring entrance into the MRI Suite will need to alert MR personnel via wall mounted intercom.
  - All admitted personnel will also need to undergo safety clearance if entering the scan

rooms.

- Everyone will be screened through the Ferromagnetic detector. If the ferrous metal detector alarms that person will not be allowed in to the MRI room until cleared by the Technologist.

ZONING:

- ***Zone I***
  - Open to general public access,
  - This is generally the reception and waiting area for the MRI suite.
  - Purpose of this zone is to channel patients, research participant and technical staff to the prescreening area (Zone II)
  - Negligible MRI hazards
- ***Zone II***
  - This is the first interaction site for patients, research participants, visitors, and others with the technical staff in the MRI suite.
  - The purpose of this zone is to restrict further public access to the suite, provide direct supervision of patients, research participant and visitors by the technical staff, and provide an opportunity to prescreen all patients, research participants and visitors.
  - All ferromagnetic objects must be collected and secured within Zone II.
  - Individuals should verify that all transport equipment is MRI-safe by viewing MRI safety label or by testing for magnetic attraction.
- ***Zone III***
  - Zone III is the entry zone to the MRI scanning room
  - Without exception, only the MRI Practitioner and certified technical staff should be allowed free access between Zones III and IV.
  - All technical staff must be prescreened upon employment prior entering Zone III to make sure no unscreened individuals are allowed access to Zone IV.
  - Coded and locked entries are employed to prevent access by unscreened individuals.

- ***Zone IV***

    - Only those personnel required so that the patient can complete the exam will be allowed in the MRI scanning room during the procedure. Family members should remain in the waiting area unless the patient requires their presence for exam completion.

    - Code red situations will require the use of MRI-safe fire extinguishers and restriction of public first responders from Zone IV, until MRI safe conditions can be established or first responders verified as MRI safe.

    - In a code red situation in Zone IV, first responders **do not** have free access to either Zone III or IV

    - Prior to any incident, local fire and police department personnel should be educated on the hazards of the MRI suite in emergency situations.

    - The entrance to this room is visually marked by signage on the normally closed room doors and on the floor indicating that the MRI machine is always on and the area is restricted.

MRI SAFETY PRE-SCREENING:

Each person must be checked for safety or pre-screened prior to entering the magnetic environment of the scanner room. An important aspect of protecting people from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the person.

- ***Individuals***

    - All individuals, including clinical, researchers, employees and students, who work within the magnetic environment, must be trained according to UT Health RGVpolicy and screened for personal safety prior to entering the magnetic field.

    - In addition, individuals who have responsibility to recruit subjects, and / or screen subjects for MRI scans are required to complete the MRI Safety Training program.

    - Any individual who has a need to enter the magnet room (i.e. facility maintenance employees, site visitors) must be screened on a case by case basis.

- ***Patients***

    - Preliminary screening of patients for MRI procedures should take place during the scheduling process. Such screening helps to prevent scheduling of patients who may be at risk for safe MR imaging.

- At the facility, it is mandatory for every MRI patient to undergo comprehensive screening in preparation for the MRI study prior to entering Zone IV (see appendix).

- It should be noted that having undergone a previous MRI procedure without incident does not guarantee a safe subsequent MRI examination.

- Family members of patients whose presence is required for exam completion are held to the same screening requirements as patients.

- Pregnancy – Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any theoretical minimal risk to the fetus by referring physician and radiologist.

- Pediatric Patients – All pediatric patients will be screened in the presence of parents or guardians to verify the proper information required.

- If the patient is unconscious and unknown, then the technologist should contact the radiologist. The radiologists should order these radiographs skull AP and Lateral, Chest PA, KUB. If there is any scar on the patient, then that area may be radiogaphed to look for any metallic objects.

- ***Implants and devices***

  Implants and devices are evolving rapidly and must be thoroughly investigated if potential patients or individuals who will enter the magnetic environment indicate their presence. Implants tested to 1.5T may not be compatible at 3.0T. Any implants for 3.0T imaging must be determined to be acceptable specifically to 3.0T. The maximum magnetic field strength currently used for patients at UT Health RGV is 3.0T. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

  - Look up the item by the manufacturer on the web site: http://www.mrisafety.com

  - If the device or object is not listed there or has not been tested at the field that the patient is subjected to, then contact the manufacturer for the following information and written documentation:

  - Have the manufacturer fax the text that states the device is MRI safe and at which magnetic field strength(s), and conditions, it is safe.

  - The text sent should include the FDA date stamp that verifies the device is MRI safe at 3.0T or the specific conditions which must be adhered to for the field strength the individual will

be entering.

- Certain pacemakers are conditional and we should follow the vendor-specific guidelines for those. If we get a request to do MRI on these patients, then the clinical team should get a form filled and signed by the cardiologist. Ideally the cardiologist should be the same who put the pacemaker, if for some reason the same cardiologist can sign the form then an in-house cardiologist should examine the patient and they can sign the form if they are familiar with these types of pacemakers. The vendor representative should come to the hospital and adjust the pacemaker settings before MRI.

- ***External Fixator Devices***

  - All external fixators are considered MR-conditional.

  - Two of the commonly used external fixators [DePuy Synthes and Stryker Hoffman (II only labeled MRI) and III] were classified as MRI conditional but not MRI safe. This means that certain conditions have to be met before we can safely do the scan i.e. the ExFix has to stay outside the magnet or stay at the edge because of risk of torque and/or tissue heating up. This is a problem especially when the patient is short and if the patient is unconscious as they can't tell if its heating up.

  - We have to follow the vendor guidelines for these fixators. So we need to know the type/model of the device and the guidelines on their website or check with the vendor's representative.

  - There are some specific instances when an MRI is needed in patients for clinical reasons where the benefits outweigh the risks.
    - When Radiology gets a request for MRIs in such patients, there should be a discussion between the radiologist and the ordering physician to ensure that the physician and the patient understand the risks. If an alternative imaging like CT can answer the query, we would still recommend that as the best option.
    - If the decision is still to proceed with the MRI, the ordering physician will have a discussion with the patient about the risk of proceeding with the MRI (as per recommendations from the attached article) and document the patient's consent to proceed with the MRI in Sunrise/EMR.
    - Ideally, we would like the patient to be conscious so that they can tell the technologist about the heating, but in some circumstances, patients may be unconscious and if they need MRI, then the physician should take consent with the family members about the risks and document that in the sunrise.

- ***Claustrophobia Screening***

    - Statistics indicate that about 10% and up to 20% of the general population is claustrophobic to some degree. In many cases patients who think they are claustrophobic are able to go through an MRI study with some reassurance.

- ***Medical Status Screening***

    - Patients must be evaluated for medical status or issues that may prevent them from lying flat or holding still for long periods of time. Patients who are dependent on continuous medication via external or internal devices should be excluded from MRI scans.

- ***Magnetic field-related issues and Screening***

    - Magnetic field-related translational attraction and torque are known to present hazards to individuals and patients with certain implants or devices.

- ***Patient Emotional Stress, Anxiety, and Sedation***

    - Patient distress can result in an adverse outcome for the MR exam. There are techniques that the MR practitioner or clinician can use to minimize the emotional distress and anxiety of the MR exam. This screening will help identify those patients that require additional education to minimize stress, interventions such as patient positioning, and/or relaxation procedures. If sedation is required, all sedation protocols will follow TJC and the American Society of Anesthesiologists guidelines.

RELATIVE CONTRAINDICATIONS:

- Pregnancy

    - <u>NONCONTRAST</u> MRI in pregnant patients:

        - UT Health RGV follows the American College of Radiology Guidelines for imaging of pregnant patients. The guidelines are detailed in the ACR Guidance Document on MR Safe Practices: 2013 (http://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety).

        - As per the ACR guidelines: “Present data have not conclusively documented any deleterious effects of MR imaging exposure on the developing fetus. Therefore, no special consideration is recommended for the first, versus and other, trimester in pregnancy.”

- As part of the screening process, if a patient is found to be pregnant, according to the ACR Safety Guidelines "consideration should be given to reassessing the potential risks versus benefits of the pending study in determining whether performance of the requested MRI examination could safely wait until the end of pregnancy".

- The radiologist will confer with the referring physician to analyze the risk-benefit ratio of performing the MR examination. The following will be documented by the radiologist in the radiology report.

    - The information needed cannot be acquired from ultrasound or other diagnostic test that does not require ionizing radiation.

    - The information needed affects the care of the patient and/or the fetus during pregnancy.

    - The referring physician feels that the scan cannot wait until after the pregnancy.

- <u>CONTRAST ENHANCED</u> MRI in pregnant patients.

    - UHS radiology adheres to the ACR Committee on Drugs and Contrast Media recommendation in regards to the administration of intravenous gadolinium contrast to pregnant patients. These recommendations are outlined in the ACR Manual on Contrast Media: 2015 (http://www.acr.org/~/media/37D84428BF1D4E1B9A3A2918DA9E27A3.pdf).

    - Studies have demonstrated that gadolinium MR contrast agents can enter the fetal circulation. Therefore, MR contrast should NOT be routinely provided to pregnant patients.

    - As per ACR guidelines, "Intravenous gadolinium should be administered only when there is a potential benefit to the patient or fetus that outweighs the possible but unknown risk of fetal exposure to free gadolinium ions."

    - The radiologist will confer with the referring physician to discuss the risk and benefit of the procedure. Informed consent will be obtained prior to the MRI examination. The following will be documented by the radiologist in the radiology report:

        - The information requested from the MRI study cannot be acquired without the use of IV gadolinium contrast or by using other imaging modalities.

        - The information needed affects the care of the patient and/or fetus during the pregnancy.

        - The referring physician is of the opinion that it is not prudent to wait to obtain this

information until after the patient is no longer pregnant.

- Certain intravascular stents and filters that have been in place for less than six weeks of surgery *(as designated "conditional 2" by mrisafety.com)*

- IUD *(historically MRI unsafe but newer implants can be MRI safe/conditional)*

- Prosthetic heart valves *(historically MRI unsafe but newer implants can be MRI safe/conditional)*

- Swan-Ganz catheters *(historically MRI unsafe but newer implants are often MRI safe/conditional)*

- Hemo-static clips (non-ferromagnetic)

- Temperature Sensing Foley Catheters (MRI Conditional)

    - Foley must be disconnected from extension cables and monitors

    - Foley must be positioned down the center of the table in a straight line (no loops)

        - The Medline Medline's 100% Silicone 400 Series Temperature Sensing Foley Catheter has specific conditions to be met before we can do the procedure. These must be followed (Mari has the pdf for those conditions) . Some of these are:

            - Static magnetic field of 1.5-Tesla or 3-Tesla only

            - Highest spatial gradient magnetic field of 720-Gauss/cm or less

            - Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg i.e., operating in the Normal Operating Mode (the Normal Operating Mode limits the MR system to a level that all persons regardless of health status should be able to tolerate) at 1.5- and 3-Tesla for 15 minutes of scanning per pulse sequence

- Older tattoos and permanent make-up that may contain ferrous particles.

    - Instruct patients to wash off removable eye makeup before exam to avoid the risk of eye injury. Be cautious scanning patients with permanent eyeliners, they may experience some discomfort during the MRI exam.

    - Instruct the patient with tattoos to immediately notify the technologist if a warm or burning sensation develops while scanning.

- EEG leads

    - MR compatible electrodes are dark-gray in color with "MR" written at the end.

Technologist should check the end of the leads and make sure “MR” is written on that. If not, then EEG leads are not MR compatible.

- There should be a sign at the head of bed, if patient has MR compatible electrodes.
- Gold cup electrodes are NOT MR COMPATIBLE.

- Retained Bullet Fragments. (The following is taken from MRISafety.com and Aunt Minnie website)
  - The majority of pellets and bullets tested in the MR environment were found to be composed of nonferromagnetic materials, however, these items are often “contaminated” by ferromagnetic metals. Ammunition that proved to be ferromagnetic tended to be manufactured in foreign countries and/or used for military applications. Shrapnel typically contains steel and, therefore, presents a potential hazard for patients undergoing MR procedures.
  - Because pellets, bullets, and shrapnel are frequently contaminated with ferromagnetic materials, the risk versus benefit of performing an MR procedure should be carefully considered. Additional consideration must be given to whether the metallic object is located near or in a vital anatomic structure, with the assumption that the object is likely to be ferromagnetic and can potentially move.
  - In an effort to reduce lead poisoning in “puddling” type ducks, the federal government requires many of the eastern United States to use steel shotgun pellets instead of lead. The presence of steel shotgun pellets presents a potential hazard to patients undergoing MR procedures and causes substantial imaging artifacts at the immediate position of these metallic objects.
  - Pure lead or copper bullets are considered safe. Regular commercially available bullets manufactured in the U.S are safe in scanners up to 7-tesla, the authors concluded. In contrast, armor-piercing bullets with steel cores and stainless steel shotgun pellets "should be considered unsafe due to movement.” However, if the composition of these bullets is not known, then risk versus benefit analysis is done.

ABSOLUTE CONTRAINDICATIONS:

The magnetic field of the MRI system can cause a ferrous implant (e.g., aneurysm clip, surgical clip, cochlear implant, etc.) or prosthesis to move or be displaced, resulting in serious injury.

Patients should be screened for implants and if movement of the implant could result injury, the patient should not be scanned.

- The following medical devices have a high probability of an MRI Unsafe designation that would absolutely contraindicate MRI examination. The make and model of the following medical devices should be searched on "www.mrisafety.com" to confirm MRI Safe/Conditional status.
    - Old generation cardiac Pacemakers (Certain types may be conditional. In these cases, we should check the vendor guidelines.)
    - Bone Growth Stimulators
    - Coronary bypass surgery if types of clips are unknown
    - Implantable drug infusion pumps
    - Implanted defibrillators
    - Spinal stimulation devices
    - Cochlear Implants
- Metallic foreign bodies of unknown composition
    - Welders are at high risk for ferrous particles in the eye.
    - Veterans may have foreign body metal particles
- In the rare situation that MRI is requested in patients with absolute or relative contraindications to MRI (as detailed in the above document):

1) The ordering physician must discuss the case with the interpreting staff radiologist with analysis of risks versus benefits. Alternative methods of achieving diagnosis must be discussed.

2) The patient must sign a consent form that includes the risk of death. In the setting of an incapacitated patient, a two physician emergency consent is required.

3) A staff radiologist must approve the MRI prior the examination being performed. The staff radiologist must document approval in the radiology dictation.

4) In the setting of intraorbital radio-opaque foreign body (FB):

    a) Ophthalmology consultation is required for analysis of FB material and FB

debulking prior to MRI.

b) The patient should be consented for risk of blindness and death.

RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS:

Safety risks from RF include potential tissue heating and burns to the patients. RF may damage electronic or implanted medical devices. Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Therefore, all conducting material not in use should be removed from the magnet bore.

Cables, wires and other accessories should be inspected regularly by the scanner operators and researchers to ensure insulation, connectors and other components are intact and functioning safely. Researchers aware of malfunctioning or broken equipment should report the item to the scanner operator.

- ***Thermal Stress***
    - Any rise in body temperature can be a hazard to patients with reduced thermo regulatory capacity due to pre-existing conditions such as cardiac impairment that results in reduced circulatory function, fever, or an impaired ability to perspire. Patients with these conditions must be carefully monitored at all times and ambient conditions in the scanning room must be strictly maintained. Insure that the magnet room temperature is at 68-74 degrees F. The heat produced must be dissipated by the body's metabolic system.
    - Care must be taken to record the proper patient weight to insure that the Specific Absorption Rate (SAR) of the RF power does not exceed the permitted level.
- ***Tissue Heating and Burns***
    - Dental hardware
        - Most dental hardware is generally safe in the MRI environment although some orthodontic components may be ferromagnetic.
    - Tattoos
        - RF heating of tattooed tissue has been reported especially with use of iron oxide containing inks. The patient should be informed of the potential for heating or burns and instructed to alert the scanner operator immediately if warming occurs.
    - Transdermal Medication Patches
        - There are currently many different types of medication patches in use. Some of which may contain a metallic component. The metallic component from a transdermal medication

patch may cause excessive heating and burn a patient undergoing an MRI procedure. It is important that any patient wearing a transdermal patch that has a metallic component be identified prior to undergoing an MRI scan.

- The Institute for Safe Medical Practices recently stated that medication patches such as Androderm, Deponit, Habitrol, Transderm-Nitro, Nicoderm, Nicotrol, and Catapres-TTS be removed prior to the MRI. In recognition that manufacturers delete and add to their product lines the aforementioned list may change accordingly. *

- All patients will be screened for Medication Patches prior to an MRI procedure.

    - Inpatients

        - The MRI Inpatient Safety Screening Form will be completed in Sunrise prior to transport of patient to MRI. The radiology nurse and/or MRI technologist will review the form for information regarding the use of medication patches as well as any other safety concerns and then modify the screening form indicating form was reviewed and patient is cleared for exam.

        - The inpatient's nurse will be notified to remove the medication patch prior to patient transport to radiology.

    - Outpatients

        - The MRI Outpatient Safety Screening Form will be completed upon patient arrival and prior to being scanned. The MRI safety form will be checked for any MRI contra-indicated items.

        - The outpatient will be asked to remove any medication patches, if necessary.

        - The outpatient will be responsible for replacing the removed patch after the MRI.

- Coils

    - Coils are the devices that transmit and receive the RF signals and can be produced in a variety of configurations. The **individual** must have some basic knowledge of coil technology to properly conduct the MRI scan. Safety issues can occur as follows:

        - Transmitting RF energy through a receive-only coil may damage or ruin the device.

        - Transmitting more RF power than the coil was designed to manage, can damage or ruin the device.

- Twisting, looping or crossing cables may cause current to be induced, resulting in damaging the coil, abnormal heating or potential arcing.

- Additional Burn Prevention Measures

  - No body surface or cables should touch the magnet bore.
  - No cables or leads should cross a metal prosthesis.
  - The patient will be reminded not to cross their legs.
  - The patient will be positioned so that there is not finger/hand/to skin contact.
  - Sheets and padding will be used to protect skin.
    - Sheets and padding are to be used with caution as to not promote an increase in body heat during the MRI.
  - The MRI will be stopped if the patient complains of an increased sensation of warmth or burning.
  - Electrical discharges/arching between conductive devices with points or edges and the MRI coils can panic and electrically burn a patient. Avoid placing any metal objects (e.g. limb braces, traction mechanism, stereo tactic devices that are not MR compatible, etc.) into the MRI magnet to help avoid such injuries.
  - Incontinent patients will be cleaned and dried prior to being placed into the magnet.
  - Patients will be instructed to remove body oils.
  - Sliding boards are not to be taken into the magnet and will be removed after use.
  - Everyone will be screened through the Ferromagnetic detector. If the ferrous metal detector alarms, that person will not be allowed in to the MRI room until cleared by the Technologist.

INFECTION CONTROL/MEDICAL WASTE:

All MR personnel will follow the guidelines outlined in the UT Health RGV Infection Control Manual located on the Infection Control Website for UHS. Incidental personnel such as housekeeping must screened to enter Zone III and Zone IV. All MR surfaces should be designed to assist with ease of cleaning for infection control purposes. All MR personnel should follow the medical waste management policy entitled Environment of Care Hazardous Materials and Waste Management Plan.

PEDIATRIC PATIENT MONITORING & SEDATION:

Children often require sedation for MRI, largely because of their inability to remain motionless during scans. All sedation protocols will comply with the TJC, American Academy of Pediatrics, and American Society of Anesthesiologists. Special attention will be provided if need for monitoring body temperature and other vital signs within the MR suite.

PATIENT SAFETY PROCEDURES:

All technologists will perform the following prior to the MR exam:

- Verify the patient information through the time-out procedure or wristband prior to all exams.
- Confirm that the imaging site and positioning is correct for patients prior to each MRI exam.

All technologists will perform the following during the MR exam:

- Maintain communication with the patient when necessary or possible to help minimize stress and support patient safety. The communication is performed through a two-way aural system or intercom.

REPORTING REQUIREMENTS - SAFETY:

Mandatory MRI safety training is required for individuals who work within the magnetic environment. Any events or occurrences that may compromise the safety of the individuals or patients working in or near the magnetic environment need to be reported and addressed.

- ***Accidents, Injuries and Incidents***
    - Any accidents causing injury to an individual or patient must be reported to the MRI Medical Director by the individual conducting the scan.

      The Food and Drug Administration (FDA) requires facilities to report deaths and serious injuries associated with the use of medical devices. If an employee suspects that a reportable adverse event has occurred involving a patient with an implanted device that has undergone an MRI procedure, it should be promptly reported to the MRI Medical Director. Mandatory reports are made using Form FDA 3500A Mandatory Reporting Form. You can download the mandatory form as a fillable PDF document at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm, which also has mailing instructions. (At this time, FDA does not have a 3500A form that can be filled out and submitted on-line).

- ***Equipment Damage or Failure***

- Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and patients. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Equipment problems should be reported as soon as reasonably possible to the scanner operator.

- ***Facility Safety Breach***

  - A facility safety breach presents a risk to individuals, researchers and patients. Examples of a facility safety breach are failed access points allowing non-trained or non-escorted individuals into the magnetic environment.

  - Open access to the magnetic environment must be addressed immediately to prevent serious injury to individuals or equipment. Other potential safety breaches include: flooding, electrical hazards and obvious structural faults. Individuals should report any breaches to the scanner operator on duty. The scanner operator should report the safety breach to the Medical MRI Director as soon as reasonably possible.

***EMERGENCY PROCEDURES*:**

- ***Written emergency procedures***

  - Written emergency procedures, applicable to the specific MRI device in use, should be made available in the areas where MRI devices are used.

  - All MRI users shall familiarize themselves with these emergency procedures.

- ***Medical attention***

  - MRI Practitioners and/or Technical Staff shall immediately seek appropriate medical attention for any individual injured within the MRI environment.

  - The emergency team must report outside the appropriate MRI scanner room to begin treatment for the patient.

    - Crash carts and other emergency equipment containing ferromagnetic material **must not** be brought into the scanning room.

    - An MRI safe approved stretcher or dockable scanning table must be available at all times near the MRI scanning room.

  - Patients requiring CPR will be removed from the scan room.

  - CPR should be performed in an MRI safe area (i.e. patient holding area) by qualified healthcare professionals.

- During any CPR event, the MR scan rooms will be secured to avoid and prevent any potential safety hazard from occurring.

- ***Emergency Stop***

  - If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the scanner operator or designee should immediately perform an emergency stop.

- ***Magnet Emergency***

  - If it is necessary to drain (quench) the magnetic field immediately (e.g. in the case of fire, or a person pinned to the magnet), pull the emergency magnet shut-off switch located on the magnet safety panel. Pulling the emergency switch quenches the magnet and causes the field to collapse within approximately 10 seconds. This should only be done in a severe emergency.

  - Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

  - If there is an exhaust vent failure during an MRI magnet quench procedure please refer to the policy in the Appendices.

- ***Ferrous Object in Magnet***

  - DO NOT attempt to remove the ferrous object from the magnet. Call the manufacturer and have the service provider remove the object safely from the magnet. Follow the notification events related to anomalous events below.

- ***Notification of injury or death***

  - Any UT Health RGV faculty, staff or student who becomes aware of an incident resulting in the injury or death of an individual caused by a MRI device shall immediately notify the MRI Medical Director.

- ***Notification of anomalous events (near misses)***

  - Any UT Health RGV faculty, staff or student who becomes aware of an event that **could have** resulted in the injury or death of an individual caused by an MRI device shall notify the MRI Medical Director within 24 hours of becoming aware of the event. An incident report will be documented in the University Hospital's Midas database. All near misses will be reviewed for process improvement by the UHS MRI quality improvement committee.

REFERENCE/BIBLIOGRAPHY:

Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2015 Edition. Shellock, Frank G., Ph.D.

MRIsafety.com

ACR Manual on Contrast Media: 2015

ACR Guidance Document on MR Safe Practices: 2013

Institute of Safe Medication Practices

Facility name and city: _____

Date of examination: _____

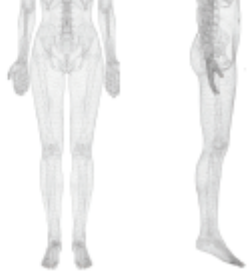
Body part imaging: _____ Reason for examination: _____

- ☐ Yes ☐ No Surgery or medical procedure of any kind

If yes, list all prior surgeries and approximate dates: _____

_____

_____



Reference/Source: Kanal's MagnetVision™ app, 2020.

Safety Screening Form for Magnetic Resonance (MR) Procedures

UT Health Rio Grande Valley

Date: _____

Name (first, middle, last): _____

Gender: ☐ Male ☐ Female Age: _____ Date of Birth: _____

Height: _____ Weight: _____

If uncertain of any answer below, please circle and leave blank to discuss with the technologist.

Why are you having this examination (medical problem)?

_____

List current medications:

☐ None

☐ _____

_____

List all allergies:

☐ None

☐ _____

_____

Date of last menstrual period _____

☐ Yes ☐ No Is there a possibility that you are pregnant?

☐ Yes ☐ No Are you post-menopausal?

☐ Yes ☐ No Are you breast feeding?

Please indicate if you have or have not had any of the following:

- ☐ Yes ☐ No Previous MRI examination

Facility name and city: _____

Date of examination: _____

Body part imaging: _____ Reason for examination: _____

- ☐ Yes ☐ No Surgery or medical procedure of any kind

If yes, list all prior surgeries and approximate dates: _____

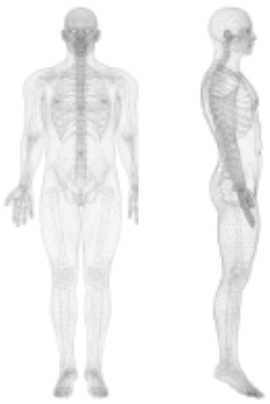
_____

_____

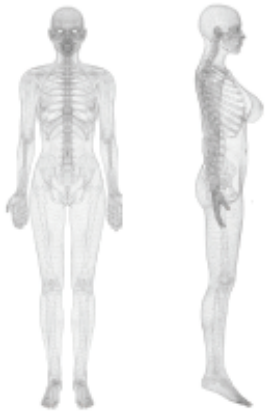
MR Hazard Checklist

Please mark the location of any implant, device or metallic foreign body inside your body or site of surgical operation.

Male:



Female:



Reference/Source: Kanal's MagnetVision™ app, 2020.

Safety Screening for Magnetic Resonance (MR) Procedures

- ☐ Yes ☐ No Injury by a metal object or foreign body (e.g., bullet, BB, shrapnel)
  If yes, explain: _____
- ☐ Yes ☐ No Injury to your eye from a metal object
  ☐ Yes ☐ No If yes, did you see medical assistance?
  If yes, describe what was found: _____
- ☐ Yes ☐ No Foreign body removed from eye
  If yes, describe what was taken out: _____
- ☐ Yes ☐ No Asthma or other allergic respiratory disease
- ☐ Yes ☐ No Kidney disease
- ☐ Yes ☐ No Diabetes
- ☐ Yes ☐ No Hypertension
- ☐ Yes ☐ No Previously received contrast agent (dye) for a CT, MRI or other X-ray or study
- ☐ Yes ☐ No Allergic reaction to CT, MRI, X-ray contrast agent (dye)
  If yes, explain: _____
- ☐ Yes ☐ No Spinal fusion procedure
- ☐ Yes ☐ No Endoscopy or colonoscopy in last three months

The following items may be harmful to you during your MR scan and may interfere with the MR examination. You must provide a "Yes" or "No" answer for every item.

Please indicate if you CURRENTLY HAVE or HAVE EVER HAD any of the following:

Surgically implanted medical devices

- ☐ Yes ☐ No Any type of electronic, mechanical or magnetic implant
  If yes, list type: _____
- ☐ Yes ☐ No Cardiac pacemaker, defibrillator or other cardiac implant (in place or removed)
- ☐ Yes ☐ No Aneurysm Clip
- ☐ Yes ☐ No Neurostimulator, diaphragmatic stimulator, deep brain stimulator, vagus nerve stimulator, bone growth stimulator, spinal cord stimulator, or any biostimulator (in-place or removed)
  If yes, list type: _____
- ☐ Yes ☐ No Any type of internal electrodes or wires
- ☐ Yes ☐ No Cochlear implant
- ☐ Yes ☐ No Implanted drug pump (e.g., insulin, baclofen, chemotherapy, pain medicine)

Safety Screening for Magnetic Resonance (MR) Procedures

- ☐ Yes ☐ No Spinal fixation device
- ☐ Yes ☐ No Any type of coil, filter or stent

  If yes, list type: _____
- ☐ Yes ☐ No Artificial heart valve
- ☐ Yes ☐ No Any type of ear implant
- ☐ Yes ☐ No Penile implant
- ☐ Yes ☐ No Artificial eye
- ☐ Yes ☐ No Eyelid spring and/or eyelid weight
- ☐ Yes ☐ No Any type of implant held in place by a magnet
- ☐ Yes ☐ No Any type of surgical clip or staple
- ☐ Yes ☐ No Any IV access port (e.g., Broviac, Port-a-Cath, Hickman, PICC line)
- ☐ Yes ☐ No Shunt

  If yes, type: _____
- ☐ Yes ☐ No Artificial limb

  If yes, what and where: _____
- ☐ Yes ☐ No Tissue Expander (e.g., breast)
- ☐ Yes ☐ No IUD

  If yes, type: _____
- ☐ Yes ☐ No Surgical mesh

  If yes, location: _____
- ☐ Yes ☐ No Radiation seeds
- ☐ Yes ☐ No Any implanted items (e.g., pins, rods, screws, nails, plates, wires)

Removable medical devices

- ☐ Yes ☐ No Hearing aid
- ☐ Yes ☐ No Removable drug pump (e.g., insulin, Baclofen, Neulasta)
- ☐ Yes ☐ No Any type of ear implant
- ☐ Yes ☐ No Artificial eye
- ☐ Yes ☐ No Any type of implant held in place by a magnet
- ☐ Yes ☐ No Any type of surgical clip or staple
- ☐ Yes ☐ No Medication patch (e.g., nitroglycerine, nicotine)
- ☐ Yes ☐ No Artificial limb

Safety Screening for Magnetic Resonance (MR) Procedures

If yes, what and where: _____

- ☐ Yes ☐ No Removable dentures, false teeth or partial plate
- ☐ Yes ☐ No Diaphragm, pessary

If yes, type: _____

- ☐ Yes ☐ No Have you recently ingested a "pill cam?"

If yes, date "pill cam" was ingested: _____

Personal

- ☐ Yes ☐ No Body piercings

If yes, location: _____

- ☐ Yes ☐ No Wig, hair implants
- ☐ Yes ☐ No Tattoos or tattooed liner
- ☐ Yes ☐ No Any hair accessories (e.g., bobby pins, barrettes, clips, extensions, weaves)
- ☐ Yes ☐ No Jewelry
- ☐ Yes ☐ No Metal-containing clothing material and/or underwear
- ☐ Yes ☐ No Magnetic cosmetics and hair care (e.g., magnetic eyelashes, magnetic nail polish)
- ☐ Yes ☐ No Electronic monitoring or tagging equipment (e.g., ankle monitor)
- ☐ Yes ☐ No Fitness tracker/biomonitor (e.g., Fitbit)

☐ Yes ☐ No Any other type of surgically implanted medical devices, removable medical devices or personal items not covered above?

If yes, type: _____

Instructions for Patients

1. You will be provided hearing protection during your scan. You are strongly urged to use the earplugs or headphones provided to you during your MR examination, since some patients find the noise levels unacceptable, and the noise levels may affect your hearing if these provided hearing protection devices are not utilized.
2. Remove all jewelry and piercings (e.g., necklaces, pins, rings)
3. Remove all body piercings
4. Remove all hair pins, bobby pins, barrettes, clips, etc.
5. Remove all dentures, false teeth, partial dental plates
6. Remove eyeglasses and hearing aids
7. Remove watches, cell phones and pagers
8. Remove all cards with magnetic strips (e.g., credit cards, bank cards, etc.)
9. Because some clothing may contain metal even when not apparent, the MR technologist will instruct you to remove all clothing and worn/removable items from your body. MR Safe clothing will be provided to you to wear during your MRI scan. This is being done to help ensure your safety during the examination.
10. If you are unable to remove any of the above items please notify the technologist.

I have read and understand the entire content of this form.

Patient signature: _____

MD/RN/RT signature: _____

MD/RN/RT printed name: _____

Date: _____

Safety Screening for Magnetic Resonance (MR) Procedures

FOR MR Office Use Only

Patient name: _____ Patient ID # _____

Referring Physician: _____

Procedure: _____ Diagnosis: _____

Clinical History: _____

Hazard Checklist for Level 2 MR Personnel

- ☐ Yes ☐ No Pulse oximetry device
- ☐ Yes ☐ No EKG pads/leads
- ☐ Yes ☐ No Endotracheal tube
- ☐ Yes ☐ No Swan-Ganz catheter
- ☐ Yes ☐ No Extra ventricular device
- ☐ Yes ☐ No Arterial line transducer
- ☐ Yes ☐ No Foley catheter with temperature sensor and/or metal clamp
- ☐ Yes ☐ No Rectal probe
- ☐ Yes ☐ No Esophageal Probe
- ☐ Yes ☐ No Tracheotomy tube
- ☐ Yes ☐ No Guidewires
- ☐ Yes ☐ No Halo vest
- ☐ Yes ☐ No Other

If yes, explain: _____

_____

If any Level 2 MR Personnel checklist items are answered yes, this should be brought to the attention to the covering MR Physician.

- ☐ Yes ☐ No Patient screened with ferromagnetic detector
- ☐ Yes ☐ No eGFR indicated for contrast

eGFR value: _____ Results date: _____

- ☐ Yes ☐ No If required, the patient was provided the Medication Guide

Cleared by:

MR Technologist: _____

Physician/Radiologist (if required) _____

05.20

SECTION III : EXHAUST VENT FAILURE DURING AN MRI MAGNET QUENCH PROCEDURE

PURPOSE:

The purpose of this policy is to establish safe guidelines.

POLICY STATEMENT:

The Department of Radiology is committed to the safety of patients and employees and therefore has established the following guidelines for maintaining safety, for the surveillance of safety issues, and staying abreast of the latest technology safety trends.

POLICY ELABORATION:

I. Overview – The cryogen vapors should vent outside the building in the event of a magnet quench. If there is a vent failure, a sudden release of vapor from the magnet into the scan room can cause asphyxiation, frostbite, or injuries due to panic. The MRI department has established specific guidelines to be followed should such a situation occur and thus avoid injury to the patient and/or the MRI personnel.

The MRI department personnel will be well acquainted with the following steps and use them as a guideline in case of an exhaust vent failure. WARNING: Helium vapor looks like steam, but is very cold. It is odorless and tasteless, breathing significant quantities will cause the voice to rise in pitch. Prolonged exposure to helium vapor could result in asphyxiation or frostbite.

II. Procedures

A. Employee Guidelines

1. Technical Staff
   a. DO NOT PANIC. Stay calm and follow procedure.
   b. Using the intercom, ask the patient to stay calm and remain on the table. Inform them that you will be shortly to offer assistance.
   c. Immediately phone for assistance.
   d. Prop open the door to the scan room.
   e. Evacuate patient from scan room.
   f. Evacuate area for at least 20 minutes.
   g. Call the MRI scanner service engineers
   h. If helium is venting into the scan room, the room might pressurize and the door might not open. Try opening the scan room door several times. After opening door, enter scan room through door and evacuate patient.
   i. If the door cannot be opened after 45 seconds, break window to relieve the room pressure. Remember if you break the window, the pressure form within the room will cause the glass shards to fly outwards and could cause injury. Break the window by tossing a chair into the window and being out of the path of flying glass.
   j. Attend to patient and seek medical assistance as required.

References / Bibliography –

Joint Commission Accreditation for Hospital DR 2.2.1 (#31 CRYO1-2) Dm 2006

SECTION III : UT Health RGV"Diagnostic Radiology Department / MRI Division" Policy in Relation to Nephrogenic Systemic Fibrosis *(NSF)* / Nephrogenic Fibrosing Dermopathy *(NFD)*

PURPOSE:

The purpose of this policy is to establish safe guidelines in concordance with the ***FDA*** and ***ACR*** recommendations. These guidelines will be used for the proper care for all patients with acute and/or chronic moderate to severe renal insufficiency ***(RI)*** and end stage renal disease ***(ESRD)*** on dialysis that require gadolinium ***(Gd.)*** Enhanced MRI/MRA study.

POLICY STATEMENT:

The Department of Radiology is committed to the safety of patients and employees and therefore has established the following guidelines for maintaining safety, for the surveillance of safety issues, and staying abreast of the latest technology safety trends.

POLICY ELABORATION:

I. **Background**: The FDA has issued a ***Health Safety Alert*** concerning a possible link between contrast agents chelated with Gd. and the new disease "NSF/NFD" that occurs in patients with ESRD on dialysis and in patients with acute and/or chronic moderate to severe RI after receiving GC. Enhanced MRI/MRA study.

II. **Definition of NSF /NFD**: An uncommon condition that causes the excessive formation of connective tissue in the skin and internal organs. The skin becomes thickened, coarse and hard, sometimes leading to debilitating contractures. It can be progressive and in some instances fatal secondary to multi organ failure.

III. **Signs and Symptoms of NSF / NFD**:

A. Eyes - yellow spots on the white of the eyes.

B. Skin
   1. Swelling, hardening and tightening of the skin.
   2. Reddened or darkened patches on the skin.
   3. Burning or itching of the skin.

C. Bones and Muscles
   1. Stiffness in the joints; problems moving or straightening the arms, hands legs or feet.

IV. **Recommendations for Health Care Professionals**:

A. Gadolinium is administered as a weight-based dose based on Radiologist protocol. The recommended amount is not exceeded. All Gd. doses are recorded in the patient's medical record with the name of the contrast agent and the exact amount administered.

B. **For all patients presenting for an MRI/MRA exam** - All patients presenting for an MRI/MRA

with Gd., will be asked to fill out the MRI Screening Form and Contrast Questionnaire. This will help us accurately identify those patients with or at risk for renal disease and take the appropriate safety measures.

C. **For all patients presenting for an MRI/MRA exam** – All patients presenting for a Gd. enhanced MRI/MRA and are **> 55 years old**; will require a current creatinine level to be available on the day of the exam. The creatinine level should ***not be older than 30 days***. If a current creatinine level is not available, an i-STAT creatinine will be obtained. Accordingly, eGFR (glomerular filtration rate) will be calculated using a tool based on the modification of diet in renal disease 4 (MDRD4) revised equation.

D. **For all patients presenting for an MRI/MRA exam** - All patients presenting for a Gd. enhanced MRI/MRA and are ***< 55 years old but associated with a risk factor such as, hypertension, diabetes , acute kidney injury, etc.,*** will also require a current creatinine level or i-STAT creatinine to be available on the day of the exam. An eGFR will be calculated using a tool as described above.

E. For all patients presenting for an MRI/MRA exam – The Radiologist will be contacted for all patients with an eGFR ≤ 30 ml/min to determine if contrast will be used, ACR eGFR < 40 as above "fluctuation in eGFR. If contrast is to be given, the patient should be consented by the Radiologist for the risk of acquiring NSF/NFD, ACR Manual (pg.86) "lowest dose possible" avoid re-administration.

F. For all patients with moderate to severe RI and ESRD on dialysis –

1. Radiologist (Staff, Fellow or Resident) to confirm if Gd. enhanced MRI/MRA is indicated or necessary.

2. Although there are no published data to establish/determine the utility of dialysis to prevent NSF/NFD in ESRD patients that are on dialysis; we still recommend performing prompt dialysis ***(within 2 hours***) following any Gd. enhanced MRI/MRA study to reduce the patient's Gd. body burden. Scheduling the dialysis session should be a joint effort between the ordering physician, the dialysis unit, and the radiology department when needed.
3. Further information can be found by following the provided link to the FDA Website at http://www.fda.gov/Drugs/DrugSafety/ucm223966.htm

V. **<u>Radiology Department Employee Responsibility</u>**:

A. Scheduling Staff / LVN Facilitator

1. The patient or the ordering medical personnel should be asked if the patient is on renal dialysis. If the answer is yes, the request will be forwarded to the LVN facilitator. A note will be placed in the RIS that the patient is on dialysis.

2. The LVN facilitator will contact the patient's nephrologist to determine that the patient can receive contrast. The facilitator will then coordinate the patient's exam with their dialysis

schedule so that the patient can be dialyzed within 2 hours of their exam.

B. Technologist / Nurse
   1. Check if the patient has ESPD and is on dialysis.

   2. If patient is on dialysis, verify that the patient had been consented by the Radiologist and is scheduled to be dialyzed within 2 hours after the exam or as per the nephrologist's orders.

   3. If dialysis has not been arranged within the appropriate time frame, the patient should be rescheduled.

   4. For patients meeting the screening criteria, check for a current creatinine (within the last 30 days) or perform an i-STAT creatinine point of care test. The eGFR is then calculated.

   5. If the eGFR is ≤ 30, the radiologist will be contacted to determine if contrast will be used. If contrast is to be given, the patient should be consented by the Radiologist for the risk of acquiring NSF/NFD.

   6. If the patient > 55 years old or < 55 years old but has associated risk factors for renal disease, a current serum creatinine level of i-STAT creatinine is used in order to calculate the eGFR.