NEW YORK INSTITUTE OF TECHNOLOGY

College of Osteopathic Medicine

MRI Policy And Procedure Manual

TITLE: MAGNETIC RESONANCE IMAGING SAFETY

PURPOSE:

Provide a safe environment for patients and staff. To establish and execute a policy to educate employees on MRI safety. This policy will provide a safer environment not only for employees, but patients as well, in the MRI area.

Contents:

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KEY STAFF:

MRI Medical Director (MRMD):

The MRMD is responsible for establishing and/or reviewing MR safety policies and guidelines for the site and overseeing all decisions regarding MR safety. The MRMD is ultimately responsible for the safety of the patient and research subject.

The MRMD is Dr. Gabriel J. Gelves, D. O.

MRI Safety Officer (MRSO):

The MRSO is charged with executing the MR safety practices as defined/ordered for the site by the MRMD/MR Physician.

The MRSO is: TBD

MRI Safety Expert (MRSE):

The MRSE serves as a resource for the MRMD and/or MRSO to provide advanced guidance, information, calculations and quantification information, etc. regarding all matters pertaining to MR safety.

The MRSE is Jonathan P. Dyke, Ph.D., DABMP (MRI)

I. Definitions

MR Safe

Poses no known hazards in any MRI environment. "MR Safe" items are non-conducting, non-metallic, and non-magnetic items (e.g. plastic tubing).

MR Conditional

May safely enter the MRI environment under specific conditions (e.g. static and time varying magnetic field strengths, gradient slew rates, and radiofrequency absorption rates).

Non-MR Conditional

An item that has not received FDA approval for conditional use in the MR environment.

MR Unsafe

Poses hazards in all MRI environments (e.g. ferromagnetic scissors).

II. Site Access Restrictions (MRI Zones)

MRI facilities follow the safety zones outlined by the American College of Radiology (ACR). These are classified into four regions:

Zone I

Areas that are freely accessible to the public without supervision.

1. Unrestricted access.

Zone II
Interface between the unregulated Zone I and the strictly controlled Zones III and IV.

1. This area is where patients are greeted, registered and screened.

2. Zone II access is not restricted.

Zone III
Areas that are strictly restricted to the general public (e.g. by lock, key, card access or passcode). Only individuals who are screened may enter this Zone and all individuals entering this Zone must be under the supervision of an MRI personnel.

Zone IV (MRI Scanner Room)
Doors to the magnet room must be locked when unattended. Patients entering this Zone must be accompanied by a level 2 MR personnel (see Section IV). MR technologists must be able to directly observe and control (e.g. via video monitors or line of sight) the entrances or access to Zone IV from their normal positions when seated at the scanner console. Zone IV should also be marked with signage indicating the presence (and hazards) of a very strong magnetic field.

See figure 1

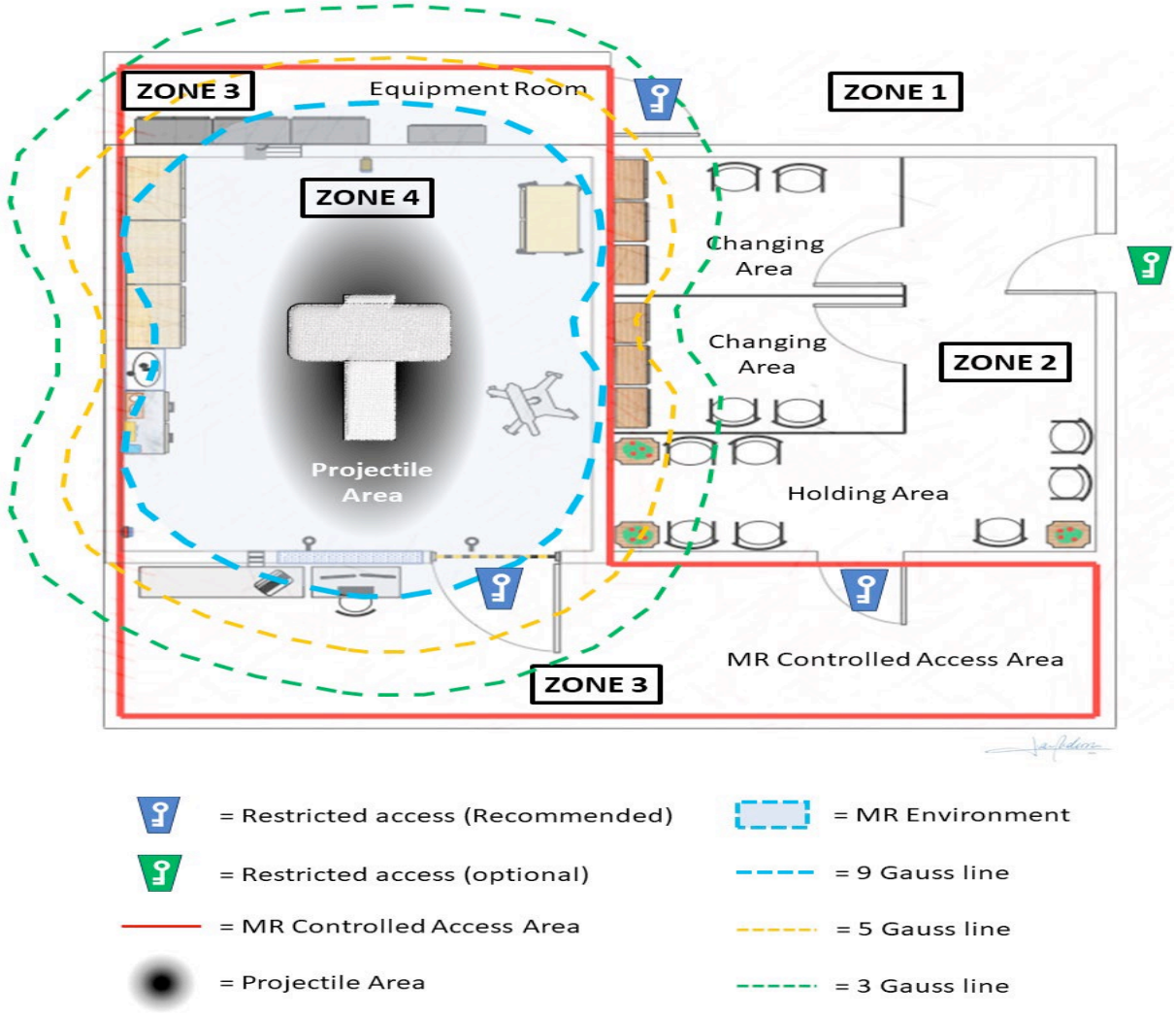

FIGURE 1. Illustrated example layout of an MR facility. This is adapted from Figure 1 in the Medicine and Healthcare
products Regulatory Agency Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use [1]. Note
depictions of "MR Controlled Access Area," "MR Environment," and "Projectile Area" as they relate to the 4-zone
model**.**

MRI Policy And Procedure Manual

MRI Safety Training

All employees working in and around the MR environment must complete annual MRI safety training. New employees are trained during orientation where the MR supervisor (or designee) presents the MR safety information and responds to questions. All annual MRI safety training refreshers are taken and documented online. During the orientation process, a video on MRI safety will be shown to all MR personnel, as well as a lecture presented afterwards. (Inclusive to Non-MR Personnel, Level 1 MR Personnel, & Level 2 Personnel). Based on the training, MR personnel are categorized as either:

Level 1 MR Personnel
Individuals who have successfully completed the basic MRI safety training to ensure their own safety when working around the MR environment (e.g. custodial staff, police).

Level 2 MR Personnel
Individuals who have successfully completed advanced MRI safety training to ensure their own safety and the safety of others when around the MR environment (e.g. MRMD, MRSO, radiologists, MR technologists, physicists).

III. Patient and Non-MR Personnel Screening

Pre-screening
MRI personnel scheduling or confirming outpatient MRI appointments will determine if the patient has any known contraindications to MRI or gadolinium-based contrast. The electronic medical ordering system screens for contraindications when the MRI is ordered.

Screening of Patients
Patients are identified upon check-in at the reception/registration desk. All adult patients must present a form of identification. A parent or legal guardian must accompany and present a form of identification for pediatric patients. Patients will be given an MRI screening form/questionnaire which is used to query the possibility of pregnancy, the patient's medical history, presence of foreign bodies, and the presence of medical implants (e.g. pacemakers, aneurysm clips, insulin pumps). The questionnaire must be completed by the patient prior to having the MRI examination. If the patient is unable to complete the questionnaire, it can be completed by a health care provider or patient representative familiar with the patient's medical history. If a reliable history cannot be obtained or if there are uncertainties, a low-dose whole body CT scout film or radiographs that include the head, neck, chest, abdomen, and pelvis must be ordered by the referring healthcare provider. Images must be reviewed by a radiologist to assess for any findings that would contraindicate MRI. Prior imaging may need to be repeated at the discretion of the radiologist as there may have been interval change in findings.

Reports of imaging alone (such as exams performed at an outside facility) are not sufficient; the images must be available for review by the radiologist. Completed MRI safety questionnaires will be reviewed and signed by the MRI nurse and/or technologist and the form added to the electronic medical record.

Screening of Visitors or Non-MR Personnel

Only patients and MRI personnel should be present in Zones III and IV. Persons accompanying the patient should wait in Zones I or II. At the discretion of the MRI technologist and/or radiologist, a patient's family member or companion may be allowed in Zones III and IV to provide support. These individuals must complete an MRI screening form (as stated above) and the form should be reviewed by the MRI technologist and incorporated into the medical record of the patient.

Any responses raising concern are reviewed by the nurse and or MRI technologist and clarified with the person who filled out the form.

Device and object screening

- All individuals entering the scanner room must remove all readily removable metallic objects (e.g. watches, cell phones, body piercings).
- Patients should be gowned before entering zone IV to ensure no unscreened objects inadvertently enter the scanner room.
- As part of the Zone III site restriction, all unknown devices entering Zones III and IV must be tested with a ferromagnetic detector.
- Devices/objects that are ferromagnetic, non-MR Safe or non-MR Conditional may still be brought into Zone IV if deemed necessary and appropriate for patient care. These devices/objects must be appropriately secured at all times.
- Never assume MR safety information about an object/device if it is not clearly documented in writing.
- A prior MRI examination with an implanted device at a given magnetic field strength is not sufficient evidence and will not be relied upon to determine status of MRI safety.
- Final decision to scan a patient with an implant/device/foreign body lies with the MRMD.

A list of common devices, along with their safety status, can be found in Appendix A. Please note that data is frequently being updated so consult with m risafety.com, individual manufacturer guidelines, and/or device cards. If there are any questions or concerns, please consult the MRMD or MRSO.

Please see Appendix H for MRI screening Protocol.

Designation of MR safety status

- Users should refer to the manufacturer for advice on the MR safety of implants if there are any questions. The following website should be an additional resource: http://www.mrisafety.com.
- Devices should never be assumed MRI safe/conditional unless documented.

When in doubt, assume the device is MRI Unsafe and assess risks and benefits of proceeding.

- All unknown devices entering Zone II must be tested with a ferromagnetic detector. Any devices beyond those stated conditionally safe in Appendix A must, in addition, have a written approval from the MRI safety. If a device is brought into these areas without approval, the MRI manager should be notified.
- All metallic objects entering Zone IV must be identified and labeled using the current FDA labeling criteria in standard ASTM F2503 (http://www.astm.org).
    - Items which are clearly ferromagnetic should be labeled with a red label indicating "MRI Unsafe."
    - Items which are nonmetallic should be identified with a square green "MRI Safe" label.
    - Items that are MRI conditional should be labeled with a triangular yellow "MRI Conditional" label.
    -

MRI Safe

MRI Conditional

MRI Unsafe

    - MRI conditional physiologic monitoring systems should be available in the scanner room to monitor unstable, sedated, or anesthetized patients during the MRI procedure. Other patient monitoring or anesthesia equipment may not be allowed in the scanning room unless it is proven to be "MR Safe" or "MR Conditional."

IV. Pregnancy

Pregnant Employees

Static magnetic fields are not associated with detrimental effects on the developing embryo or fetus. Therefore, pregnant employees are permitted to work in and around the MRI environment during all stages of their pregnancy. However, it is recommended that pregnant employees do not remain in the scanner room during scanning.

Pregnant Patients

The MRI safety questionnaire includes screening items for pregnancy. Since there is no documented evidence of deleterious effects of MRI on the developing fetus, pregnant patients may undergo an MRI examination. However, a pregnancy test is available for any female of child bearing age upon request or for those that are

uncertain about pregnancy status. The radiologist should be made aware of any pregnant patient undergoing MRI.

Pregnancy and Gadolinium-based Contrast Agents
Gadolinium-based contrast agents (GBCAs) are contraindicated during pregnancy (see Gadolinium products administration policy: Refer to NYIT Policy Appendix D.)

GBCAs can cross the placenta and have been identified in the amniotic fluid. Patients with a recent positive pregnancy test (e.g. urinary test, serum beta HCG) or who state they are pregnant should not be administered GBCAs without informed consent.

The radiologist should be notified immediately and will contact the ordering provider. The decision to administer GBCAs to a pregnant woman must be made by the radiologist in conjunction with the patient's health care provider after considering the risk and benefits and excluding the utility of a non-contrast MRI or alternative imaging modalities. If the patient has previously decided that she will seek termination of the pregnancy, that information must be documented.

In all cases where a pregnant woman undergoes MRI with GBCA administration the radiologist or the patient's health care provider must discuss with the patient the risks and benefits and a standard hospital informed consent procedure form should document the informed consent and signed by both parties.

V. Hazards in the MRI Environment

Static magnetic fields and fringe fields Biologic:
Patients undergoing MRI may experience transient vertigo, nausea, paresthesia (tingling in extremities), muscle twitching, magnetophosphenes, and/or metallic taste in the mouth. There are no known long term health effects at clinical magnetic field strengths.

Forces and torque:
Ferromagnetic objects experience attractive forces with the magnet and may become dangerous projectiles if allowed to accelerate towards the magnet. Ferromagnetic objects will experience strong torques to align themselves with magnetic fields. Implants may rotate and cause damage to surrounding tissue.

Lenz effects:
When conductors move through a magnetic field, Lenz forces oppose their movements. The forces may impair movement of conductive (including non-ferrous) implants. A stapes prosthesis may experience large forces opposing movement if a patient's head is moved very quickly.

Implantable devices:

Strong magnetic fields can disrupt the function of implanted medical devices. Shunts, pacemakers, and drug pumps may cease to function as intended.

Time-varying magnetic gradient fields

Peripheral nerve stimulation:

Fast gradient switching (dB/dt) can result in peripheral nerve or muscle stimulation, which may be uncomfortable but does not pose a health risk. There is a theoretical risk of cardiac stimulation, resulting in ventricular defibrillation, but this requires at least 20 times the energy required for peripheral nerve stimulation.

Acoustic Noise:

The loud 'knocking' noise from changing gradient magnetic fields during image acquisition may cause discomfort or temporary hearing loss. The MRI technologist will inform the patient about the various noises during the scan and offer hearing protection (e.g. earplugs and/or headphones) to all patients. All non-patients in the scanner room during image acquisition will also be offered hearing protection.

Radiofrequency (RF) fields

Heating:

RF fields in MR deposit significant energy in subjects that may lead to heat stress. Restrictions on RF exposure fields are used in MR to limit body core and organ specific temperature elevations.

Thermal burns:

Specific absorption rate (SAR), the RF power absorbed per unit mass, is used to estimate the potential for heating of the patient's tissues. MRI technologists will monitor SAR levels for each patient. For routine MRI procedures, scanning should be done in the normal operating mode. Specific MRI examinations outside the normal operating mode are termed controlled operating mode and must be performed only after appropriate consideration of the medical circumstances. MRI technologists should be familiar with the following:

- All electrical connections (e.g. monitoring devices, leads) must be physically checked prior to scanning to ensure integrity of the thermal and electrical insulation.
- All unnecessary electrically conductive materials external to the patient should be removed from the MR scanner prior to scanning.
- Looping wires, electrodes, leads, and touching limbs act like loop coils to absorb RF. Burns can occur at the contact points of these loops. Pads, pillows, and other non-conductive materials should be placed to prevent formation of these conductive loops.

- Care should be taken to ensure that the patient does not come directly in contact with the inside of the scanner bore. Pads should be placed between the patient and the inner bore.
- Straight wires can pose burn hazards. Wires close to the resonant length of 12 cm for 3 T and 24 cm for 1.5 T support the formation of induced standing waves which can absorb RF and lead to burns.
- Metallic materials preferentially absorb RF energy which may lead to burns. Metallic materials include threads and copper or silver-impregnated clothing; as such, patients are required to remove their own clothing and change into hospital-provided gowns if available.
- Please see Appendix G for RF burns policy.

Cryogen
Only trained service personnel may handle cryogens. During a refill, cryogens will be delivered and maintained in a secure area away from patient areas.

Contrast Agent Safety
Please refer to the policies on "Gadolinium Products: Administration" which can be found on: Appendix D

Sedated Patients
Adult and pediatric patient sedation, analgesia, and anesthesia for any reason should follow ACR, ASA, and TJC standards. In addition, sedation providers must comply with institutional protocol: Please see ACR–SIR Practice Parameter for Sedation and Analgesia ACR–SIR PRACTICE PARAMETER FOR MINIMAL AND/OR MODERATE SEDATION/ANALGESIA

Non-Responsive Patients
A risk benefit analysis must be conducted with the radiologist and referring clinician.

Patient Communication
Patients are provided hearing protection in Zone IV. Patients are given a squeeze ball which can be pressed to alert the technologist and nurse that they require immediate attention. Patients are instructed to squeeze the ball if they experience discomfort, pain, or have any concerns. Patients in Zone IV are also under direct visual and auditory (two-way microphone/speaker) observation by the technologist and/or nurse at all times.

Claustrophobia, Anxiety, and Emotional Distress
Techniques to alleviate patient claustrophobia, anxiety, and emotional distress include:

- Inform the patient about the MRI procedure (e.g. procedure, noise,

vibrations). Patients must never be asked to remain in the magnet if they are experiencing distress.

- If a patient expresses claustrophobia, they should be informed about sedation/anesthesia options. Screened personnel or companion may remain in the magnet room with the patient during the examination. If clinically feasible, the patient's feet should be positioned into the bore first. Maintain verbal and visual contact with the patient during the whole examination.

If at any time, the patient uses the squeeze ball or asks to stop the exam, the technologist will terminate/pause the scan immediately and assess the patient's concern.

VI. Emergencies

Medical Emergency

Adult and pediatric MRI compatible crash carts and emergency resuscitation equipment should be available in all MRI suites.
This equipment should be properly labeled and verified as "MRI Safe." MRI staff must be familiar with the location of the crash carts and be aware that while the cart itself may be MRI compatible, the contents may not be and the cart should not be brought into Zones III and IV. Patients requiring resuscitation must be moved from MRI Zone IV to Zone II in an area with monitoring equipment if possible. All cardiopulmonary arrest codes and resuscitation codes are run in Zone II or I.

Medical Emergency Procedures

1. Stay calm.
2. Enter the scan room and immediately remove the patient from the scan room.
3. The patient should be removed from Zone IV to a magnetically safe location.
4. All cardiopulmonary arrest and resuscitation codes are run in Zone II or Zone I.

Fire Emergency

Staff must be familiar with hospital emergency and disaster procedures including the location of exits and fire extinguishers and their use, and emergency phone numbers.

Fire Emergency Procedures

1. Stay calm.
2. Disable all electric power by pressing the emergency "off" button.
3. Enter the scan room and immediately remove the patient from the scan room.
4. Call the fire department.

5. Close all doors to the area to confine the fire.
6. Screen all personnel, including firefighters, for entry into restricted magnetic field areas.

Quench

A quench occurs when a superconducting magnet suddenly loses its field and the helium supply rapidly boils off. A quench can occur spontaneously (uncontrolled) or intentionally (controlled) by pushing the "magnet stop" button. A controlled quench should only be initiated by authorized personnel in the event of a potentially life-threatening emergency (e.g. individual in respiratory distress after being pinned to the magnet by a magnetic object). Under normal conditions, most of the helium will escape safely through the quench pipes to the outside air, and the quench presents no serious danger. In the event of blockage or failure of the venting system, some of the helium gas will vent into the scanner room. This is an emergency situation. Helium itself is colorless, odorless and tasteless. Helium vapor is extremely cold, and causes water condensation, which looks like steam. Prolonged exposure to helium vapor can result in asphyxiation or frostbite.

Quench Procedures (MR technologists and trained support staff):

1. Instruct the patient to remain calm.
2. Open all doors and secure the scan room door open.
3. Immediately remove the patient from the scan room.
4. If the scanner room door cannot be opened, that could indicate a pressure increase in the room due to improper helium venting. In the rare event that a person is trapped inside the scan room and the scan room door won't open, break the scanner room window to relieve the pressure.
5. Contact the following personnel:
    a. MR supervisor or manager
    b. Biomed or Philips service engineer
    c. Physicist
6. Evacuate the area for at least 20 minutes. The area must be cleared by facilities or scanner service personnel before reentry.
7. Complete a service report.

VII. Reporting Incidents

All MRI safety incidents (e.g. thermal burns reactions to contrast agent, patients introduced into the scanner with implanted devices that are not MRI safe) or "near incidents" will be reported immediately to the facility supervisor and medical director. All MRI centers use NYIT Policy and Procedure Manual Number: X Equipment Occurrences/Medical Devices. FDA reporting via Medwatch will be done In accordance with policy, which can be found on Appendix F.

Pediatric patients must be accompanied by a parent or legal guardian and the parent or legal guardian will be required to present a form of identification and review the standard screening form and act on behalf of the pediatric patient. The following should also be considered for pediatric patients:

- Pediatric patients should be gowned before entering Zone IV to minimize the possibility of metallic objects entering the scan room.
- Children may not be reliable historians and, especially for older children and teenagers, should be questioned both in the presence of parents or guardians and separately to maximize the possibility that all potential dangers are disclosed.
- Comfort items brought from home should be discouraged from entering the scan room.
- Special attention is needed in monitoring vital signs of pediatric patients.
- Pediatric sedation should follow the sedation guidelines developed by the American Academy of Pediatrics, the American Society of Anesthesiologists, and The Joint Commission on Accreditation of Healthcare Organizations. In addition, sedation providers must comply with institutional protocol.

IX. Infection Control and Medical Waste

The MRI technologists should routinely clean the scanner table, pads, coils, and inner bore to prevent transmission of inflections. The following infection control procedures will be followed:

- Gloves and other personal protective equipment are worn any time there is a risk of encountering blood or other bodily fluids. Gloves are also worn when working with a cleaning disinfectant.
- Hands are washed before and after every patient encounter, as well as before and after glove use.

- The scanner and any surface that comes into contact with patients must be thoroughly cleaned and disinfected before and after each patient exam. This includes the cleaning of any physiological monitoring equipment that comes into contact with patients.
- Proper drying time of the disinfectant is observed as per manufacturer's recommendation.

REFERENCES:

1. Kanal, E, Barkovich, AJ, Bell, C, Borgstede, JP, Bradley, WG, Froelich, JW, Gimbel, JR, Gosbee, JW, Kuhni-Kaminski, E, Larson, PA, Lester, JW, Nyenhuis, J, Schaefer, DJ, Sebek, EA, Weinreb, J, Wilkoff, BL, Woods, TO, Lucey, L, Hernandez, D (2013). ACR guidance document on MR safe practices: 2013.J Magn Reson Imaging, 37, 3:501-30
2. MR safety Website http://www.mrisafety.com
3. Frank Shellock, PhD. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2016 Edition
4. Woods TO. Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. Document issued on: December11,2014;http://www.fda.gov/downloads/MedicalDevices/DeviceRegulation and Guidance/Guidance Documents/ucm107708.pdf

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Appendix A: Devices and their Safety Status

MRI Unsafe

- CO_2 based breast expanders
- Gastric reflux device (LINX Reflux Management System)
- Harrington rods prior to 1960
- Implantable pediatric sternum device
- Insulin pumps
- Metallic foreign body in eye
- "Triggerfish" contact lens
- Temporary transvenous pacing leads
- Transdermal patch
  Generally considered MRI unsafe secondary to the presence of metallic components in medicinal patches. Heating of patches containing fentanyl may result in a serious overdose. Therefore, they should be removed and replaced after scanning if this can be done without affecting patient treatment.

MRI Conditionally Safe

- Coronary artery stents (including multiple/overlapping)
- Orthopedic joint implants
- Prosthetic heart valves
  MRI is not considered hazardous for patients with prosthetic heart valves or annuloplasty rings. The attractive forces exerted on the prostheses are small compared to the force exerted by the contracting heart. There have been no reports of injury from MRI performed in patients with heart valve prostheses or annuloplasty rings.

MRI Conditional

(https://radiology.ucsf.edu/patient-care/patient-safety/mri/)
Conditional devices that require reprogramming should be reprogrammed by personnel familiar with the device, usually a clinician from the department specializing in the device.

- Brain aneurysm clips
  Specific information (i.e. manufacturer, type/model, and material) about the clip **must** be known, especially the material used to make the clip so that only patients or individuals with non-ferromagnetic or weakly ferromagnetic clips are allowed into the MRI environment.

- Breast tissue expander
  Tissue expanders are generally considered MRI unsafe. However, these may be done at 1.5T if certain requirements are met. Please refer to breast tissue expander guidelines in Appendix C.

- Cardiac loop recorders
  Typically contain no lead wires or large loops of electrically conductive material. Product details regarding the specific loop recorder in question should be reviewed prior to scanning. The main issue to consider with MRI is that data stored on the device may be altered or erased. Data should be downloaded before the time of study, and this issue should be discussed with the cardiologist who manages the loop recorder. Because loop recorders contain ferromagnetic components, patients may feel slight movement during scanning. While not a safety hazard, patients should be made aware of this before scanning.

- Cochlear implants
  Cochlear implants usually have ferromagnetic components and are activated by electronic and/or magnetic mechanisms. However, some cochlear implants are MRI conditional and the patient can be scanned in line with the manufacturer's guidance.

- Epidural catheters
  Epidural and peripheral nerve catheters contain conducting wire that can heat up during MRI. All epidural catheters must be researched with the manufacturers for contraindication or conditional imaging guidelines. If there is no information available pertaining to the epidural catheter, it must be removed prior to imaging.

- Feeding tubes
  Most are safe or conditional except for Mclean-Ring Enteral Feeding Tube

- Foreign bodies (metallic)
  Metallic foreign bodies may contain ferrous materials and the risk vs. benefit of performing an MRI procedure should be considered carefully. Some questions to consider include:

    - Is the object located near a vital or sensitive anatomical structure (e.g. vessels/globe)?
    - Is the object likely to experience significant force/torque?
    - Is the object firmly embedded within scar tissue/bone?

  Radiographic screening is recommended in patients with a history of gunshot wounds. Plain film radiographs are usually sufficient to confirm that metallic debris is located within subcutaneous, intraosseous or otherwise non-vital tissues; however, suspected proximity to large arteries or viscera should be further investigated with low-dose non-contrast CT when there is ambiguity on plain films.

- Harrington rods
  Artifact and potential heating are the main concerns. Imaging at 1.5T is preferred but can also be performed at 3T with attention to SAR limits and padding. If the rods were placed prior to 1960, heating is a major concern and MRI is contraindicated. Also note, there are other spinal fixations (not Harrington) for which there are other guidelines and should be reviewed prior to imaging

- Implantable drug infusion pumps
  The magnet can interfere with proper function of the pump and tissue heating is also of concern. Always review manufacturer guidelines for the specific pump before MRI.

- Intrauterine device
  Most commonly used devices are safe or conditional. Older stainless devices exist that have not been investigated.

- Neurostimulators
  Patients with neurostimulators should not undergo MRI unless the device is MRI conditional and all manufacturers stated conditions for safe operation during scanning are met.

- Ocular implants
  The potential exists for the implant to be moved or dislodged, causing tissue damage. The retinal tack made from ferromagnetic material may injure a patient undergoing an MRI scan. However, some are MRI conditional -- refer to respective manufacturer information.

- Pacemakers, ICDs (implantable cardioverter-defibrillators), pacing wires
  Previously pacemakers and ICD devices were considered absolute contraindications to MRI because of potential issues with movement, modification of function, inappropriate triggering, heating, and electromagnetic interference. However, recent studies have shown that limited MRI of patients with nondependent pacemakers in a controlled and monitored environment can be performed safely if strict guidelines are followed. Because of these studies and the approval of several MRI conditional systems, pacemakers are now considered a relative contraindication. Note that guidelines from the American Heart Association (AHA) and the Food and Drug Administration (FDA) do not support MRI in pacemaker patients who do not have MRI conditional/approved systems. Pacemakers/ICDs may be imaged 6 weeks after placement.
- All studies must be performed based on workflow indicated in Appendix B. Studies will be performed on MRI conditional devices. For "non-conditional" cardiac devices (i.e., potentially MR unsafe devices), risk-benefits and alternative options should be considered, informed consent need be obtained and EP team is prepared to monitor throughout the duration of the studies. Temporary epicardial pacing leads can be imaged if cut at the skin. Temporary external transvenous pacing leads are an absolute contraindication to MRI.

- Penile implants
  Most penile implants are MR conditional, although a few are considered MRI unsafe. Specific information about the penile implant is needed.

- Programmable CSF shunts
  Most are MRI conditional and the respective manufacturer information should be followed. The pressure setting of programmable hydrocephalus shunts may be unintentionally changed by the magnetic field associated with MRI procedures. Patients must have a follow-up appointment with a physician after the exam to confirm/check settings.

- Scleral buckle

- Stents, grafts, filters
  These devices typically become securely attached to the vessel wall after surgery in ~6-8 weeks due to tissue growth but some may be scanned early. Please check with mrisafety.com and/or manufacturer guidelines. To date, there has not been reported cases of excessive heating in association with MRI and these types of devices.

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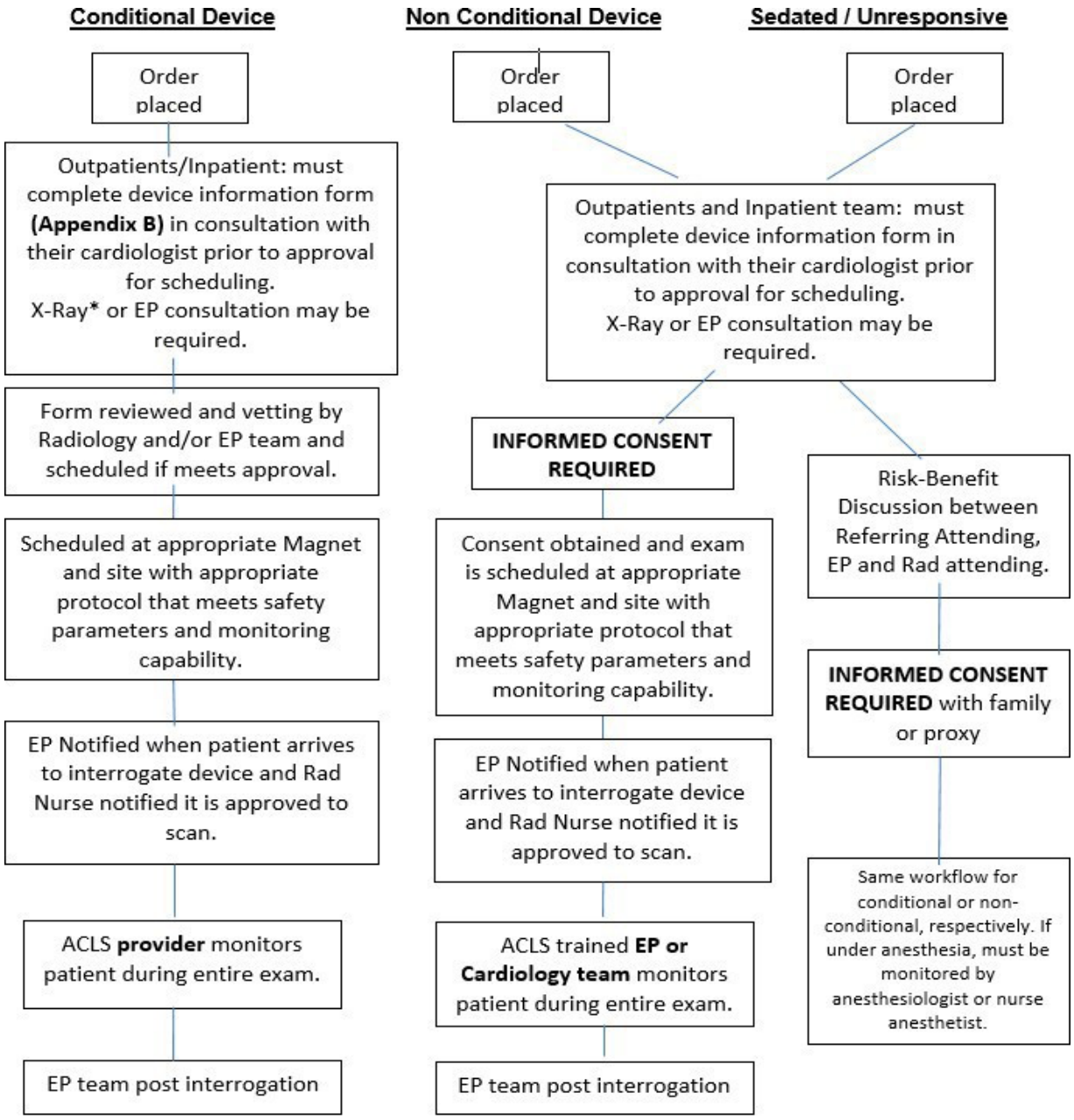
Appendix B: Pacemaker/ICD Workflow



***A chest X-ray on file is required for a patient with implantable cardiac device. If there is no imaging on file, patient is uncertain or a poor historian or there has been a recent change in the device(s), a chest x-ray will be required.**

Appendix C: Patients with Ferromagnetic Port Containing Breast Tissue Expander

Purpose: To provide necessary Magnetic Resonance Imaging (MRI) for patients with breast tissue expanders.

Background: Breast tissue expanders are generally listed as MRI unsafe as a result of movement or displacement of the object in an MR environment. Therefore, in general, the presence of this object is considered to be a contraindication for an MR procedure and/or for an individual to enter the MR environment. However, in certain clinical scenarios, it may be necessary to perform an MR on a patient with an indwelling breast tissue expander that is being removed after imaging.

Certain Institutions have significant experience with imaging patients with indwelling breast tissue expanders for perforator flap angiography (PFA) at 1.5 Tesla, prior to breast reconstruction. To date, there have been no complications reported, with more than 150 patients successfully imaged with saline filled tissue expanders manufactured by Natrelle, Mentor, and Sientra. MRI for patients with tissue expanders is permitted for other indications if: 1) there is no alternative examination that could give equivalent information, 2) informed consent is obtained, and 3) appropriate guidelines are followed.

Risks include (not all risks are listed and some may not yet be known): pain, movement of the device, heating of the device, malfunction of the device so it cannot be filled with saline nor can saline be removed, removal of device may be required after the MRI if complications occur and artifacts may be present on the MRI particularly if imaging the breast, chest or upper abdominal region and this may interfere with diagnostic interpretation

Applicability: NYITCOM.

Procedure:

1. All efforts will be made by the staff at NYIT to identify patients with tissue expanders prior to scheduling. These patients must provide an implant card or surgical report indicating the exact make and model of their implanted tissue expander. CO_2 (AIREXPANDER) tissue expanders which contain an indwelling CO_2 cartridge that may be triggered by the MR and discharge the entire cartridge of CO_2 cannot be scanned under any circumstances and therefore is an absolute contraindication to MRI

2. Patients with indwelling, saline filled, breast tissue expanders scheduled for a MRI will be imaged if written consent is obtained from the patient by the referring MD or Radiologists following discussion of risks/benefits and of potential imaging alternatives.
3. MRI Guidelines
   a) Implant must be in place for at least 14 days prior to imaging.
   b) Field strength should not exceed 1.5T. Exception: The breast tissue expander, Integra Breast Tissue Expander, (Model 3612-06 with Standard Remote Port, PMT Corporation, Chanhassen, MN), may undergo MRI testing at 3 T.
   c) Implant must be filled with ≥ 240 mL of saline or ≥ 360 mL of air to reduce torque.
   d) Prone positioning preferred when possible.
   e) Consent must be obtained because this is not currently classified as an MR conditional device by the FDA.
   f) MRI must be monitored by PA, Nurse or MD and as per routine protocol, patients should be given the squeeze-ball to activate a signal audible to the technologist in the event they are uncomfortable.
   g) These studies should not be performed in sedated or non-responsive patients who are not able to communicate reliably.

References:

1. Marano et al. Effect of MRI on Breast Tissue Expanders and Recommendations for Safe Use. Journal of Plastic, Reconstructive and Aesthetic Surgery 2017
2. Thimmappa et al Breast Tissue Expanders with Magnetic Ports: Clinical Experience at 3T. Plastic Reconstructive Surgery 2016

Appendix D: MR Contrast Agents

No patient is to be administered prescription MR contrast agents, typically gadolinium-based contrast media (GBCM), without orders from a licensed physician or advanced practice provider practicing under a supervising physician [1].

Research study participants may receive MR contrast agents as directed by the study protocol after they agree to enroll in the study that has undergone ethics committee (i.e., institutional review board) approval and sign the appropriate informed consent (and assent, as appropriate).

Qualified MR Personnel may establish and attend peripheral intravenous (IV) access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area.

IV injection–qualified MR Personnel may administer MR GBCMs via peripheral IV routes as a bolus or slow or continuous injection as directed by the orders of a licensed site physician or advanced practice provider.

Practices relating to the administration of these agents and recommendations regarding GBCM usage, adverse reactions, nephrogenic systemic fibrosis, and retained or residual gadolinium in the body should follow the ACR Committee on Drugs and Contrast Media [2]. The most recent version of the ACR Manual on Contrast Media may be downloaded from the ACR website at Contrast Manual | American College of Radiology (acr.org).

References

1. American College of Radiology; Society for Pediatric Radiology. ACR-SPR practice parameter for the use of intravascular contrast media. Published 2022. Accessed April 22, 2024. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IVCM.pdf

2. ACR Committee on Drugs and Contrast Media. ACR Manual on Contrast Media. American College of Radiology; 2023. https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

Appendix E

Adverse event reporting

MedWatch is the FDA' nationwide adverse event reporting system that serves to monitor medical device performance after a device is introduced into interstate commerce. Manufacturers, consumers, and user facilities (such as hospitals) all report under MedWatch. FDA also has an alternate hospital-based reporting mechanism known as the Medical Product Safety Network, or MedSun, which is a group of hospitals who report to FDA.

The database that stores reported events is known as the Manufacturer and User Device Experience (MAUDE) database, and FDA makes a publicly-releasable version of most MAUDE reports available on its website15. Reporting requirements for device manufacturers and user facilities are outlined in 21 CFR 803 (Medical Device Reporting). In accordance with 21 CFR 803.50(a), medical device manufacturers must submit an adverse event report to FDA within 30 calendar days of becoming aware that the device they market:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and this device or a similar device that the manufacturer also markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

In accordance with 21 CFR 803.30(a), user facilities must submit an adverse event report to FDA and the manufacturer within 10 working days of becoming aware that:

1. A device has or may have caused or contributed to the death of a patient at the facility.
2. A device has or may have caused or contributed to a serious injury to a patient at the facility.

21 CFR 803.30:

(a) You must submit reports to the manufacturer or to us, or both, as specified in paragraphs (a)(1) and (a)(2) of this section as follows:

(1). ***Reports of death.*** You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must submit the information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the

requirements of § 803.12(b).

(2). ***Reports of serious injury.*** You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12 (b).

(b) What information does FDA consider "reasonably known" to me? You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available because of reasonable follow-up within your facility. You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.

Appendix F:ACR–SIR PRACTICE PARAMETER FOR MINIMAL AND/OR MODERATE SEDATION/ANALGESIA
PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR).

The goal of this practice parameter is to assist physicians in the safe administration of sedation/analgesia and monitoring of patients receiving sedation/analgesia without the participation of an anesthesiologist or a certified registered nurse anesthetist. Sedation/analgesia allows patients

to better tolerate diagnostic imaging and image-guided procedures by relieving anxiety, discomfort, or pain. It facilitates and may optimize diagnostic imaging, image-guided interventions, and radiation oncology procedures that require patient cooperation.

The monitoring practice parameters in this guidance document apply to patients who receive minimal sedation or moderate sedation. Patients receiving a single, low-dose anxiolytic agent under usual circumstances do not necessarily require monitoring.

The administration of deep sedation/analgesia requires a greater level of skill and experience and more intensive monitoring than is described herein. Deep sedation is within the scope of practice of qualified interventional radiologists but is outside the scope of this document.

Special consideration should be given to patients undergoing sedation in a magnetic resonance imaging (MRI) environment. Relevant issues are addressed by the American Society of Anesthesiologists (ASA) Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging.
Sedation is a dynamic continuum ranging from minimal sedation/anxiolysis to general anesthesia.

Minimal sedation or anxiolysis is defined by the Joint Commission and the ASA as "a drug-induced state during which the patient responds normally to verbal commands." The ASA further states that "although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected".

Moderate sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains a continuous and independent ability to maintain protective reflexes and a patient airway and can be aroused by physical or verbal stimulation. Planned levels of sedation/analgesia beyond moderate sedation are outside the scope of this document.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia may be administered by a physician, nurse, or licensed independent practitioner under the supervision of a physician. Appropriately trained medical personnel should be immediately available to treat any sedation-related adverse event, including at least one individual in the procedure room with the knowledge and skills to recognize and treat airway complications.

A. Supervising Physician

The supervising physician should maintain the following:

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1. Sufficient knowledge of preprocedural workup, patient monitoring equipment, airway management, sedation medications and their reversal agents, and post sedation management.

2. Appropriate continuing education in accordance with the ACR Practice Parameter for Continuing Medical Education (CME).

Current Basic Life Support (BLS) certification. For pediatric sedation, personnel certified in Pediatric
Advanced Life Support (PALS) should be present. For adult sedation, personnel certified in Advanced
Cardiac Life Support (ACLS) or an institutionally approved alternative (e.g., Advanced Radiology Life Support) must be in the room or immediately available. Privileges to perform sedation at their health care institution.

B. Health Professional Responsible for Monitoring the Patient

There must be a physician, licensed independent practitioner, or nurse other than the practitioner performing the procedure present to monitor the patient throughout the period of sedation/analgesia. This individual must not be a member of the procedure team. This individual may administer the medications used for sedation/analgesia and may assist with minor, interruptible tasks during the procedure if the patient's level of sedation analgesia and vital signs are stable.

This professional should:

Be a physician, licensed independent practitioner, or nurse authorized by the facility, whose primary job is to monitor the patient.

Be appropriately privileged by the institution.

Have current certification in ACLS or an institutionally approved alternative (eg, Advanced Radiology Life Support). If children are being sedated, certification in PALS is needed as well.

Be knowledgeable in the use, side effects, and complications of the sedative agent(s) and reversal agents to be administered.

Be knowledgeable and experienced in monitoring vital signs, using pulse oximetry, capnography when appropriate, and cardiac monitoring, including the recognition of apnea and airway obstruction, cardiac dysrhythmias, and treating associated complications.

Meet the credentialing requirements of the facility

III. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation/analgesia outside the operating room, ie, by personnel other than anesthesiologists. Patients who are ASA class III or IV may require additional consideration.

Similarly, the Mallampati score is a simple test that can be a good predictor of sleep apnea and difficulty with bag mask ventilation and intubation, should it be necessary. In addition, patients with Mallampati Class III or IV should be given additional consideration. When the patient's history and comorbidities, current condition, and expected goals and objectives of sedation, either before or during the procedure, exceed the experience or resources of non-anesthesiology sedation personnel, there should be a low threshold for consultation with an anesthesiologist.

These practice parameters specifically exclude the following:
1. Patients whose sedation is managed by the anesthesiology or critical care service
2. Patients on mechanical ventilation
3. Patients who are ASA class V; such patients should be sedated by anesthesiologists

IV. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, physician's assistant, or other appropriately trained individual for the presence of risk factors that may increase the likelihood of an adverse effect. If risk factors are present, consultation with an anesthesiologist may be considered.

Sedation/Analgesia Positive-pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with an airway abnormality, which may increase the likelihood of airway obstruction during spontaneous ventilation.

Additional risk factors include, but are not limited to, the following:
- Adverse experience with sedation analgesia as well as regional or general anesthesia
- Recent catastrophic event, intensive care unit (ICU) admission, surgery, or interventions
- Sedation or anesthesia within 24 to 48 hours of the planned sedation
- Septicemia
- Polypharmacy and polyintravenous therapy
- Lung disease
- Respiratory impairment
- Cardiovascular disease
- Critical aortic stenosis
- Congestive heart failure
- Congenital heart disease
- Hemodynamic instability
- Neuromuscular and metabolic diseases

• Symptomatic brain stem dysfunction
• Apnea or hypotonia
• Sleep apnea or snoring
• Facial deformity or airway defect (birth defect or from trauma), which would be difficult for bag valve mask (BVM) resuscitation or intubation
• Liver failure
• Restricted hepatic and renal clearance
• Symptomatic gastroesophageal reflux or poor gastric emptying

V. PATIENT EVALUATION AND MANAGEMENT

Sedation as described in this practice parameter should be performed in accordance with ASA guidelines, as described below:

Adult patients and legal guardians providing consent should be informed of and agree to the administration of sedation/analgesia before the procedure begins. Minor patients should be informed of the procedure and provide their assent as appropriate. The requirement for written informed consent should follow facility policies and procedures and state and local laws and regulations.

A. Patient Preparation Before Sedation

Guidelines for preprocedural fasting should be followed.

B. Evaluation Before Sedation

1. Electrocardiogram tracings and relevant laboratory values, when appropriate, should be available for review.

2. A focused history and physical examination should be performed and recorded. This should include evaluation and documentation of ASA and Mallampati score. It should include the patient's previous experience with sedation/analgesia, current medical problems, current medications, drug allergies, history of a difficult airway, frequent or repeated exposure to sedation/analgesic agents, any significant comorbidities, and pregnancy, as appropriate. A physician or advanced practice provider should perform the presedation evaluation.

3. Prior to initiating sedation, an assessment of recent oral intake recent illness, pulmonary

status (including upper airway), cardiac status, baseline vital signs, level of consciousness, pulse oximetry, capnography (if available), and electrocardiogram (when applicable) should be performed and recorded.

A responsible adult must accompany outpatients after discharge. This adult will provide contact
information and receive clear postprocedural instructions including methods by which to contact medical personnel if needed.

C. Management during Sedation

1. Qualitative clinical signs, such as chest excursion, may be useful.
2. During moderate sedation, the adequacy of ventilation should be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.
3. Intravenous access must be maintained.
4. Normothermia should be preserved.
5. Patients should be protected from pressure-related and position-related injuries.
6. All patients should be continuously monitored throughout the procedure by physiologic measurements that should be recorded (at least every 5 minutes). These measurements include, but are not limited to, level of consciousness, respiratory rate, pulse oximetry, capnography (if possible), blood pressure (as indicated), heart rate, and cardiac rhythm. The types of measurements taken should comply with facility policies.
7. Supplemental oxygen with size-appropriate equipment.
8. Suction equipment.
9. Defibrillator with backup emergency power and an emergency cart, including equipment for intubation and ventilation.
10. The route, dosage, and time of all sedation and reversal agents should be documented on the sedation record by the health professional responsible for monitoring the patient.
11. Drug antagonists and intravenous fluids.
12. For pediatric patients, intravenous sedative/analgesic drugs should be given based on the patient’s weight in incremental doses that are titrated to the desired endpoints of sedation and analgesia. Weight-based dosing should operate within the maximum dose limit guidelines for each medication. For all patients, sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by non-intravenous routes (e.g., oral, rectal, intramuscular, inhaled), allowance should be made for the time required for drug absorption before supplementation is considered.
13. In adult patients, intravenous sedative/analgesic drugs are given in incremental doses that are titrated to the desired endpoints of sedation and analgesia. In smaller adults, weight-based dosing may be considered.
14. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the medical condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (e.g., additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The combinations of sedative and analgesic agents may potentiate

respiratory depression. This underscores the need to dose each agent appropriately as well as the need to monitor respiratory function.

D. Recovery Following Sedation

1. The patient must recover in an area where continuous monitoring and resuscitative equipment (e.g., suction, oxygen) are immediately available. A code cart must be immediately available. Monitoring should include, but is not limited to, the level of consciousness, respiratory rate, pulse oximetry, blood pressure, and heart rate and rhythm and should comply with facility requirements.
Levels of consciousness and vital signs must be monitored at intervals consistent with recovery status until all return to presedation levels and/or the patient meets established discharge criteria. A

patient may not leave the recovery area without accompanying monitoring personnel until vital signs and level of consciousness are at acceptable levels as determined by facility policy.

2. If intravenous access is used during the procedure, it should be maintained until the patient is ready for discharge. If use of reversal agents was required, the level of consciousness and vital signs should return to acceptable levels for a period of 2 hours from the time of administration of the reversal agent before monitoring ends. (Use of reversal agents may be associated with relapse into a deeper level of sedation than intended after successful rescue, and repeated doses may be required.)
The monitoring personnel will notify a supervising physician (who should remain available until recovery is complete) of any significant change in the patient's clinical status.
Qualified monitoring personnel (as described in Section IV) must be immediately available to the patient from the initiation of sedation until the patient has adequately recovered or has been turned over to the appropriate personnel delivering recovery care.

VI. SEDATION-RELATED DOCUMENTATION

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures.
Adequate documentation of all aspects of patient evaluation and monitoring is essential for high-quality patient care. This documentation should include, but is not limited to, the following:
1. Presedation assessment, including ASA criteria and airway assessment (such as Mallampati score) and pregnancy
2. Preprocedural timeout documentation
3. Dose, route, site, and time of administered drugs must be part of the permanent medical record.
4. Patient's response to medication and the procedure

5. Inspired concentrations of medical gases, such as oxygen and nitrous oxide, their rate and duration, and method of administration
6. Physiological data from monitoring
7. Any rescue interventions, including ventilatory support, or use of reversal agents as well as the patient's response
8. Any significant adverse reactions and their management A record should be kept for all patients receiving sedation, indicating sedation failure and adverse effects (e.g., vomiting, hypoxic events, resuscitation, and 24-hour follow-up when possible) and possible explanations for adverse outcomes.

Patient care areas using sedation and analgesia should have policies and procedures for reporting
complications encountered during sedation and analgesia to the quality assurance committee.

VII. DISCHARGE CRITERIA

A. The patient should not be discharged until vital signs, level of consciousness, and motor function have returned to the patient's preprocedural baseline, as determined by the health care professional responsible for monitoring the patient and dependent on the patient's destination. Recovery according to a standardized scoring system (such as the Aldrete score) should be documented.
B. For outpatients, discharge instructions must be given to the patient or accompanying responsible adult. The discharge instructions should include, but not necessarily be limited to, the following:
1. Physician contact information, including after-hours contact information, in the event of postprocedural problems
2. Advice against driving or operating machinery for a minimum of 12 hours
3. Advice against alcohol intake for 24 hours
4. Advice regarding diet and activity
5. Advice regarding follow-up instructions
6. Advice regarding sedation-related adverse effects and when to seek medical attention
7. Instructions regarding preexisting and/or new medications

VIII. EQUIPMENT

Facility policies for monitoring and evaluating the function of all equipment should be followed. Any location where sedation is administered and recovery from sedation is provided must have equipment and drugs for emergency resuscitation readily available [2]. It is critical that a complete range of sizes of emergency and monitoring equipment be available in the immediate area for all ages and sizes of patients treated at the facility. The equipment may be in a code cart and should include the following:

1. Oxygen supply from a portable or fixed source, with a backup oxygen supply.

2.Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannula, face masks, and oral airways and resuscitation equipment (e.g., manual resuscitator,
laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (e.g., a nonrebreather mask). Suction apparatus capable of producing continuous suction at a negative pressure of 150 mmHg that is regularly checked for adequacy according to facility policies.
3. Suction catheters appropriate for patients' airways must be available.
4. Appropriate emergency medications and equipment, including a defibrillator, must be immediately
available to treat adverse reactions associated with administered medications. The equipment and
medications should be monitored according to facility policies. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Equipment function should be checked on a regular basis according to facility policies. Equipment checks should be documented in accordance with facility policies.
5. Monitors
a. Pulse oximeter with probes appropriate for the patient's size. Pulse oximeter should have both visual and audible outputs
b. Blood pressure measuring device with cuffs appropriate for the patient's size
c. Multilead electrocardiographic monitors as appropriate for the patient's medical history
d. A means of monitoring ventilation, either visually or through a device
e. Capnography (if available)
6. A stethoscope
7. A telephone
8. An emergency light source, such as a flashlight
9. Emergency electrical power (or battery backup) for all electrical equipment listed above

For sedation performed in the MR suite, special equipment requirements apply, as indicated in the Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging: An Updated Report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging.

QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification
Class I Class II Class III Class IV Class V Class VI A normal healthy patient
A patient with mild systemic disease
A patient with severe systemic disease
A patient with severe systemic disease that is a constant threat to life
A moribund patient who is not expected to survive without the operation
A declared brain-dead patient whose organs are being removed for donor purposes

APPENDIX B

Factors that may be associated with difficulty in airway management include, but are not limited to, the following:
• Previous problems with anesthesia or sedation
• Stridor
• Snoring or apnea
• Dysmorphic facial features (e.g., Pierre Robin syndrome, trisomy 21)
• Craniocervical abnormalities
• Significant obesity (especially involving the neck and facial structures)
• Short neck, limited neck extension, neck mass
• Tracheal deviation
• Small mouth, protruding incisors, loose or capped teeth, high-arched palate
• Macroglossia
• Tonsillar hypertrophy
• Nonvisible uvula
• Micrognathia
• Retrognathia
• Trismus

APPENDIX C

Suggested Fasting Protocol
Summary of ASA Recommendations for Preoperative Fasting and Use of Pharmacologic Agents to Reduce Risk of Pulmonary Aspiration:
Ingested material
- Clear liquids† - Breast milk - Infant formula - Nonhuman milk‡ - Light meal§ 2-h minimum fasting period*
4-h minimum fasting period*
6-h minimum fasting period*
6-h minimum fasting period*
6-h minimum fasting period*
(e.g., 8 h or more) may be needed
Pharmacologic

- Recommendations (medication type and common examples)
Gastrointestinal stimulants
- Metoclopramide May be used/no routine use
Gastric acid secretion blockers
- Cimetidine - Famotidine - Ranitidine - Omeprazole - Lansoprazole

Antacids
Sodium citrate Sodium bicarbonate Magnesium trisilicate May be used/no routine use
Antiemetics
- Ondansetron
Anticholinergics
- Atropine No use
- Scopolamine No use
- Glycopyrrolate No use
Combinations of the medications above No routine use

These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee complete gastric emptying.
*The fasting periods noted above apply to all ages. †Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. ‡Because nonhuman milk is like solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (eg, 8 h or more) may be needed in these cases. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.
In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone.

Appendix D

Modified Mallampati Score
• Class I: Soft palate, uvula, faucets, pillars visible.
• Class II: Soft palate, major part of uvula, fauces visible
• Class III: Soft palate, base of uvular visible
• Class IV: Only hard palate visible

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Appendix G: RF Burns Policy:

Purpose: Although rare, MRI scanners have the potential to cause serious radio-frequency radiation (RF) burns. The purpose of this policy is to ensure patient comfort and safety.

Scope: MRI safety policies and procedures will be comprehensive and apply to providers, employees and visitors.

Procedure: During exam:

1. All MRI patients must be monitored throughout the MRI procedure; both through auditory and visual feedback.

2. All MRI patients are given an emergency call button to stop the exam in the event of an emergency, heating, peripheral nerve stimulation, or excessive heating.

3. All MRI patients are to be instructed before the examination that they may become warm during the exam. However, a hot or burning sensation is not normal, and the MRI technologist should be alerted immediately.

4. All MRI technologists are instructed in positioning the RF coil and the patient on how to not create or induce an RF loop.

5. Manufacturer settings actively monitor RF absorption rates as well as maintain normal operation mode during MRI examination. Technologists are instructed to always maintain normal operating mode throughout exam duration. (Manufacturer settings will not permit greater power absorption rates such as “First Level Operating Mode,” unless permissions granted by user. This would require escalated permissions by supervising MRSO.)

6. If a patient notifies the technologist of the possibility of localized heating, the exam must be stopped and the patient visually assessed to ensure there are no RF burns.

7. If no evidence of burns, the MR exam may continue, ensuring only low SAR mode protocols.

8. If the patient continues to experience heating, the exam should be immediately stopped, and the MRI supervisor should be notified.

After exam:

1. Any patient complaints of heating, swelling, redness, or evidence of burning after the MRI examination it will be brought to the attention of the nurse, the radiologist, and the chief MRI technologist. Proper medical attention is to be given to the patient: for example:

cold packs, or if necessary, refer the patient to his/her private physician.

2. Internal Patient Incident forms must be completed and filed as appropriate.

3. Take photographs to document the burn, if applicable.

4. A service call must be opened with the vendor (Philips) requesting service to investigate proper functioning and safety of MRI scanner.

5. FDA MedWatch must be notified immediately following the patient RF burn incident.

6. The vendor must make a recommendation as to if the MR scanner is safe to continue scanning patients

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Appendix H: MR Screening Policy

Purpose:

To ensure a policy is in place to properly screen employees and patients from the dangers in a magnetic field environment.

Scope: MRI safety policies and procedures will be comprehensive and apply to all patients and non-MR personnel.

Procedure:

1. Only MRI safe nonferrous medical devices may be brought into the MRI scan room, including MRI conditional wheelchairs, stretchers and oxygen tanks.

a. In the event a patient presents with their own oxygen tank it will be switched out for an MRI safe in-house oxygen tank.

b. Patients may not bring personal belongings into the MRI environment. All patient personal property must be placed in a provided locker. If a patient is not comfortable with this policy, they may lock their personal items in their vehicle.

c. Any patient that is not able to walk on their own without assistance of crutches, walkers, or personal wheelchairs MUST be transferred outside the room to the sites MRI compatible wheelchair or stretcher to avoid injury to the patient and/or staff.

2. All patients presenting for a scan must be screened by two MRI personnel, one of the personnel must be the MRI technologist. MRI Procedure Screening Form

• To ensure patient safety, completion of the MRI screening form including a detailed history on possible implants or metallic objects is required prior to every MRI scan.

• This form will be signed by the patient and scanned into our EMR system.

• Two people will review the form before the patient goes into the MRI room.

• A handheld metal detector or a magnet (1000 gauss) available to further ensure that the patient is ferrous free before entering MRI room.

• The MRI tech should have the patients always remove footwear and examine the feet/ankle area for ferrous materials