

MR Imaging Safety Siting and Zoning Considerations



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KEYWORDS

- MR imaging • Safety • Zones • Standards • Practice • Physical environment • Construction • Renovation

KEY POINTS

- In the past 20 years, MR imaging seems to have steadily produced increasing risk of harm. By contrast, safety initiatives have substantially reduced risk of harm from ionizing radiation usage in diagnostic settings.
- MR imaging safety, as an initiative, has suffered from the absence of formal standards of training or implementation.
- Physical environment MR safety (PEMS) has a significant potentiating capability for clinical and operational safety practices, when effectively integrated. When executed poorly, PEMS initiatives can actively undermine clinical and operational safety practices.
- Although several PEMS initiatives are only practical as a part of a major capital project, many PEMS improvements can be implemented without meaningful interruption to MR imaging patient care services.

INTRODUCTION/BACKGROUND

MR imaging safety, as a discipline, has been poorly formed in practice. With neither radiologists nor MR imaging technologists having formal curriculum in MR imaging safety as a part of their professional education, and with scant licensure or accreditation standard requirements for MR imaging safety that directly combat the sources of MR imaging harm, the structure and practice of MR imaging safety has developed in an alarmingly ad hoc manner, particularly when contrasted with contemporary practices for ionizing radiation safety. In this regard, MR imaging safety has become a victim of its own marketing.

In the past decade, alone, the stochastic risk from diagnostic exposure to ionizing radiation has fallen significantly due to concerted safety efforts on multiple fronts, although very small numbers of deterministic radiation burns continue to occur. It seems that the improvements in radiograph-based imaging technology coupled

with practice changes inspired by programs such as “Image Gently” and “Image Wisely” have made marked improvements in the safety of diagnostic modalities that use ionizing radiation.

By contrast, technological improvements in MR imaging over the past 20 years have largely increased risk concerns (eg, more powerful magnetic fields, greater radiofrequency (RF) power, increased slew rates), and there have been no comparable public awareness campaigns for MR imaging to identify or reduce risks or to better report the adverse events that do occur. In this timeframe, MR imaging–classified adverse event report rates to the US Food and Drug Administration (FDA) have accelerated faster than the number of examinations performed.¹ Said plainly, the data suggest that, unlike diagnostic radiography, we are injuring more MR imaging patients today than we were 20 years ago (Fig. 1).

When we adjust our focus from the macro to the individual practitioner, we see enormous variability

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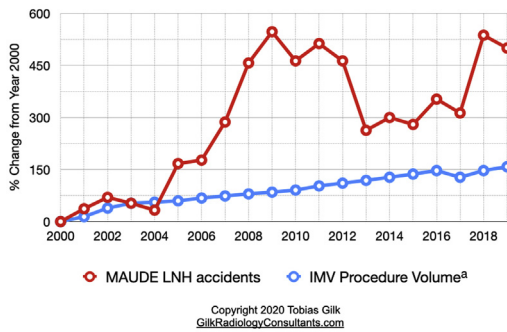


Fig. 1. Chart comparing change in MR imaging total procedure volume versus change in reported MR imaging adverse events from the year 2000 as baseline. ^a Interpolated data for years 2008, 2009, 2012, 2013, 2014, and 2015. (Courtesy of T. Gilk, M.Arch., Kansas City, MO.)

in the nature of MR imaging safety training and protections. Contemporary MR imaging safety practices often echo the parable of the 3 blind men who come across an elephant for the first time: each man touching a different part of the elephant and describing the nature of the whole animal based on the part he is touching. In the absence of a formal structure, each of us is free to (erroneously) presume that our own individual perception is both typical and complete. The myth of “the safe modality” inhibits a broader understanding of MR imaging safety risks and the effectiveness of existing practices to effectively manage those risks.

The areas of MR imaging safety that are more typically related to daily practice are those that pertain to operations and clinical decision-making. These areas of practice, while perhaps still lagging behind established best practices, are more familiar and accessible to MR imaging providers and practitioners. Physical environment MR safety (PEMS), by contrast, is substantially dissociated from the daily realm of health care administrators, radiologists, and technologists. But if the built environment of MR imaging (or any health care service) is effectively the hardware of the mechanism of health care delivery, then the appropriateness of this hardware to the software (clinical and operational practices) is of great importance.

PHYSICAL ENVIRONMENT MR SAFETY EXISTING LITERATURE

Although a healthy (and growing) body of MR imaging safety practice literature exists, it largely formally resides in the realm of recommended best practices and not standards. Even omnibus MR imaging safety publications such as the 2020

American College of Radiology (ACR) Manual on MR Safety² are presented largely as an anthology of discreet best practice policies and not as a formal structure for MR imaging safety, nor as the ACR’s own standards for operation of an ACR-accredited MR imaging provider.^{3,4}

Within the realm of physical environment safety for MR, from the AAPM Report 20, to the original 4 Zone model from the ACR, to the Sentinel Event Alert #38 from the Joint Commission (TJC), recommendations for PEMS safety have existed, in one form or another, since 1986.^{5–7} In the 2010 edition of the Facilities Guidelines Institute (FGI) Guidelines for Design and Construction of Health Care Facilities, the 4 Zone model became a requirement for the many adopting jurisdictions that use FGI as a health care design standard, although this applied only prospectively to new or renovated facilities.⁸ In the Joint Commission’s 2015 Diagnostic Imaging Standard, TJC adopted language substantially similar to that of the ACR’s 4 Zone model (and yet, TJC’s language is significantly less specific).⁹ As an accreditation standard, this requirement applies retroactively to even existing MR imaging facilities within Joint Commission accredited sites. The 2018 US Veteran Health Authority Directive 1105.05 on MR safety similarly requires the implementation of the 4 Zone model and further requires line-of-sight and situational awareness as elements of MR imaging suite design and construction.¹⁰

Because of differences in equipment, patient populations, and clinical needs, PEMS is not well served to copy-and-paste layouts and so it is understandable that the existing standards tend to be rather abstract in their stated requirements. There are infinite design permutations of a 4 Zone concept that can be (should be) tailored to the particular volume, acuity, intervention, and procedural requirements of an individual provider. Simply providing a 4 Zone model, in and of itself, is no assurance of the appropriateness or suitability of a design to the particular operational needs of a given MR imaging provider.

AIMS OF THIS PAPER

This paper works within a formal set of 3 categorical classifications of MR imaging safety practices (clinical MR imaging safety, operational MR imaging safety, and PEMS), which, together, represent a functionally comprehensive structure for thinking of MR imaging safety. From this structure, this paper explores the role that PEMS plays within the comprehensive MR imaging safety structure, the nature of PEMS risks and interventions, and the importance of PEMS considerations. In the end,

the goal is that the reader appreciates both the necessity and insufficiency of contemporary PEMS licensure and accreditation standards and how opportunities for improvements to physical environment safety within the MR suite should be identified and carefully planned for.

DISCUSSION

Looking just at MR imaging–classified injuries within the FDA’s Manufacturer and User Facility Device Experience database (FDA product code LNH), we see that the most commonly identified MR imaging injuries are, in descending order, burns, projectiles, and hearing damage.^{11,12} Substantial prevention of these 3 most frequently reported MR imaging device injuries is possible through existing best practices.¹³ These best practices can be categorized as clinical (eg, obtaining complete patient clinical history to identify potential contraindications), operational (eg, providing appropriate padding to reduce burn potential), and physical environment (eg, maintaining access controls to prevent unscreened persons/equipment from entering controlled access regions of the MR imaging suite).

All 3 categorical classifications of MR imaging safety interventions—clinical, operational, and physical environment—are necessary, and prevention of any adverse event type often depends on the successful interrelation of prevention strategies among all three. Effective clinical screening of persons is inhibited in the absence of acoustically private areas to review screening forms. Physical screening of persons is inhibited in the absence of appropriate changing areas, belongings storage, and screening ferromagnetic detection. Proper segregation of screened from unscreened persons is inhibited when there are not effective segregated subwaiting areas and appropriate access controls for the zones. The degree to which operational, clinical, and physical environment MR safety are entangled and mutually supporting cannot be overstated. The benefits of rigorous adherence to operational and clinical

safety best practices will be substantially undermined in a physical environment that is not similarly prepared to support those practices and mitigate the risks inherent to MR.

PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS PREVENTING ACCESS OF UNSCREENED INDIVIDUALS

The use of suite diagrams/floor plans has supported a misconception that the 4 Zone model maps ascribe designations to individual rooms or functions. Although designating zones by rooms is the practical implication, zoning (and the resulting access control implications) is the result of risk designations. Zone 4, the MR imaging scanner room, is the only room that has a defined zone (by virtue of the presence of the MR imaging scanner with direct, unfettered access from within the room). All other zones are defined by their presence of MR imaging physical hazards or potential access to regions of MR imaging physical hazard (Fig. 2).

The MR imaging control room is often (mis-)understood to be, by definition, a Zone 3 space. It can be a Zone 3 space if either of the 2 risk conditions are met: free physical access into the MR imaging scanner room (Zone 4) or an MR imaging physical hazard is present (eg, static magnetic field strength of 5 Gauss/0.5 mT or greater). If there is no MR imaging physical hazard in the control room, and the door to the MR imaging scanner room is physically locked, in that moment the control room is technically not a Zone 3 area, although from a functional standpoint it is prudent in most instances to treat it as a persistent Zone 3. The understanding of Zoning based on risk is particularly important as interventional and intraoperative MR grows, with shifting patterns of usage and access, depending on varied clinical demands. Dynamic MR environments, where MR scanners may move between rooms, may require dynamic functional Zone definitions established based on varying risk factors.

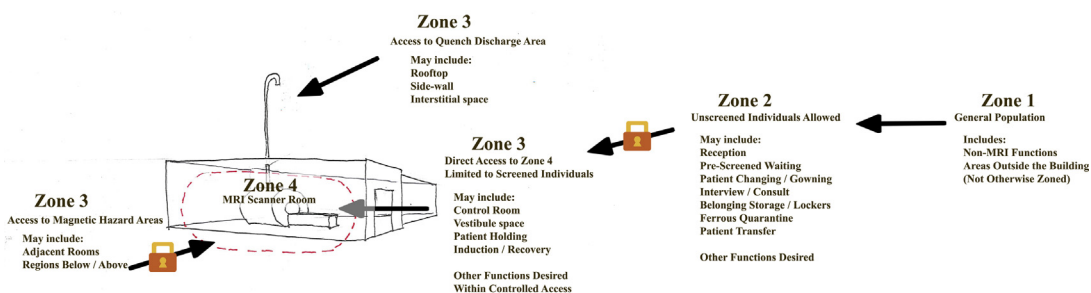


Fig. 2. Risk conditions defining MR imaging Zones.

Because of both the persistence of MR imaging static magnetic field risks in most of the MR imaging sites and the casual imperceptibility of static magnetic fields, it is appropriate to compare the clandestine nature of MR imaging risks with those of radioactive materials; both are devoid of smell, taste, or overt physical sensation. As with a hot laboratory or cyclotron facility's physical restrictions to protect against inadvertent radiation exposure, similar care must be taken with MR imaging facilities to ensure that individuals are not permitted independent access to areas with magnetic field hazards, and this includes facility personnel who may be accustomed to wide-ranging access (eg, maintenance, housekeeping, security, senior management). For example, the 5 G line may cross substantially into an adjacent equipment room, posing a potential risk to individuals with implanted devices that unwittingly enter this space, particularly if there is no clear marking and delineation that this space is technically Zone 3. Access controls, strictly linked to contemporary clinical screening and appropriate safety training, must be rigorously enforced. Increasingly it is the expectation to take the controlled access portions of the MR imaging suite off of facility-level master key access programs and—as with a hot laboratory—tightly control the individuals to whom free access is granted, often tying it to document completion of MR safety training.

Within the MR imaging suite it is wise for the layout to permit the MR technologist/radiographer to have commanding situational awareness from the operator's console. This should include line-of-sight into the MR imaging scanner room with a clear view of a patient inside the scanner, the entrance into the MR imaging scanner room, and entry into the control area. In hospital settings where higher acuity patients are scanned via MR, or where sedation/anesthesia are used, additional consideration should be given to facility layouts to provide observation capabilities for patients who may be temporarily held, undergoing preexamination preparation or postexamination recovery within the MR imaging suite. As such, there should be accommodations made at the planning stages to have, for example, availability of piped-in medical gases within Zone 3 and/or Zone 4.

PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS FOR UNSCREENED OBJECTS

Although MR imaging hazards related to either RF magnetic fields or time-varying gradient

exposures occur only during an active MR examination, the static magnetic field risks are omnipresent (“the magnet is always on”). One powerful strategy to reduce the associated risk of projectile accidents is to strive to eliminate any and all equipment and materiel that contain ferrous materials or components. Although 100% elimination of ferrous materials may not be possible, dedicated efforts to creating ferrous-free working environments, particularly when used in concert with ferromagnetic detection screening, can markedly reduce the risk factors for projectile accidents.

Ferromagnetic detection (FMD) systems are devices with excellent sensitivity and specificity developed to identify the presence of magnetic or magnetizable materials that may be projectile hazards in proximity to the MR imaging scanner. Required in many places with new MR imaging equipment installations or MR imaging suite construction, FMDs have, in a relatively modest time-frame, become standard within many regulatory or accreditation regimes.^{7,14,15}

FMD systems are most typically deployed in 2 different locations, with different screening objectives. Screener-type systems are frequently placed within Zone 2, with patient changing/gowning functions and patient-belonging lockers. The use of screener-type FMDs provides a quality-control validation, particularly when a patient has been changed into MR safe scrubs or gown, as to whether a patient truly did put away all of their belongings that ought not proceed to the MR imaging scanner room (eg, cell phone, money clip, “lucky” pocketknife, firearm). In contrast, doorway-type systems are frequently placed at the entry door into Zone 4. These are intended not only to help catch anything that a patient may have picked up following Zone 2 screening, as well as to provide a measure of screening for staff, visitors, contractors, vendors, and equipment that may be approaching the MR imaging scanner room with the intent to enter. Doorway entry systems may also assist with accreditation compliance criteria related to effective screening of individuals before entering Zone 4.

It is worth noting that FMD products are available in various configurations, facilitating many different siting options. Of all the various siting options, it is strongly recommended to not place an FMD inside the entrance to Zone 4 (on the MR imaging scanner room side of a doorway). Space permitting, doorway FMD systems should be placed shortly before the doorway into Zone 4, with a designated “taxiway” approaching the door that is as clear as possible of extraneous materiel. This taxiway can also be a functional

space for any time-out procedures and final clearances before entering the MR imaging scanner room.

PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS FOR KNOWN FERROMAGNETIC/MR CONDITIONALLY LIMITED OBJECTS

Notwithstanding efforts toward a ferrous-free working area, many pieces of equipment intended for use in the MR imaging scanner room will have ferromagnetic components and have static magnetic field conditions for safe usage. For equipment such as MR Conditional anesthesia machines, infusion pumps, respirators, biopsy devices, and contrast injectors, specific static magnetic field and spatial field gradient limitations may exist for safe and effective use.

Two recommendations for addressing magnetic field conditions within Zone 4 are to provide an indication on the flooring of the MR imaging scanner room that shows the boundary location for the governing safety indicator (ie, static magnetic field strength or spatial field gradient) and tether points to limit the movement of equipment within the room to areas outside of the boundary areas.

Floor markings can be in the form of a change in flooring material (changing color, or pattern, or texture) at the boundary, creating an alternate appearance immediately around the MR imaging scanner or a line or closely spaced series of points around the MR imaging scanner. With multiple pieces of MR Conditional equipment with different static field conditions, it is recommended to provide a single boundary based on the most restrictive MR Conditional piece of equipment, instead of multiple boundaries for different pieces of equipment, which may become confusing to staff.

Although floor markings are useful visual cues, often it is very easy to move rolling equipment beyond the defined safety boundary.¹⁶ Sites may also wish to consider tether points in the cabinets, wall, or floor of their MR imaging scanner room such that movable equipment is prevented from crossing safety boundaries within the room. Please take note, however, that retrofitting anchors for tether points, particularly in floors or walls, has the potential to damage RF shield enclosures. Only undertake retrofit installations into floors or walls with the guidance and approval of your RF shield vendor. Any construction activities within an MR imaging scanning room with an at-field MR imaging scanner, including the modification of cabinetry, should only be undertaken with great care and attention to safety (Fig. 3).



Fig. 3. Tethering of mobile MR imaging unsafe equipment in Zone 4 in interventional MR imaging suite. Note the fixed-length cable tether system that limits movement of the ultrasound system to the (caution) yellow and black striped floor markings at a distance from the magnet. The yellow and black marking matches that on the ultrasound system chassis. The red line marks 300 Gauss; the blue line marks 100 Gauss. (Courtesy of Dr. K. Gorny, Mayo Clinic, Rochester, MN.)

For sites that use non-MR Conditional medication pumps or other equipment serving the patient from within the control room, you may wish to consider tether points for non-MR Conditional equipment near the waveguide simply so that the presence of the equipment in the control area does not imply that it is appropriate to bring into the MR imaging scanner room. Consider as well the size, type, and location of the waveguides, whether door jamb type that do not require disconnecting tubing or through-wall type that do.

Within the MR imaging suite, it is also wise to consider the inclusion of dedicated transfer areas, within Zone 2 or Zone 3, where patients on conventional wheelchairs or gurneys can be moved over to MR Conditional transports. Consider also dedicated “quarantine” closets where known ferromagnetic materials (eg, wheelchairs, oxygen cylinders, unsafe medication pumps) may be sequestered to help prevent inadvertent use within the controlled access parts of the MR imaging suite.

PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS FOR RADIOFREQUENCY HEATING

Focal heating (thermal injury, burns) is the single-most frequently reported MR imaging adverse event in the United States. The preventions for RF burns pertain to appropriate use of patient preparation, positioning, padding, and the use of MR Conditional patient monitoring equipment.

Although the “last mile” of each of these efforts pertains directly to the actions of the MR technologist, the physical environment plays important roles.

The provision of patient changing and patient belongings storage assists with the patient preparation. The provision of appropriately designed and located storage for bulky positioning aides and patient padding will facilitate their beneficial use. Appropriate storage for patient monitoring equipment and consumables (eg, MR Conditional electrocardiogram leads) also facilitates the appropriate processes to reduce patient harm that may result from the use of non-MR Conditional devices.

In addition, the design of heating, ventilating, and air conditioning (HVAC) systems can help facilitate the maintenance of proper temperature, relative humidity, and airflow within Zone 4, optimizing the shedding of accumulated thermal load of the patient that is the natural bi-product of an MR examination.

PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS FOR CRYOGEN SAFETY

Most of the MR imaging scanners make use of liquefied cryogenics, typically liquefied helium, to facilitate superconductivity of the primary magnetic field coils. Although rare, under some failure conditions significant quantities of boiled (gaseous) helium could escape into the MR imaging scanner room. The alarming thermal expansion of helium when warming from the temperatures required to keep it in a liquid state ($< -270^{\circ}\text{C}$) to atmospheric temperatures creates substantial pressure increases.

Many years ago the conventional wisdom had been that doors accessing MR imaging scanner rooms should swing outward from the room, such that a rapid pressure increase within the MR imaging scanner room would push the door open and discharge the accumulating pressure¹⁷ and prevent a “positive pressure entrapment” situation. Changes in RF door technology, however, have made outward-swinging direction of a door ineffective as a safety feature for many more contemporary MR imaging suites. Although some outdated standards persist in recommending (or requiring) outward-swinging doors, these standards do not reflect contemporary best-practice. Outward-swinging doors can impede line of sight viewing of the Zone 4 doorway by the technologist seated at the console if the door swings toward the console.

MR imaging scanner rooms should have positive pressure relief mechanisms, in the form of

hatches or, preferably, pressure escape pathways designed as a part of the room’s HVAC ductwork systems. With such a system in place, the direction of the swing of the door accessing the MR imaging scanner room is immaterial as a safety protection.

In the event of a cryogen release from the MR imaging scanner (ie, quench), the expanding helium gas should be conveyed through the helium exhaust pipe, more commonly referred to as the quench pipe. The quench pipe effectively serves as a flue or chimney, conveying the escaping helium gas to a safe discharge point. Because of the pressures that develop in quench pipes, and the potential for failure, all MR system manufacturers require annual quench pipe inspections to verify the integrity and patency of quench pathways. In addition, any quench event, or any other event that may have caused building damage at any point along the path of the quench pipe (eg, fire, structural damage, earthquake, water infiltration, etc), should trigger a full repeat inspection of the quench pipe.

At the quench pipe discharge point, an identifiable clear area must be maintained free of operable windows or HVAC air intakes, which might facilitate the reintroduction of helium gas back inside the building. Serviceable equipment in this exclusion zone should be minimized, preferably prohibited, within the clear area. This area should be clearly marked, if not access-restricted, to protect the safety of persons who may be working near the discharge point. MR system manufacturers will provide horizontal and vertical clearance requirements specific to their products, but an exclusion zone of 8 m (25 feet) from the quench pipe discharge point generally accommodates most, if not all, commercial superconducting MR system manufacturer criteria.

Recently, commercial superconducting MR systems have become available that use such small quantities of liquid helium that quench pipes, and specific cryogen safety PEMS preparations to the MR imaging room construction are not recommended by the manufacturer. Nonsuperconducting MR systems, and the new very low-volume cryogen superconducting MR products, will not need these cryogen-specific PEMS interventions. It should be noted, however, that today these very low-volume cryogen systems represent a small proportion of the MR imaging market, and designs for siting these systems may wish to consider that a future replacement magnet may have additional siting requirements for cryogen safety.

TIMELINESS OF PHYSICAL ENVIRONMENT MR SAFETY INTERVENTIONS (CONSTRUCTION, RENOVATION, EQUIPMENT UPGRADES)

Once operational, it is both a financial and patient care burden to interrupt the productivity of an MR imaging suite to implement changes. Unlike operational practices or clinical policies that ought to be regularly reviewed and refined, the physical facility is often “frozen in time,” capturing the decisions made in the moment of planning, and not substantially rethought until the next MR imaging installation or replacement (and even then sometimes the proposed solutions are copy-and-paste). Because of the very limited “window of opportunity” for PEMS interventions, and likely long delays between these opportunities, MR imaging providers are well advised to prospectively consider what of their physical environment serves their MR imaging safety needs well and what does not.

With new equipment or new facilities, seize the opportunity to execute on previously planned maps of an idealized workflow and safety experience. With experienced MR imaging or radiology planners, transform that workflow into diagrams of functions and zones and rooms. Anticipate how your clinical and operational needs are likely to change in the next 5 years and ask if your functional diagram readily accommodates those anticipated changes (or what would be necessary to make it do so).

Although many PEMS interventions depend on substantial capital projects, some are easily accomplished between planned major projects with little disruption to clinical operations. Items such as providing an MR imaging suite with MR Conditional support equipment (infusion pumps, anesthesia machines, patient monitoring), installation of FMDs, physical delineation of static magnetic field limitations for MR Conditional equipment or of a time-out area before entry, or even plastic-chain or fabric strap doorway barrier devices can each be implemented rather easily and have positive effects on the physical environment safety of an MR suite. Although some PEMS interventions may be impractical in the absence of a significant renovation, that fact should not dissuade MR imaging providers from analyzing the physical environment safety of their facility and planning the interventions, even if they are comparatively modest, to strengthen the protections against MR imaging accidents and injuries.

ESSENTIAL NATURE OF PHYSICAL ENVIRONMENT MR SAFETY AS A PART OF COMPREHENSIVE MR SAFETY

The more familiar operational and clinical MR safety interventions are often potentiated or subverted as a product of the physical environment in which they take place. MR imaging safety best practices will be made more effective, or possibly functionally impractical, based on the choices that are made with respect to the “bricks and mortar” of an MR imaging provider’s facility.

The architect Le Corbusier once stated that the “house is a machine for living,” the notion being that we design a space to specifically support the desired activity. The physical spaces we inhabit for delivering patient care are similar; they should be designed and crafted with the specific intent of facilitating the care outcomes we wish to see, including safety. In fact, the more unfamiliar the hazards or objectives, the more care should be dedicated to the crafting of this environment to encourage and facilitate best practice behaviors.

SUMMARY

It is human nature that—as each of the 3 blind men with the elephant—we presume our perspective gives us a reasonably complete view of the problem. However, because of the nature of our daily responsibilities related to MR imaging safety we tend to emphasize more the immediate operational considerations for the technologist and the clinical considerations for the radiologist. PEMS is not typically emphasized in daily responsibilities for anyone in the direct patient care path for MR imaging and as a result may easily be overlooked and poorly acted on at individual facilities. It is for this reason that insightful consideration of PEMS should be elevated by those in the patient care pathways particularly when there are planned MR imaging system upgrades, new system installations, or facility modifications. Successful integration of clinical, operational, and PEMS depends on an effective dialogue among the 3 at points at which each can be tailored to work more effectively with the others.

Clinics care points

- Effective MRI safety must develop clinical MR safety, operational MR safety, and physical environment MR safety (PEMS) in concert.
- PEMS, often divorced from daily staff duties, has the risk of being overlooked or ignored.

- Failure to develop PEMS also has the potential to degrade efficacy of each clinical and operational MR safety.
- While some PEMS interventions are only practical in the context of MRI equipment installation or construction project, many options can be deployed without a major capital project.

DISCLOSURE

Employee, RADIOLOGY-Planning, an architectural design firm specializing in radiology facility design. Owner, Gilk Radiology Consultants, a consulting firm that provides MR imaging safety consultation services.

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