09 September, 2013

The Joint Commission

Re: Proposed Standards Changes for Diagnostic Imaging Services

Sir or Madam:

First, I want to thank you for the development of these draft standards. Within imaging, the de facto separation between enterprise-level accreditation and modality-level accreditation has left large voids in patient safety protections, particularly in the realm of MRI (which, unlike ionizing modalities, is devoid of state or federal safety regulations). I am encouraged to see this gulf begun to be bridged with this current effort. That said, I strongly believe that the draft changes omit effective responses to a number of known MRI risks, including the risks and preventions clearly elucidated in The Joint Commission’s own Sentinel Event Alert #38 (SEA#38), *Preventing accidents and injuries in the MRI suite*.

Initially, though it may not be a meaningful part of the proposed standards changes themselves, I would recommend removing the word “Diagnostic” from the title of the document and any future reference to this body of standards. Its presence suggests that there is a separate standard for any imaging directly involved in intervention / therapy. Removing the word “Diagnostic” should help convey that these standards are meant to apply to the application of any governed imaging device or service, whether used in a strictly diagnostic sense, or as a part of an interventional application. Particularly when imaging services are incorporated in dynamic interventional / operative environments, the imaging safety standards become even more important.

Additionally, while I recognize that these proposed standards changes are all focused on imaging services, I strongly recommend that parallel standards be put forward to deal with the comparable safety and quality issues associated with radiation therapy (both beam therapy and isotope therapy). Nearly all of the draft EPs for CT and PET should have radiation therapy corollaries.

I would like to take this opportunity to provide my feedback on the proposed changes for the Hospital Accreditation Program. With respect to the specific proposed standards changes, you will note that my responses are focused on MRI safety, and that the majority of my comments / recommendations promote the integration of TJC’s own SEA #38 guidance into the proposed standards. In fact, I am including a table at the end of each of my specific EP recommendations which cross-references the individual recommendation with SEA #38, the 2010 FGI *Guidelines for Design and Construction of Health Care Facilities* (TJC’s referenced design and construction standard), and the ACR *Guidance Document on Safe MR Practices* (cited / referenced by both SEA #38 and FGI Guidelines).

Please interpret my comments for the Hospital Accreditation Program, below, as being universally applied to all TJC accreditation program standards.
EC.02.01.01 The hospital manages safety and security risks.

EP 1 I propose that the phrase “Risks are identified from internal sources such as ongoing monitoring of the environment…” be coupled with a specific citation to PI.01.01.01 and PI.02.01.01. When it comes to radiology risk management, I am concerned that providers have not been conducting the risk assessments associated with these services, even in the wake of SEAs for both MRI and ionizing radiation. I think it is appropriate to point providers to the PI section of TJC standards to remind them of the radiology safety data that they are supposed to be collecting for just this purpose.

EP 14 Given that the overall objective of this standard section is the management of safety and security risks, I fail to see how the first bulleted point of this EP is appropriate. “[C]laustrophobia, anxiety, or emotional distress” are not safety or security issues. If TJC feels strongly that these provisions are necessary, it is my recommendation that they be relocated to another standard.

EP 16 Given statements and performance objectives outlined in SEA #38, I believe that there should be additional bulleted points under EP 16 to capture and communicate industry standard guidance on MRI safety, including TJC’s own prior SEA #38 guidance. I strongly recommend that the following be added: “- Provide signage that clearly indicates the beginning of a restricted access zone at the entrance to any area that immediately precedes the entrance to the MRI scanner room, or any area in which the static magnetic field is accessible at field strength of 5 gauss (0.5 mT) or greater. Additionally, provide signage that clearly indicates the beginning of a hazardous area at each entrance to the MRI scanner room. - Designate an MRI Safety Officer and an MRI Medical Director. - Utilize ferromagnetic detection systems for screening of persons and objects introduced to the MRI controlled access area(s). - Develop and regularly maintain MRI-specific policies and procedures, reviewed and approved by the MRI Medical Director, to include safety training, injury prevention protocols, contrast agent risk management, and other elements relevant to MRI equipment and clinical uses.”

* As a design and construction code, 2010 FGI can not comment on practice issues.
EC.02.04.01 The hospital manages medical equipment risks.

I propose that EPs 8 through 11 be added to address the risks that result from the MRI system’s static magnetic field, time varying magnetic fields, and use of radiofrequency energy. As with prior recommendations, these derive directly from risks and performance objectives identified in SEA #38. I strongly recommend that the following be added:

| **EP 8** | “For hospitals that provide magnetic resonance imaging (MRI) services, The hospital protects patients against burn risks by the following: | | |
| - Removing non-medically necessary electrically conductive elements from the patient in the area(s) subject to RF deposition. | | | ✓ |
| - Adhering to MRI system manufacturer’s guidance on patient padding / separation distances from active RF transmit coil elements. | | | ✓ |
| - Positioning the patient to prevent RF burns, including the prevention of large-loop skin-to-skin contact.” | | | ✓ |

| **EP 9** | “For hospitals that provide magnetic resonance imaging (MRI): The hospital protects persons in the MRI exam room from hearing damage by following MRI system manufacturer’s guidance on hearing protection for all persons remaining in the MRI scanner room during MRI examination.” | | |

| **EP 10** | “For hospitals that provide magnetic resonance imaging (MRI): The hospital utilizes medical equipment or devices (e.g. medication pumps, ventilators, patient monitors) within the MRI scanner room that have been tested and labeled ‘MR Safe’, ‘MR Conditional’, ‘MR Unsafe’, in accordance with applicable ISO / ASTM International standard(s). “ | | |

| **EP 11** | “For hospitals that provide magnetic resonance imaging (MRI) services: The hospital protects persons in the MRI scanner room by prospectively marking the location of static magnetic field values that would exceed the ‘MR Conditional’ rating of medical equipment or devices used in the MRI scanner room.” | | ✓ |

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* As a design and construction code, 2010 FGI can not comment on practice issues.
** While SEA #38 does speak to patient positioning to prevent burns, it does not speak specifically to the issue of large-caliber body loops. It could be argued that the intention for the prevention of this type of burn is included in SEA #38.
EC.02.04.03 The hospital inspects, tests, and maintains medical equipment.

I propose that an EP 23 be added to speak specifically to the risks associated with cryogenic liquids used in superconducting MRI. This, again, is an injury type identified in SEA #38, and what I propose is also very similar to universal recommendations from MRI system manufacturers. I recommend the following be added:

**EP 23** “For hospitals that provide magnetic resonance imaging (MRI) services with superconducting MRI systems: The hospital annually inspects the MRI scanner room cryogen vent, overpressure relief, and exhaust fan(s) for condition and maintains policies and procedures for cryogen and system quench safety. In addition, the hospital will develop and maintain a policy defining regularly scheduled preventive maintenance of the MRI system’s cryogen vent by trained Field Service Engineers and documentation of such service.”

* SEA #38 does make specific mention of risks associated with cryogens in the narrative, but does not offer performance criteria that respond directly to these known risks.

** 2010 FGI includes cryogen vent design & construction requirements, but not inspection requirements. However, it does specifically cite equipment manufacturer specifications which almost universally call for annual inspections.

EC.02.06.05 The hospital manages its environment during demolition, renovation, or new construction to reduce risk to those in the organization.

I propose that an EP be added to call upon hospitals to identify and record the three-dimensional extents of the 5 gauss volume to help assure that the access control elements identified in EC.02.01.01, EP 16 are applied to all areas where there are magnetic field hazards, even areas identified as being outside the MRI suite. This proposed EP also relates directly to risks identified in SEA #38. I recommend that the following be added:

**EP 5** “For hospitals that provide magnetic resonance imaging (MRI) services: The hospital documents the three-dimensional extents of the 5 gauss (0.5 mT) threshold of the static magnetic field. If the magnetic field is constrained through the use of passive magnetic shielding, containment of the 5 gauss threshold shall be field verified. If the 5 gauss threshold extends beyond the MRI scanner room, all areas into which there is potential exposure to static magnetic field of 5 gauss or greater will be conspicuously indicated and access controlled.”

* SEA #38 does make specific mention of restricting device or equipment from potentially dangerous interactions with magnetic fields. While no specific static magnetic field strength is indicated in this section of SEA #38, the included broad reference, coupled with FDA thresholds, could easily be interpreted to indicate the substance of the proposed.
HR.01.02.05 The hospital verifies staff qualifications.

I propose that an EP be added with meaningful qualifications for MRI operators, on par with those for CT (EP 19). I strongly recommend that the following be added:

| EP 21 | “For hospitals that provide magnetic resonance imaging (MRI) services: The hospital verifies and documents that a radiologic technologist who performs MRI exams has the following qualifications:  
- Registered by the American Registry of Radiologic Technologists (ARRT)  
- Certified by the ARRT in radiography and/or magnetic resonance  
- Trained and experienced in operating MRI Equipment” |

* As a design and construction code, 2010 FGI can not comment on practice issues.

HR.01.05.03 Staff participate in ongoing education and training.

I propose that the wording for EP 25 be revised and harmonized with the criteria for CT as identified in EP 14. Specifically, that MR staff (including technologists, see proposal for HR.01.02.05) participate in ongoing education. I strongly recommend that the proposed language be revised to the following:

| EP 25 | “For hospitals that provide magnetic resonance imaging (MRI) services: The hospital verifies and documents that technologists who perform MRI examinations and supporting MRI department staff participate in ongoing education. Ongoing education must include annual training on the following MRI safe practices:” |

* As a design and construction code, 2010 FGI can not comment on practice issues.

MM.06.01.01 The hospital safely administers medications.

I propose that an EP 14 be added to address the unique medication safety concerns associated with gadolinium based contrast agents used in MRI. I strongly recommend that the following be added:

| EP 14 | “Before administering a gadolinium based contrast agent (GBCA), the patient shall be screened for risk factors for renal insufficiency. If the patient presents with risk factors for renal insufficiency, an estimated glomerular filtration rate (eGFR) must be calculated and recorded in the patient’s medical record prior to administration of GBCA.” |

* SEA #38 does make specific mention of risks associated with MRI contrast agents in the narrative section of the document, though it does not provide specific performance criteria in the recommendations section of the Alert. This proposed EP provides the elemental framework for effectively managing this risk.

** As a design and construction code, 2010 FGI can not comment on practice issues.
**PI.01.01.01 The hospital collects data to monitor its performance.**

As the third most frequently type of reported MRI injury (and having been identified as a safety concern in SEA #38), it is perfectly appropriate to include an EP adding auditory injuries to the list of risks that are monitored for performance improvement. I strongly recommend that the following be added:

| EP 49 | “For hospitals that provide magnetic resonance imaging (MRI) services: The hospital collects data on reported hearing injuries that occur during MRI exams.” |

* As a design and construction code, 2010 FGI can not comment on practice issues.

**PI.02.01.01 The hospital compiles and analyzes data.**

To strengthen the relationship between Performance Improvement and Environment of Care risk management criteria, I recommend that an EP 15 be added:

| EP 15 | “For hospitals that provide magnetic resonance imaging (MRI) services: Information collected on patient burns, ferrous-based item incidents and injuries, and hearing injuries shall be used to manage safety for MRI services.” |

* As a design and construction code, 2010 FGI can not comment on practice issues.
Thank you for this opportunity to provide feedback and commentary on the proposed standard changes for Diagnostic Imaging Services. I believe that the initial draft will be significantly bolstered in the standards’ ability to prevent injury if the above recommendations are also incorporated. Particularly given that the overwhelming majority of the above are derived directly from TJC’s own SEA #38, these recommendations should meet with easy approval.

In further support of the above proposed standard changes, attached please find a copy of SEA #38, which I have color-coded to indicate which of its recommended protections are represented in the draft standards changes you have put forward. As you review it and compare it with the specific criteria of the draft standards, you will note how few of the SEA #38’s protections are represented in the draft standards. I encourage you to look to your own prior identified safety protections and include the recommended language, above.

I am also enclosing an excerpt from the 2010 edition of the FGI *Guidelines for Design and Construction of Health Care Facilities*, TJC’s referenced design & construction standard, showing the design & construction standards for MRI facilities.

As a final attachment, I am re-sending a pre-publication draft of a research paper undertaken by Dr. Emanuel Kanal and me. The paper provides an analysis of MRI accident reports to the FDA, detailing the types and frequencies of reported injuries. For your purposes, I believe that the attached is invaluable in demonstrating how the proposed standards changes contained in this response could be profoundly effective in reducing the rates of the most common sources of MRI injury.

Not contained within the attached pre-publication draft of that research paper is the supplemental analysis that Dr. Kanal and I performed with the accident rate data. When we were able to look at the causation of reported injury accidents, we were able to identify a small set of criteria for each burns, projectiles, and hearing damage injuries that would be, in the case of burns and projectiles, able to virtually eliminate those classifications of injury accidents (97% and 94%, respectively). This supplemental analysis was presented at the 2012 RSNA meeting, and a video of that presentation is available at http://www.youtube.com/watch?v=c-iMRYXhlzg

If you or your colleagues have any questions about any of my recommended standards EPs (or proposed changes to other standards EPs), or wish to discuss anything herein, you are invited to contact me at your convenience. It would be my pleasure to again provide my thoughts and recommendations for MR safety to the Joint Commission.

Thank you, again, for this opportunity to help assure meaningful, implementable, and minimally-burdensome quality and safety standards for the unique hazards present in the MRI environment.

Very respectfully,

Tobias Gilk

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Enclosures: Sentinel Event Alert #38, *Preventing accidents and injuries in the MRI suite* (color coded)
2010 FGI Guidelines for Design and Construction of Health Care Facilities (MRI section excerpt)
Pre-publication copy of *MR Adverse Event Testing* by T. Gilk and E. Kanal.
Issue 38, February 14, 2008

Preventing accidents and injuries in the MRI suite

Magnetic resonance imaging (MRI) was applied to health care in the late 1970s to provide never-before-seen two- and three-dimensional views of body tissue and structure. Today, more than 10 million MRI, or MR, scans are done in the United States each year. (1) While the capabilities of the MRI scanner are well-recognized, its inherent dangers may not be as well known. The following types of injury can and have occurred during the MRI scanning process:

1. "Missile effect" or "projectile" injury in which ferromagnetic objects (those having magnetic properties) such as ink pens, wheelchairs, and oxygen canisters are pulled into the MRI scanner at rapid velocity.
2. Injury related to dislodged ferromagnetic implants such as aneurysm clips, pins in joints, and drug infusion devices.
3. Burns from objects that may heat during the MRI process, such as wires (including lead wires for both implants and external devices) and surgical staples, or from the patient's body touching the inside walls (the bore) of the MRI scanner during the scan. (2)
4. Injury or complication related to equipment or device malfunction or failure caused by the magnetic field. For example, battery-powered devices (laryngoscopes, microinfusion pumps, monitors, etc.) can suddenly fail to operate; some programmable infusion pumps may perform erratically; (3) and pacemakers and implantable defibrillators may not behave as programmed.
5. Injury or complication due to failure to attend to patient support systems during the MRI. This is especially true for patient sedation or anesthesia in MRI arenas. For example, oxygen canisters or infusion pumps run out and staff must either leave the MRI area to retrieve a replacement or move the patient to an area where a replacement can be found.
6. Acoustic injury from the loud knocking noise that the MRI scanner makes.
7. Adverse events related to the administration of MRI contrast agents.
8. Adverse events related to cryogen handling, storage, or inadvertent release in superconducting MR imaging system sites.

The most common patient injuries in the MRI suite are burns and the most common objects to undergo significant heating are wires and leads. Other objects associated with burns are pulse oximeter sensors and cables, cardiorespiratory monitor cables, safety pins, metal clamps, drug delivery patches (which may contain metallic foil), and tattoos (which may contain iron oxide pigment). Less common injuries involve pacemakers. The American College of Radiology (2) recommends that implanted cardiac pacemakers and implantable cardioverter/defibrillators should be considered a relative contraindication for MRI. Any exception should be considered on a case-by-case basis and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise. (2)

While only one missile-effect case has been reported to the Joint Commission, they are more common than is generally recognized. Many people—including health care workers—are unaware that the magnets in the MRI scanner are always "on" and that turning them "off" (quenching) is an expensive and potentially dangerous undertaking, involving the controlled release of cryogenic gases that can be deadly if released into a contained area. As a result of the magnets, many of the objects pulled into the MRI scanner are cleaning equipment or tools taken into the MRI suite by housekeeping staff or maintenance workers.

Risk reduction strategies

Conventional metal detectors have been used to help identify metal objects in and on patients, but they are not 100 percent accurate and can give false-positives and false-negatives. (4) Furthermore, metal detectors cannot alert personnel to all objects that are subject to heating, malfunction or failure during an MRI scan. (5) However, the recent availability of ferromagnetic detectors may help in screening patients for objects left on their person, according to Dr. Emanuel Kanal, chair of the ACR's Magnetic Resonance Safety Committee. A recent study concludes that ferromagnetic detectors have 99 percent sensitivity. (6)

A report on projectile cylinder accidents in the American Journal of Radiology (7) recommends strategies to prevent missile-effect accidents, including implementing protocols that allow maintenance and housekeeping personnel to enter the MRI suite only after proper safety education and when no patient is in the suite. A number of preventive measures for hazards in the MRI-environment are recommended by Dr. Kanal (8) and are supported by the ECRI Institute (9), including:

Joint Commission recommendations

The Joint Commission offers the following recommendations and strategies to health care organizations for preventing accidents and injuries:

1. Restrict access to all MRI sites by implementing the four zone concept as defined in the ACR Guidance Document for Safe MR Practices: 2007. (2) The four zone concept provides for progressive restrictions in access to the MRI scanner:
   - Zone I: General public
   - Zone II: Unscrened MRI patients
   - Zone III: Screened MRI patients and personnel
   - Zone IV: Screened MRI patients under constant direct supervision of trained MR personnel

2. Use trained personnel to screen all non-emergent patients twice, providing two separate opportunities for them to answer questions about any metal objects they may have on them, any implanted devices, drug delivery patches, tattoos, and any electrically, magnetically, or mechanically activated devices they may have. If the patient is unconscious or unable to answer questions, question the patient’s family member or surrogate decision maker. If this person is unsure, use other means to determine if the patient has implants or other devices that could be negatively affected by the MRI scan (e.g., look for scars or deformities, scrutinize the patient’s history, use plain-film radiography, use ferromagnetic detectors to assist in the screening process, etc.). (2), (8)

3. Ensure that the MRI technologist has the patient’s complete and accurate medical history to ensure that the patient can be safely scanned. All implants should be checked against product labeling or manufacturer literature specific to that implant, or peer-reviewed published data regarding the use of that device. Technologists should be provided with ready access to this information.

4. Have a specially trained staff person who is knowledgeable about the MRI environment accompany any patients, visitors and other staff who are not familiar with the MRI environment inside the MRI suite at all times. (2), (8)

5. Annually provide all medical and ancillary staff who may be expected to accompany patients to the MRI suite with safety education about the MRI environment and provide all staff and patients with appropriate educational materials (e.g., guidelines, brochures, posters) that explain the potential for accidents and adverse events in the MRI environment.

6. Take precautions to prevent patient burns during scanning including:
   - Ensure that no items (such as leads) are formed into a loop, since magnetic induction can occur and cause burns. (4)
   - If the patient’s body touches the bore of the MRI scanner, use non-conductive foam padding to insulate the patient’s skin and tissues. (2)
   - Place a cold compress or ice pack on EKG leads, surgical staples, and tattoos that will be exposed to radiofrequency irradiation during the MR imaging process. (2)

7. Only use equipment (e.g., fire extinguishers, oxygen tanks, physiologic monitors, and aneurysm clips) that has been tested and approved for use during MRI scans. (2)

8. Proactively plan for managing critically ill patients who require physiologic monitoring and continuous infusion of life sustaining drugs while in the MRI suite.

9. Provide all MRI patients with hearing protection (i.e., ear plugs).

10. Never attempt to run a cardio-pulmonary arrest code or resuscitation within the MR magnet room itself.

References

1 “Fatal MRI Accident is First of Its Kind,” www.webmd.com/content/Article/34/1728_85340.htm
4 Radiographic Imaging CEU Source, LLC, Part 6, MRI Safety For Health Care Personnel


7 “Projectile Cylinder Accidents Resulting from the Presence of Ferromagnetic Nitrous Oxide or Oxygen Tanks in the MR Suite,” AJR:177, July 2001

8 Emanuel Kanal MD, Magnetic Resonance Safe Practice Guidelines of the University of Pittsburgh Medical Center, 2001.


10 American Society of Testing and Materials F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment


For additional MRI Safety Resources, visit the Joint Commission Resources website.

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A view window shall be provided to permit full view of the patient.

The angle between the control and equipment centroid shall permit the control operator to see the patient’s head.

The control room shall be located to allow convenient film processing.

### 2.2-3.4.2.3 Patient toilet
A patient toilet shall be provided. It shall be convenient to the procedure room and, if directly accessible to the scan room, arranged so a patient can leave the toilet without having to reenter the scan room.

### 2.2-3.4.3 Diagnostic X-Ray

#### *2.2-3.4.3.1 Space requirements
Radiography rooms shall be of a size to accommodate the functional program.

#### *2.2-3.4.3.2 Tomography and radiography/fluoroscopy rooms
Separate toilets with hand-washing stations shall be provided with direct access from each dedicated gastrointestinal fluoroscopic room and to an adjacent passage so that a patient can leave the toilet without having to reenter the fluoroscopic room.

#### *2.2-3.4.3.3 Mammography rooms

#### 2.2-3.4.3.4 Shielded control alcove
(1) Each x-ray room shall include a shielded control alcove. For mammography machines with built-in shielding for the operator, omission of the alcove shall be permitted when approved by the certified physicist or state radiation protection agency.

(2) This area shall be provided with a view window designed to provide full view of the examination table and the patient at all times, including full view of the patient when the table is in the tilt position or the chest x-ray is in use.

#### 2.2-3.4.3.5 Hand-washing station
A hand-washing station shall be provided within the procedure room unless the room is used only for routine screening such as chest x-rays where the patient is not physically handled by the staff.

### *2.2-3.4.4 Magnetic Resonance Imaging (MRI)

#### 2.2-3.4.4.1 Space requirements

(1) Space within the overall MRI suite shall be provided as necessary to accommodate the functional program and to meet the minimum technical siting requirements provided by the MRI equipment manufacturer.

(2) MRI suites as well as spaces around, above, and below (as applicable) shall be designed and configured to facilitate adherence to U.S. Food and Drug Administration requirements established to prevent unscreened individuals from entering the 5-gauss (0.5 millitesla) volume around the MRI equipment.

*(3) The MRI scanner room shall be large enough to accommodate equipment and to allow clearance in accordance with manufacturers’ recommendations.

### APPENDIX

A2.2-3.4.3.1 Radiography rooms should be a minimum of 180 square feet (16.72 square meters). (Dedicated chest x-ray may be smaller.)

A2.2-3.4.3.2 Tomography and radiography/fluoroscopy (R&F) rooms should be a minimum of 250 square feet (23.23 square meters).

A2.2-3.4.3.3 Mammography rooms should be a minimum of 100 square feet (9.29 square meters).

A2.2-3.4.4 Cryogen storage in the MRI suite. Cryogen storage may be required in areas where service to replenish supplies is not readily available.

a. If provided, the space should be a minimum of 50 square feet (4.65 square meters) to accommodate two large dewars of cryogen.

b. If provided, cryogen storage areas should be designed and constructed to protect occupants from pressure, thermal, and asphyxiation risks that arise from discharge of cryogenic gases.

A2.2-3.4.4.1 (3) If anesthesia support is anticipated, additional space, electrical outlets, and gas lines may be required.
2.2 SPECIFIC REQUIREMENTS FOR GENERAL HOSPITALS

2.2-3.4.4.2 Design configuration of the MRI suite

(1) Suites for MRI equipment shall be planned to conform to the four-zone screening and access control protocols identified in the American College of Radiology’s “Guidance Document for Safe MR Practices.”

(2) The layout shall include provisions for the following functions:
   (a) Patient interviews and clinical screening
   (b) Physical screening and changing areas (as indicated)
   (c) Siting of ferromagnetic detection systems
   (d) Access control
   (e) Accommodation of site-specific clinical and operational requirements

(3) An anteroom visible from the control room shall be located outside the MRI scanner room so that patients, health care personnel, and other employees must pass through it before entering the scanning area and control room. This room shall be outside the restricted areas of the MRI’s magnetic field.

*2.2-3.4.4.3 Control room

(1) A control room shall be provided with a full view of the patient within the MRI scanner.

(2) The control console shall be positioned so the operator has a full view of the approach and entrance to the MRI scanner room.

2.2-3.4.4.4 Hand-washing station

Hand-washing stations shall be provided convenient to the MRI scanner room, but need not be within the room.

*2.2-3.4.4.5 Patient preparation, holding, and recovery area or room. This shall comply with Section 2.2-3.5.4, requirements for the same area or room under Section 2.2-3.5 (Interventional Imaging Services).

2.2-3.4.4.6 Computer room

A computer room shall be provided.

2.2-3.4.4.7 Equipment installation requirements

(1) Power conditioning shall be provided as indicated by the MRI manufacturer’s power requirements and specific facility conditions.

(2) Magnetic shielding shall be provided at those sites where magnetic field hazards or interferences cannot be adequately controlled through facility planning.

APPENDIX

A2.2-3.4.4.2 (4) A risk of injury or death is posed by the penetration of areas in which the magnetic field strength is equal to or greater than 5 gauss by unscreened persons or ferromagnetic objects or equipment.

A2.2-3.4.4.3 Control rooms should be a minimum of 100 square feet (9.29 square meters), but may be larger depending on the vendor and magnet size.

A2.2-3.4.4.5 When patient holding areas are provided, they should be located near the MRI unit and should be large enough to accommodate stretcher(s). When anesthesia/edation is provided, monitored induction/recovery areas with appropriate medical gas services should be provided (these areas may be incorporated with patient holding). All MRI providers should designate a code treatment area outside the MRI room.

A2.2-3.4.4.6 A computer room may range from 150 square feet (13.94 square meters) to 380 square feet (35.30 square meters) depending on the vendor and magnet strength. Self-contained air conditioning supplement is normally required.

A2.2-3.4.4.7 (1) Power conditioning and voltage regulation equipment as well as direct current (DC) may be required.

A2.2-3.4.4.7 (2) Magnetic shielding can often be avoided in new construction when suite design and planning are employed to mitigate magnetic field hazards. Magnetic shielding is not required for MRI equipment operation.

Magnetic shielding may be required to restrict the magnetic field plot. Radio frequency shielding may be required to attenuate stray radio frequencies. The area around, above and below the MRI suite shall be reviewed and evaluated for the following:

Possible occupancy by person(s) who could have pacemakers or other metal implants.

Equipment that can be disrupted by a magnetic field. Examples include but are not limited to personal computers, monitors, CT scanners, and nuclear cameras.

After reviewing and evaluating the surrounding space, appropriate magnetic shielding should be provided based upon the type of MRI scanner to be installed.
(3) For super-conducting MRI equipment, cryogen venting, emergency exhaust, and passive pressure relief systems shall be provided in accordance with the original equipment manufacturer's specifications.

2.2-3.4.4.8 Special design elements for the MRI scanner room

(1) General. Use of ferromagnetic materials that may interfere with the operation of the MRI scanner shall be avoided or minimized in MRI scanner rooms.

(2) Architectural details

(a) The floor structure shall be designed to support the weight of MRI scanner equipment and to prevent disruptive environmental vibrations. Floor loading along the pathway required for equipment removal and replacement shall also be considered.

(b) Wall, floor, and ceiling assemblies shall accommodate the installation of required radio frequency (RF)-shielded assemblies. All doors, windows, and penetrations into the RF-shielded enclosure shall be RF-shielded.

(c) In addition to RF shielding, individual sites may also require magnetic shielding on some or all surfaces to contain portions of the magnetic field not contained by the RF shield.

(d) A knock-out panel or roof hatch is recommended for delivery and removal of the MRI scanner.

(e) MRI rooms shall be marked with a lighted sign with a red light to indicate when the magnet is on.

(3) Surfaces, fixtures, and equipment

(a) Because of the dangers of magnetic fields, servicing finishes, fixtures, and equipment within the MRI scanner room is potentially hazardous. Finishes, fixtures, and equipment should be selected to minimize the need for maintenance and servicing.

(b) Facilities may wish to use finishes or markings to identify the critical values of the magnetic field surrounding the MRI scanner, including the 5-gauss exclusion zone or other magnetic field strength values that may impair the operation of equipment.

(c) Because MRI scanners are increasingly being used as an interventional platform for image-guided biopsies and procedures, changes in infection control provisions, equipment, and finishes brought about by changes in clinical use shall be considered.

(3) Ventilation requirements. An insulated cryogen quench exhaust pipe as well as room exhaust and pressure equalization shall be provided where superconducting MRI scanners are installed to protect occupants in the event of a cryogen breach.

2.2-3.4.5 Ultrasound

2.2-3.4.5.1 Space requirements. Space shall be provided as necessary to accommodate the functional program.

(1) Area. Rooms used for ultrasound examination/treatment shall have a minimum clear floor area of 120 square feet (11.15 square meters).

(2) Clearances. A minimum clear dimension of 3 feet (91.44 centimeters) shall be provided on three sides of the table/stretcher.

2.2-3.4.5.2 Hand-washing station. A hand-washing station shall be provided within the procedure room.

2.2-3.4.5.3 Patient toilet

(1) A patient toilet, directly accessible from the procedure room, shall be provided.

(2) The patient toilet shall be permitted to serve more than one procedure room.

2.2-3.4.6 Support Areas for Diagnostic Imaging Services

The spaces included in this section are common to the diagnostic imaging department and are minimum requirements unless stated otherwise.

2.2-3.4.6.1 Control desk and reception area

2.2-3.4.6.2 Offices for radiologist(s) and assistant(s). Offices shall include provisions for viewing, individual consultation, and charting of film.