

PET/MR Part 1: Establishing a PET/MR Facility

Kamvosoulis P¹ & Currie G^{2,3}

¹Magnetic Resonance Department, New York-Presbyterian / Weill Cornell Medical Center, New York, USA

²School of Dentistry and Health Science, Charles Sturt University, Wagga Wagga, Australia

³Department of Radiology, Baylor College of Medicine, Houston, USA

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Learning objectives:

- demonstrate an understanding of the principles associated with PET/MRI department design
- demonstrate strong conceptual understanding of the technologies driving PET/MRI from the context of department design and implementation
- develop robust frameworks to support decision making in establishing a PET/MRI facility
- demonstrate awareness of safety and regulatory implications of in PET/MRI facility design

Abstract

The emergence of position emission tomography (PET) and magnetic resonance imaging (MRI) as a hybrid modality has generated widespread interest in the technology and techniques. While adoption and utilization is unlikely to be as expansive as PET and computed tomography (CT) hybrid systems, PET/MRI is an important modality that requires a broad insight for nuclear medicine professions generally, and deeper insights for those engaged in PET/MRI practice. This manuscript provides an insight into the considerations and challenges associated with establishing a PET/MRI facility. Each clinical site will present unique requisites for establishing a PET/MRI facility and, indeed, each PET/MRI vendor will have specific site requirements. Nonetheless, this manuscript provides a general insight into common considerations but should not be considered exhaustive. Here development of the facility, staffing of the facility, and implications of both radiation and magnetic resonance (MR) safety are considered from the context of facility design. Given the nature of PET is well established amongst the readership of this journal, the manuscript provides an emphasis on MR factors. This manuscript is the first in a four-part integrated series sponsored by the SNMMI-TS PET/MR Task Force in conjunction with the SNMMI-TS Publication Committee. In subsequent editions, PET/MRI will be explored based on technology principles (part 2), protocols and procedures (part 3), and applications and clinical cases (part 4).

Introduction

Positron emission tomography (PET) fused with simultaneously obtained magnetic resonance imaging (MRI) was established to fill the demand for high contrast tissue information gained from the MRI with molecular imaging data provided by the PET. Conventionally, the exquisite molecular level insights of PET have been combined in hybrid devices with the high resolution of computed tomography (CT). This approach provides both accurate anatomical localization and the opportunity for accurate attenuation correction of the PET data. While dose reduction strategies have been implemented in both PET and CT, the combined PET/CT scanner remains hindered by high radiation doses to the patient. Furthermore, the nature of imaging is such that the imaging in PET/CT is sequential in nature rather than simultaneous. The value of PET/MRI is the substitution of the high resolution CT data (excellent for hard structures and lung tissue) with the high contrast detail, no ionizing radiation and multiple sequences of the magnetic resonance (MR) data (excellent for soft structures) (1). Furthermore, PET/MRI allows simultaneous imaging protocols to reduce motion artefacts and mis-registration but confronts challenges associated with attenuation correction (1,2). While PET/CT remains the equipment of choice for many clinical scenarios, there are a number of clinical scenarios that are particularly suited to PET/MRI including, without being limited to, pediatric patients and soft tissue tumors. The technology will be detailed in part 2 of this series and protocols and clinical utilization in parts 3 and 4 respectively. There are three main aspects of establishing a PET/MR facility:

1. Engineering is associated with facility design, siting and both radiofrequency (RF) and radiation shielding.
2. Safety is associated with signage, facility access and workflow.
3. Staff includes qualifications, training and capability.

Engineering Factors

PET/MR Facility

Unlike a PET/CT site, establishing a PET/MR facility is not well documented in the literature (3,4). Building a PET/CT program within an existing nuclear medicine practice is relatively seamless if the space requirements exist and the fundamental planning considerations are uniform (albeit thicker shielding and dedicated uptake rooms). Regardless of the presence of an MRI unit, the radioactive materials (RAM) license must be added to the authorized user (AU) of the practice or amended to include 511KeV emitters. Conversely, the safety requirements of a MR facility provide restrictions on how and where the PET/MRI system should be installed (5,6). It is essential to properly plan the facility's layout in consideration of the typically 3T superconducting magnets.

If the planned PET/MRI is not co-located with an existing nuclear medicine facility, planning needs to accommodate the scanner requirements, radiopharmacy / hot laboratory, uptake rooms, waiting rooms and appropriate building permits, local and regional health department clearance, and licenses. Establishing a hot laboratory has been previously detailed (7) and regulatory requirements outlined through the Nuclear Regulatory Commission (NRC) (8). These requirements include the direction of the facility's radiation safety officer in overall radiation safety design.

Site Development

One of the first considerations in developing a PET/MR facility is to determine where to place the system and this will depend on the type of system being installed. Developing a PET/MR facility should accommodate the workflow the facility anticipates and should be guided by a "working from the outside in" approach. As with any site installation or major equipment upgrade in radiology and nuclear medicine, coordination and planning require engagement of an internal contractor and architect project team. Suitability testing of the environment is essential, and this includes vibration suitability and magnetic homogeneity. For example, the metal associated with moving elevators can produce artefact. Equipment vendors generally provide checklists which includes, without being

limited to, permits, clear access to the magnet room free of hazards, cooled water supply, power supplies and other vendor specifications. Site preparation is essential and more detailed than the installation of PET or PET/CT. There are a number of basic steps associated with establishing a PET/MR facility; site selection, design and construction contracts, site evaluation, planning and design drawings, obtaining permits, construction, and then system delivery, installation, training and commissioning. It is important to keep in mind that, for PET/MRI, a stepwise plan requires the integration of radiation shielding and planning by a qualified radiation health physicist. This is an essential step because the radiation management plan may impact on site suitability or site location for the PET/MR installation; a suitable MRI site may not be suitable for PET/MRI and, likewise, a suitable PET/CT site may not be suitable for PET/MRI.

Shielding

Shielding is an essential design requirement to contain and exclude. That is, shielding must be able to restrict both the magnetic field and radiation emission to the scanning room at the same time as preventing external electromagnetic signals or radiation from penetrating the room and creating interference. To that end, lead shielding in the walls are required for the scanner room, the uptake rooms and the radiopharmacy.

To maintain a homogenous magnetic field and restrict the magnetic field to the scanning room it is essential to introduce RF shielding to all six sides of the scanning room. The primary concern with any magnet installation is the limits of the 5 Gauss line (0.5mT), in that this perimeter is the last point of safety as the magnet is approached and magnetic field strength increases. The 5 Gauss line is the *minimum* safe distance of patients with a pacemaker and implantable cardioverter defibrillator devices (figure 1, left) because these devices are likely to be compromised by the static magnetic field (9). To prevent accidental introduction into the 5 Gauss line, the perimeter is constrained within the technologist-only accessible doorway leading to the magnet room. As per vendor specifications, if a secure doorway is not possible then another barrier must be placed, for instance, a metal-detecting automatically operated gate. Figure 1 (right) provides an example of a secure door with signage, warning signs and an automatically triggered

ferromagnetic detector. An additional recommended safety measure is the installation of a ferromagnetic detector (FMD) at the magnet doorway. As an additional level of safety, a FMD system could also be placed at the entrance to the restricted zone (zone 2 or zone 3 screening point).

At the 1 Gauss (0.1mT) limit, the magnetic field can affect electronic equipment that is not intended to function within the fringe field, for example computer monitors. Today, manufacturers have created contrast injectors, patient monitoring devices and medicine pumps that function appropriately within the 5 Gauss line, but a computer monitor will suffer deleterious effects in a 1 Gauss field. Magnetism, similarly to radioactivity, is not linear and transmits in all directions. Figure 2 illustrates the influence of magnetism in a typical department design including the fringe fields and impact on the surrounding environment. These representations are prior to the room being supported with fringe field containment, more commonly known as RF (radiofrequency) shielding. The magnetic field strength at the foot of a fully retracted imaging table reaches greater than 200 Gauss while the center of the bore surpasses 2000 Gauss. It is interesting to note that a nuclear medicine scanner will be affected by as low as 0.5 Gauss. The complexities of how the PET imaging equipment avoid this phenomenon will be detailed in part 2 of this series. For PET/MR itself, the walls have four layers of shielding; the outer layer being lead for radiation shielding, then steel for magnetic shielding, followed by air for acoustic shielding and then the inner shielding is copper for RF shielding.

Facility Layout

An MR facility is based on four safety zones developed by the ARC as depicted in figure 3. It should be kept in mind that a PET/MR facility will have additional radiation zones associated with waiting rooms, uptake rooms and the radiopharmacy. This approach to partitioning the facility prevents the accidental introduction of unsafe metals or unauthorized staff / patients / members of the general public into the MRI room. MR zoning can be thought of as a multi-level filtration system, with the end goal of all metal having been removed and all implants / devices / equipment cleared for the appropriate magnetic strength. All properly established MR facilities label the rooms by both the zone

number and the name of the zone. This extends to PET/MR facilities. Other than these zones also providing a degree of radiation safety, they are also an effective means for infection control (10).

Zone 1 represents the area outside of the facility at the entrance to the waiting or reception area that are accessible to the general public. By extension, these are the same areas in a PET/MRI department. Zone 1 is the point at which the patient makes first contact with MRI staff who provide the patient with standard MR documentation relating to the exam (for example, information relating to “What to Expect During Your MR Procedure” or “Risks Associated with Gadolinium Based Contrast Agents”) and paperwork / consent is completed. The most important form for the MRI patient is the “MR Screening Form” which will be discussed in detail in part 3 of this series. For this manuscript it is essential that the reader understand the form is to be reviewed by all staff who contact the patient, beginning with the front desk who can advise the patient and/or alert the nursing and technologist staff to information that the patient provided on the form. Zone 3 is the control room and access to the control room is restricted. Access needs to be controlled by an effective means that can be differentiated by both approved and non-approved personnel. Zone 4 is the magnet room where access is tightly restricted including through signage and physical barriers. Zones 3 and 4, like zone 1, are the same for MRI as for PET/MRI.

Zone 2 might be thought of as the most important. Zone 2 is the area between zone 1 and zones 3 and 4. Patients or others move through zone 2 to either the control room or magnet room under direct supervision of MRI trained staff. In PET/MRI, zone 2 might also include the PET patient waiting area, radioactive toilets, and uptake rooms. The radiopharmacy / hot laboratory is then the only part of a PET/MR department not covered under the 4 zone system but clearly restricted access as for zone 3 applies. Nonetheless, given the complexity of magnet fields and radiation exposure in a PET/MR facility, these zones can be translated into a MRI floor plan (figure 4). Zone 2 includes the patient dressing area and the inpatient curtain bay area. Zone 2 is the point where the screening form is completed with the patient, patients can ask additional questions, and in some cases screening with a hand-held or pillar-type metal detector (11). Additionally, all non-

MRI staff are screened in Zone 2 by performing the same activities as patients; completing the MR safety form and placing all metal objects into lockers, including pagers, mobile phones, pens, keys, wallets, paper clips, identification badges, stethoscopes and similar objects.

Room Layout

Suggested room dimensions vary among vendors but to the minimum space requirements facility planners should add approximately 30% to accommodate MRI coils, MRI phantoms, power injector, cardiac monitor, anesthesia equipment, position and mobilization devices, linen and patient comfort items, and space to allow free movement of multiple staff. The typical design should have ready access to radiopharmacy and injection/uptake rooms while being isolated from other electromagnetically sensitive equipment (figure 4). Design needs to consider restricting access to zone 2, zone 3 and zone 4 but also to radiation zones.

Safety Factors

MRI

When planning a PET/MR facility, the general safety consideration of a standard MRI system needs to be accommodated. This includes the magnetic fringe field and static magnetic field discussed previously. The inner three layers of shielding help mitigate some of these safety issues. The RF shielding (inner layer) uses copper typically to prevent interference within the PET/MRI suite from external electromagnetic sources. The steel layer provides shielding to contain the magnetic fringe field within the suite. MR produces airborne and structural noise. The air layer of shielding helps to reduce the noise produced by the MRI scanner but with noise in the range of 80-120 dBA (equivalent to a jack hammer), planning is essential to minimize impact of MR on noise sensitive equipment or hospital functions. Other than the air layer in the shielding layers, door and ceiling material should offer acoustic attenuation, ducting connecting rooms minimized, and the suite should be buffered from adjacent noise sensitive areas. Structural noise can be reduced during planning with the inclusion of isolation joints or elastomeric elements. Despite the planning, ear protection is mandatory during procedures for patients. MRI

scanners are particularly susceptible to vibration including levels lower than human detection. Vibration may be associated with internal footfall (people walking in the area) and building elevators, external road traffic, building works and rail traffic, or intrinsic associated with scanner generated vibration. Planning requires a rigorous vibration survey to allow optimal floor design that includes vibration isolation pads. MR also produces a safety concerns associated with a potential helium quench. The helium venting system must be comprised of components functionally robust under helium gas temperatures (12 degrees Kelvin or -260 degrees Celsius). Furthermore, the design needs to accommodate the 1000N forces (helium exit, expansion on evaporation) expected during a quench. The exit to environment needs to be positioned so as to be inaccessible to people (for example, 5m above walking access) and should not be located near operating windows or air intakes. Regardless of the design, clear signage should be employed.

PET

Over and above the safety issues typical of designing a MR facility, the addition of PET to the PET/MRI hybrid system adds a layer of complexity to safety. The primary issue relates to ionizing radiation which is not a consideration for standard MRI. Shielding the scanning room and radiopharmacy are obvious requirements but secondary waiting rooms to keep radioactive patients separated from others, uptake rooms and separate bathroom facilities should also be part of planning considerations. The outer layer of shielding of a PET/MRI suite is typically lead to provide attenuation of radiation. This functions in both directions, shielding the outside environment from the patient and protecting the PET system from external radioactive interference. In many cases, this design will need to accommodate the presence or absence of existing nuclear medicine facilities.

Signage

Signage plays an important role in a PET/MR facility; ensuring adherence to health department and Nuclear Regulatory Commission codes. This includes nuclear medicine signage relating to radioactive materials, "hot zones", restricted zones, bathroom facilities,

waiting areas and pregnancy status. It also includes MRI signage relating to the four MR zones (zone 1 or general public area outside the MR environment, zone 2 or path patients are brought through for their procedure between zone 1 and zone 4, zone 3 or control room, and zone 4 or magnet room), and warnings that the “Magnet Always On”, “Do Not Enter”, “Authorized Personnel Only”. These should be displayed according to national authorities like the American College of Radiology (ACR) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). For PET/MR, the MR zones also afford the opportunity to develop radiation safety restricted access zones; especially radiopharmacy and scanner rooms.

Staffing Factors

PET/MRI is essentially a new modality and it is relevant to consider the type of personnel involved in a facility that combines PET and MRI, most notably because of the unique radiation and MR safety considerations (2,12,13). The requirements of an MR facility are based on staff and patient restrictions through MR safety education. A thorough MR safety program’s implementation is based on a multi-tiered approach, beginning with the front desk staff, the MR safety officer (MRSO), the physician on duty, nursing staff and the final checkpoint, the imaging technologist who performs the final screening. This is necessary to ensure the patient is free of unsafe implants, ensure that conditional implants are imaged appropriately at the correct magnetic field strength and heating parameters, that the patient is free of personal items, medication patches and external devices, such as cardiac monitors, temperature probes and unsafe EKG leads. This is not an inclusive list and an MR facility should consult their MRSO for a complete list of all unsafe devices or patient adjuncts. Not all sites will have a designated MRSO but all sites should have staff who assume the role and responsibilities. This makes it essential to understand the importance of and responsibilities for MR safety in each department.

The requirements of a PET facility are focused on radiation shielding, and a radiopharmacy or secure area where radiopharmaceuticals can be stored. Personnel involved in all aspects of handling, administering, cleaning, assessing and maintaining radiation safety must be properly trained to perform such tasks. The ideal personnel with

training inclusive of these tasks is the Nuclear Medicine Technologist (NMT) who is registered and, in many regions, licensed to perform these functions. Staff who lack NMT training and registration but continue to perform these functions are working outside the scope of their licensure.

PET/CT confronts similar challenges. In many departments, a patient and the PET/CT equipment is managed by two staff, a qualified NMT (PET) and a qualified radiographer (CT). The opportunity for dual qualification is attractive for both employer and employee. Practices vary globally but some radiographers have undertaken additional training to be registered or licensed to perform PET. In some instances, NMT can do additional training to perform diagnostic CT. Both radiographers and NMTs are well suited to do the additional training in MR. Given NMTs are already qualified for PET, it is a simpler process for a NMT to train in MRI than a radiographer to train in both MRI and PET. Regardless of who is trained, it is essential that all PET/MRI staff are well trained in safety aspects of both PET and MRI, including radiopharmaceuticals and contrast. Specifically, all staff must be equipped to respond to emergency health condition of the patient, fire emergency, helium quench, RF burn, projectile risk, contrast reaction, radiation area surveys and spills, patient contamination, and security threats within the constraints of a PET/MR facility. While safety training and procedural training of PET/MRI staff is critical, it is also important to provide appropriate training for all staff working in or near PET/MR. This includes safety training for maintenance staff, janitorial staff, administrative staff, and orderlies.

Conclusion

Hybrid imaging with PET/MRI has an important role in patient management and this will be explored in more detail in part 4 of this series. Success with PET/MRI requires careful planning for facility siting and design to overcome challenges and safety considerations posed by each modality individually or in combination. Specific design features of PET/MRI will be detailed in part 2 of this series. The synergistic relationship evident in PET/MRI afford opportunity for integration into broader patient management (for example, radiation therapy and surgery) and this potential needs consideration in department

planning. Managing establishing a PET/MR facility with respect to engineering, safety and staffing requires careful, proactive and holistic PET/MR facility design.

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Figure 1: On the left a secure MR doorway with FMD and the 5G line demarcated by floor color change and roof lighting. On the right, an example of the secure PET/MR door with zone 4 signage, wall mounted FMD and pregnancy sign. Images courtesy of New York-Presbyterian Cornell Weill Medical Center and Memorial Sloan Kettering Cancer Center.

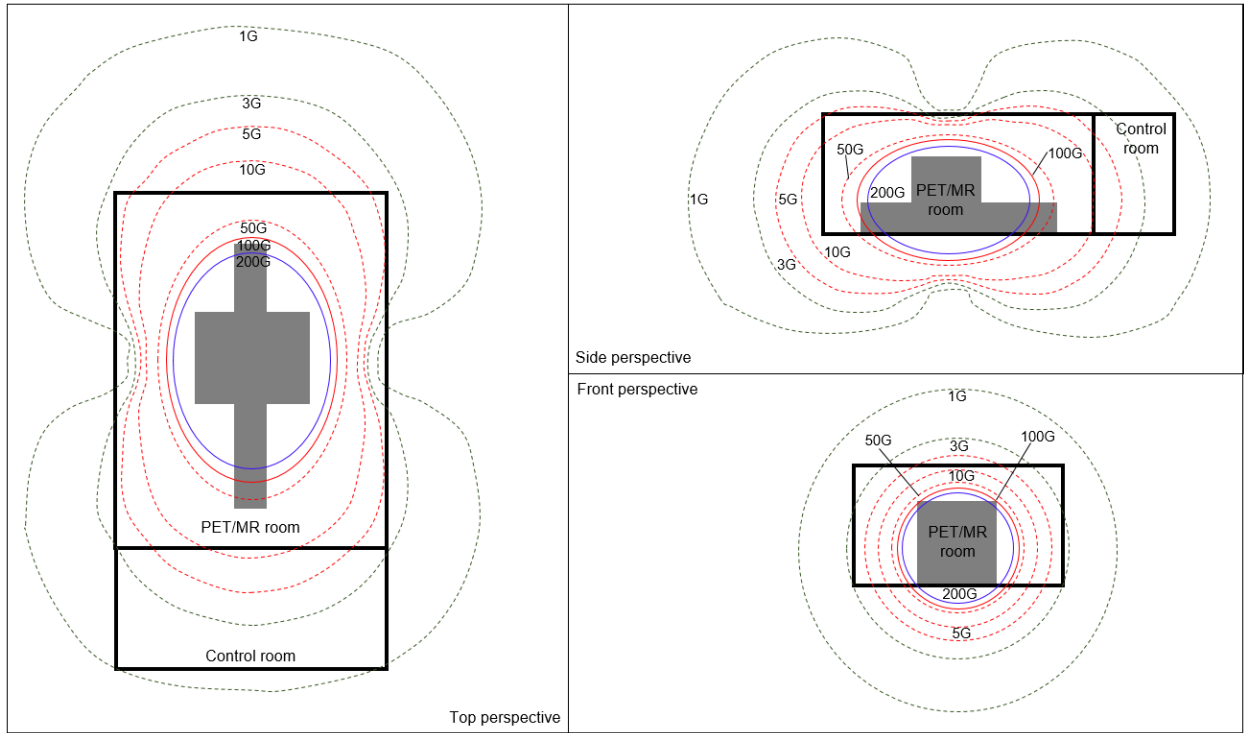


Figure 2: A typical PET/MR footprint with Gauss lines for 200G (blue), 100G (solid red), 50G, 10G, 5G (all dashed red), 3G and 1G (dashed green).

PET/MR Zone 1 General access	PET/MR Zone 2 Preparation/transfer
PET/MR Zone 3 Control room	PET/MR Zone 4 Scanner room

Figure 3: Example of signage used to demarcate MR zones. The color coding can be used on floorplans for first responders, emergency exit plans and even floor tape and door trim to help identify the zones.

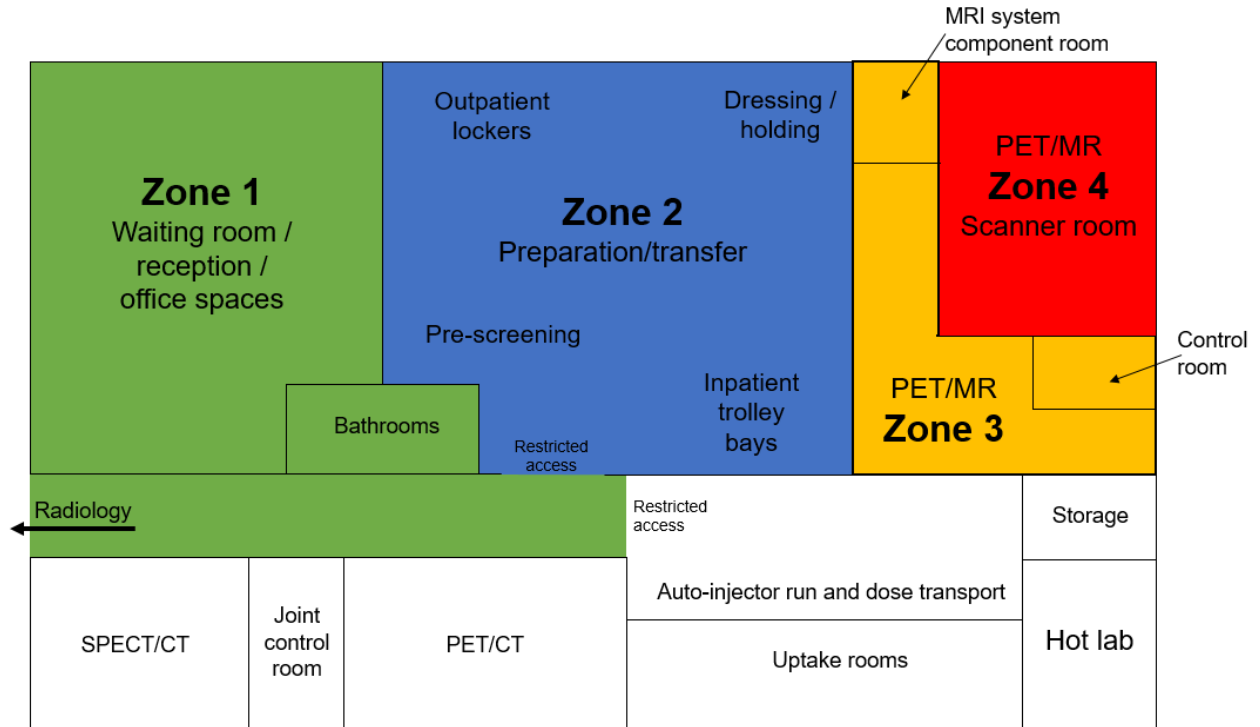


Figure 4: Schematic of a typical department design incorporating PET/MR highlighting the color-coded zones. Non-colored zones are specific to nuclear medicine and will have radiation based restrictions.