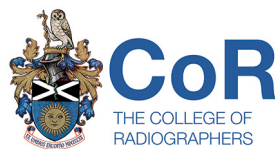


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Institute of Physics and
Engineering in Medicine



Imaging equipment from procurement to installation and commissioning

The role of the medical physicist

July 2023

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Introduction

The procurement, installation and commissioning of imaging equipment is a lengthy process requiring a multidisciplinary team (MDT) approach. This brief guidance is written by Institute of Physics and Engineering in Medicine (IPEM) experts in medical imaging physics on behalf of the Clinical Imaging Board (IPEM, RCR and College of Radiographers).

The guidance is for project teams to ensure the inclusion of key personnel completion of key steps in the process, to avoid common mistakes and to ensure compliance with current guidance and legislation (see Appendix C). The other appendices provide more detailed advice for imaging equipment employing ionising radiation (Appendix A) and magnetic resonance imaging (Appendix B).

The guidance covers seven main steps in the process: Appointment of essential medical physics personnel, Pre-procurement, Procurement, Project initiation, Project design, Construction and installation, Commissioning and acceptance.

1 Appointment of essential medical physics personnel

The following Specialist Radiation Advisers (SRA) are appointed by the healthcare provider to oversee legislation compliance for different imaging modalities and to advise and act on patient, staff, and public safety. Please contact your medical physics department in the first instance.

RPA – radiation protection adviser (RPA), advises on staff and public safety under the Ionizing Radiation Regulations 2017 (IRR17).

MPE – medical physics expert (MPE), advises on patient safety under the Ionising Radiation (Medical Exposure) Regulations 2017 - (IR(ME)R17).

RWA – radioactive waste adviser, advises on obtaining radioactive source or waste permits from the Environment Agency (EA), and together with the RPA would advise on the Environmental Permitting Regulations (EPR) 2016 regarding the storage and disposal of radioactive material as well as environmental radiation protection.

MRSE – magnetic resonance safety expert (MRSE), advises on all safety aspects of magnetic resonance imaging (MRI) according to Medicines and Healthcare Products Regulatory Agency (MHRA) guidelines (2021) and the Control of Electromagnetic Fields at Work Regulations (CEMFWR) 2016.

2 Pre-procurement

The pre-procurement phase is about identifying the appropriate members of the project team, including the appropriate SRA, identifying the technical and clinical needs for the new facility as well as considering the feasibility of using the proposed location(s).

3 Procurement

The procurement phase involves developing a technical specification and assessing quotations against this. The SRA will be required to contribute to the technical performance specifications in the context of the clinical specifications before the tender goes out to the system vendors for quotation.

Once the quotations have been received the SRA together with the estates and facilities manager will go through the vendor pre-installation manuals and installation plans and provide reports to the project manager on the suitability of each quote with respect to decisions made about location in the pre-procurement phase.

4 Initiation

The SRA will join the project installation team and will liaise with the building contractors and estates and facilities manager to provide input on the project timelines and milestones.

The SRA may be required to join the project meetings to check pre-procurement specifications have been included in the installation plans.

5 Design

The calculations needed for appropriate shielding outlined in the pre-procurement phase must be reviewed with the vendor installation manager. For nuclear medicine facilities, including systems using Positron Emission Tomography (PET), the location and duration of the patient post-injection will influence the appropriate design of the facility and require

input from the RWA. For MRI facilities any static magnetic field shielding calculations should ideally be performed by the MRI system vendor, or their subcontractor, and reviewed by the MRSE. Additionally for MRI there must be careful consideration for the placing of warning signs, environmental controls, for example, temperature and humidity, hospital gases, water cooling, electrical power outlets, wave guides and ancillary equipment, and appropriate direct current (DC) lighting circuits. The use of any ferromagnetic materials in the structure should be carefully reviewed.

6 Construction and installation

The SRA will liaise regularly with the project manager and vendor installation manager to check that the pertinent timings of certain milestones are met. The effectiveness of radiation or magnetic/RF shielding must be checked by the RPA or MRSE respectively before and after installation of imaging equipment, as well as ensuring that all other works have been completed before sign-off. Connection to picture archiving and communication system (PACS), radiation dose management systems, and radiology information system (RIS) must be confirmed. Remote service connection to the vendor must be established.

7 Commissioning and acceptance

Before final sign-off the SRA should be satisfied that a Critical Examination (CE) has been completed. The purpose of the CE is to facilitate the installer/supplier in demonstrating to the purchaser that:

- The designed safety features and warning devices operate correctly
- There is sufficient protection for persons from exposure to ionising radiation
- The equipment is safe to use in normal circumstances.

Suitably trained staff, for example, Clinical engineering, must be involved in the procurement and electrical safety/acceptance testing of any auxiliary equipment. The modality specific MPE or MRSE will perform acceptance testing of the system and compare with vendor specifications.

Appendix A

Installation guide for imaging equipment employing ionising radiation

This guidance is for members of the project teams working with clinical services, equipment suppliers/installers and building contractors to procure, install and commission new imaging equipment. It provides the key steps in the process to ensure compliance with the relevant radiation protection legislation and to ensure that projects progress appropriately.

Pre- procurement

- A project team should be assembled including representation from the following where appropriate:
 - Relevant clinicians and managers
 - Radiographers/nuclear medicine (NM) technologists/IR(ME)R Operator
 - Specialist Radiation Adviser (SRA)
 - Chief technology officer (IT and network connectivity)
 - Estates and facilities management
 - Procurement.
- The project team should develop an outline clinical and technical specification as part of the bid for capital equipment or leasing to ensure suitable resources are requested for the clinical need.
- Potential locations should be evaluated according to:
 - Site access and load-bearing considerations
 - An estimate of the radiation shielding requirements
 - Provision of chilled water requirements to the facility and any backup systems
 - Provision of appropriate air handling units for examination room air changes
 - Provision of adequate power to the facility and any backup provisions, for example, generators
 - Modality specific issues such as the storage and dispensing of radioactive substances.

Procurement

- Develop formal clinical and technical performance specification.
- Evaluate equipment via presentations, sites visits and tender responses.
- Develop formal order.
- *Note:* It may be useful to involve the RPA, and for NM/PET, the RWA at this stage if the equipment and building works are procured at the same time, for example, via a turnkey contract.

Project initiation

- Appoint project manager and form team with the following membership:
 - Clinical team
 - Appropriate physics advisers: X-ray/CT (RPA, MPE), NM/PET (RPA, RWA, MPE)
 - Estates including the Fire Officer, IT and infection control.
- Develop project plan.

- Inform RPA/MPE of construction and equipment installation timescales and agree acceptance commissioning dates and timescales with RPA/MPE. Typically, two or more weeks' notice of commissioning dates is required. The commissioning dates will need to be rearranged if projects are delayed and will need to take account of the notice period above.
- Installer to agree the engineering support required for commissioning (for example, engineer provided on site for first day as minimum).

Project design

For NM/PET projects the RWA as well as the RPA should be involved in these steps.

- Project team to provide RPA with room and equipment layout drawings for comment.
- Site to inform RPA of workload, room usage and expected views/beam directions. RPA may give indicative shielding requirements at this stage for planning and costing purposes.
- For areas where unsealed radioactivity will be used, the RWA will need to be involved in decisions on materials used and design (for example, coved flooring and splash back to disposal sink specification) to aid decontamination and bench design to enclose potential spills.
- RPA to review and sign off room plans and equipment layout before the works are agreed.
- Once a final layout is agreed RPA to provide a formal specification for all the shielding and other radiation protection requirements. Measurements of the existing shielding may need to be made on site at this stage.
- Cooperation of employer's arrangements for radiation protection to be made between the site, builders, equipment installer and any other relevant parties prior to commencement of equipment installation. RPA to advise as required.
- For NM/PET projects RPA/RWA/MPE to check whether amendments are needed to EPR 2016 permit to accommodate new sources.
- Clinical team to undertake the risk assessment process.

Construction and installation

- For areas where unsealed radioactivity will be used, the RWA will need to check the specified materials have been installed. Additionally, they will need to check there are no gaps in any seals.
- Installer to determine who is carrying out the CE and make any contractual arrangements.
- For NM/PET projects, RWA to check installation of benches/materials used for flooring and splash backs around radioactive disposal sinks. Any issues/snagging to be addressed before commissioning and acceptance testing.
- Make connections to RIS and PACS and dose management software where used.

Commissioning and acceptance testing

- RPA and MPE to commission the unit and carry out the CE (if appropriate) or review the installer's CE report.

- RPA/MPE to sign off the equipment from a medical physics perspective and radiologists/radiographers to sign off from a clinical perspective.
 - Applications work with clinical team to ensure that local protocols are installed, staff are trained in the use of the equipment and to begin the dose optimisation process.
 - Review and finalise the risk assessment. This informs all other radiation protection controls required because of the new unit.
-

Appendix B

Installation guide for magnetic resonance imaging (MRI)

This brief guidance is for members of the project teams working with clinical services, equipment suppliers/installers and building contractors to procure, install and commission new MRI equipment. It provides an overview of the key steps in the process to avoid common mistakes. Note that this document does not cover the installation of hybrid MRI systems such as PET/MR or MR-linear accelerators (MR-linac), which require a multidisciplinary physics approach.

Pre-procurement

- A project team should be assembled including representation from the following where appropriate:
 - Relevant clinicians and managers
 - MR responsible person
 - MR radiographers
 - MR physicists
 - Magnetic resonance safety expert (MRSE)
 - Estates and facilities management including fire officer
 - Chief technology officer (IT and network connectivity)
 - Procurement.
- The project team should develop an outline clinical and technical specification as part of the bid for capital equipment or leasing to ensure that appropriate resources are requested to meet the clinical need. The MRSE should be involved in any discussion of the location of the MRI system if this is a new installation, or refurbishment of an existing facility if the system is being replaced.
- Potential locations should be evaluated according to:
 - Site access, load-bearing and mechanical vibration considerations
 - Presence of any large moving ferromagnetic objects, electrical power cables, and electromagnetically sensitive equipment in the vicinity
 - Provision of chilled water requirements to the facility and any backup systems
 - Provision of appropriate air handling units for examination room air changes
 - Provision of adequate power to the facility and any backup provisions, for example, generators.
- Potential vendor pre-installation manuals/site planning guides should be reviewed to identify any siting issues, and ideally potential MR system vendors should be engaged as early as possible to contribute to siting or upgrading discussions.
- Discussions should take place on the merits or otherwise of turnkey solutions.

Procurement

- The appropriate members of the project team should develop the clinical and technical specification tender.
- The vendor-proposed solutions should be evaluated via the tender responses, as well as via presentations and site visits (either physically or virtually).
- A detailed list of system deliverables should be drawn up including all hardware and software options chosen by the project team.

- The shortlisted vendors should deliver outline plans of the facility that should be critically reviewed in terms of location within the existing buildings, clear establishment of the MR controlled access area and MR environment, and the requirement for any additional magnetic shielding. A suitable vendor for the RF cabin should also be selected. The MRSE can help in reviewing the plans.
- Suitable building contractors should be appointed, either as part of a turnkey solution from the MRI equipment vendor or independently. The building contractor should ideally have experience of MRI system installations and be aware of the issues associated with the installation of any ferromagnetic hardware into the MR magnet room. The building contractor must ensure that all construction aspects comply with the vendor pre-installation manuals/site installation guides.

Project initiation

- Appoint a project manager (PM) and create project initiation document.
- Co-opt additional members onto the project team as required (for example, infection control, nursing, IT, PACS and anaesthetics).
- Appoint a vendor installation manager.

Design

- Detailed project plan to be drawn up by the PM including milestones and deliverables.
- Detailed room plans to be developed and reviewed in the context of the surrounding areas including areas above and below the MR environment.
- The MRSE should review and approve final site plans.
- Any static magnetic field shielding calculations should be performed either by the MRI vendor or a suitably qualified and experienced third-party company and reviewed by the MRSE. MRSE's do not usually perform magnetic field shielding calculations.
- The 3 mT magnetic field contour should be demarcated by a different colour of flooring. This can be ascertained from the vendor drawings.
- Careful consideration should be given to the requirements to maintain the vendor stated examination room temperature and humidity ranges and the requirement for an air handling unit to maintain the required number of air changes per hour.

Construction and installation

- The PM should manage all aspects of the construction and equipment installation.
- Regular updates should be provided to the project team.
- The RF cabin integrity should be checked before delivery of the MRI system by the RF cabin vendor. These tests should be witnessed by the MRSE.
- There must be appropriate provision of power and chilled water, and the quench pipe must be in place before the MRI system can be delivered. Ideally the MRI system should be delivered into a clean and dust-free environment.
- Once the RF cabin is resealed after MR system delivery its integrity should be rechecked. These tests should be witnessed by the MRSE. Appropriate continuity testing should be in place if there is any possibility that continuing works may damage the cabin. The RF cabin vendor/tester must issue a certificate stating that the RF cabin meets the vendor specifications.

- Oxygen sensors must be connected to emergency extractor fans and checked by the MRSE.

Commissioning and acceptance testing

- The MRSE should independently check that the static magnetic field in publicly accessible areas adjacent to the MR facility, including above and below, does not exceed 0.5 mT (5 G).
- The MRSE should also check other safety-related systems (for example, oxygen level monitor, emergency run-down unit (quench) buttons, emergency power-off buttons, emergency table release).
- Connection to PACS and RIS should be confirmed via end-to-end testing.
- Vendor remote diagnostics connectivity should be confirmed.
- Appropriate signage should be used (for example, IPEM recommended signage). www.ipem.ac.uk/ScientificJournalsPublications/MRISafetyNotices.aspx
- Following completion of the vendor installation testing the MRSE should review the vendor's test results and undertake independent acceptance testing/status testing prior to sign-off of the system as ready to undertake clinical imaging.

Appendix C

Relevant legislative framework and guidance

1. The Health and Safety at Work etc Act 1974. www.legislation.gov.uk/ukpga/1974/37/contents
 2. The Ionising Radiations Regulations 2017 (IRR17). www.legislation.gov.uk/uksi/2017/1075/contents/made
 3. Work with ionising radiation: Ionising Radiations Regulations 2017: Approved Code of Practice and Guidance. <https://books.hse.gov.uk/bookstore.asp?ACTION=BOOK&PRODUCTID=9780717666621>
 4. The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). www.legislation.gov.uk/uksi/2017/1322/made
 5. IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (2020). www.rcr.ac.uk/system/files/publication/field_publication_files/irmer-implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-nuclear-medicine.pdf
 6. Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy (2020). www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf
 7. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009. www.legislation.gov.uk/uksi/2009/1348/contents/made
 8. The Environmental Permitting (England and Wales) Regulations 2016. www.legislation.gov.uk/uksi/2016/1154/contents/made
 9. Environmental Protection Act 1990. www.legislation.gov.uk/ukpga/1990/43/section/10
 10. The Special Waste Regulations 1996. www.legislation.gov.uk/uksi/1996/972/made
 11. The High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005. www.legislation.gov.uk/uksi/2005/2686/contents/made
 12. The Control of Electromagnetic Fields at Work Regulations (2016). www.legislation.gov.uk/uksi/2016/588/contents/made
 13. Magnetic resonance imaging equipment in clinical use: safety guidelines (2022). www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use
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