



Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Mater PET/CT Centre
Undertaking Name:	Mater Private Hospital
Address of Ionising Radiation Installation:	Dublin 7
Type of inspection:	Announced
Date of inspection:	21 November 2022
Medical Radiological Installation Service ID:	OSV-0007399
Fieldwork ID:	MON-0035040

About the medical radiological installation:

The Mater Private Network provides a full diagnostic radiology, nuclear medicine, cardiology, PET/CT and radiotherapy service at the Mater Private Hospital (MPH), Eccles Street. A PET/CT service is provided at the Mater PET/CT centre which is located at the Mater Misericordiae University Hospital (MMUH). The centre is a stand-alone centre purpose built in 2005 for PET/CT scanning. The centre provides full body PET/CT scanning, brain scanning and prostate scanning using a state-of-the-art digital PET/CT scanner. Prior to 2022 the Mater PET/CT centre was a joint venture/public-private partnership between MMUH and MPH. The centre was located in MMUH and staffed and operated by MPH for both public and private patients. The centre first opened in 2005. In February 2022, the PET/CT scanner was replaced and the centre ownership transferred to MMUH. The Mater Private now operate the centre one day per week according to a service level agreement. On the day the centre is operated by MPH, governance falls under the Mater Private Hospital governance structures.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA’s findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Monday 21 November 2022	09:30hrs to 14:35hrs	Noelle Neville	Lead

Governance and management arrangements for medical exposures

An inspection was carried out at the Mater PET/CT Centre on 21 November 2022 by an inspector to assess the facility's compliance with the regulations. As part of this inspection, the inspector visited the clinical area, spoke with staff and management and reviewed documentation. The inspector noted that the Mater PET/CT Centre demonstrated compliance with each regulation reviewed, namely Regulations 4, 5, 6, 8, 10, 11, 13, 14, 16, 17, 19, 20 and 21.

The Mater PET/CT Centre had a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation. The inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures. In addition, the inspector noted strong involvement in, and oversight of, radiation protection by medical physics experts (MPEs) across a range of responsibilities.

Overall, the inspector was satisfied that a culture of radiation protection was embedded at the Mater PET/CT Centre and clear and effective governance and management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

The Mater PET/CT Centre had a policy titled *Process for Referral and Justification of Medical Radiological Procedures*, the most recent version of which was issued in November 2022. This policy clearly outlined who can refer for medical radiological procedures at the facility. The inspector was satisfied from reviewing a sample of referrals and speaking with staff and management that referrals for medical radiological exposures were only accepted at the Mater PET/CT Centre from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at the Mater PET/CT Centre.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). The inspector reviewed documentation including governance structure organograms and spoke with staff and management in relation to governance arrangements in place at the Mater PET/CT Centre.

The inspector was informed, that prior to 2002, the Mater PET/CT Centre was a joint venture, public-private partnership between the Mater Misericordiae University Hospital (MMUH) and the Mater Private Hospital (MPH). The centre was located in MMUH and staffed and operated by MPH for both public and private patients. In February 2022, the PET/CT scanner was replaced and the centre ownership transferred to MMUH. The MPH now operate the Mater PET/CT Centre for one day a week according to a service level agreement. The inspector noted that close collaboration was evident between the MMUH and MPH in relation to oversight and use of the PET/CT scanner and on the day the centre is operated by MPH, governance falls under the MPH governance structures.

Mater Private Hospital was the undertaking for the Mater PET/CT Centre and the Mater PET/CT Centre had a radiation safety committee (RSC). The inspector reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership including the chief operations officer who was also the designated manager, MPEs, the group director of quality and patient experience, radiologists and the radiography services manager. The committee met twice a year and reported to the QUEST (Quality using Safe and Effective Treatments) committee, the QUEST committee reported to the Group Board Quality and Patient Safety Committee who in turn reported to the Mater Private Board.

Overall, the inspector was satisfied that the Mater Private Hospital, as the undertaking for the Mater PET/CT Centre, had strong oversight and clear and effective governance and management structures in place to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that all medical exposures for ionising radiation at the Mater PET/CT Centre were carried out under the clinical responsibility of an individual entitled to act as practitioner as per Regulation 5. The inspector was also satisfied from a review of a sample of referrals, documentation and speaking with

staff that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological exposures. The inspector also noted that the practical aspects of medical exposures were only carried out by persons entitled to act as practitioner. In addition, practitioners and MPEs were involved in the optimisation process for medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at the Mater PET/CT Centre.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificates of MPEs at the Mater PET/CT Centre and was satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

The inspector noted strong involvement in, and oversight of, radiation protection by MPEs across a range of responsibilities outlined in Regulation 20(2) at the Mater PET/CT Centre. MPEs took responsibility for dosimetry including carrying out a range of dose audits. MPEs were members of committees at the Mater PET/CT Centre including the RSC and QUEST committee. The inspector was informed that MPEs gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. MPEs were involved in several optimisation projects, including the application and use of DRLs. In addition, MPEs at the Mater PET/CT Centre carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection.

The inspector noted that MPEs also liaised with the Mater PET/CT Centre's radiation protection adviser as required by Regulation 20(3).

Judgment: Compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices

The inspector was satisfied that MPEs were appropriately involved at the Mater PET/CT Centre, with the level of involvement commensurate with the radiological risk posed by the facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector visited the Mater PET/CT Centre clinical area, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the facility. The inspector noted that the Mater PET/CT Centre demonstrated compliance with each regulation reviewed, namely Regulations 8, 11, 13, 14, 16 and 17, further detail of which is provided in the report. Overall, the inspector was satisfied that the Mater PET/CT Centre demonstrated that systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

The Mater PET/CT Centre had a policy titled *Process for Referral and Justification of Medical Radiological Procedures*, the most recent version of which was issued in November 2022. This policy outlined the justification process and who was responsible for carrying out this process at the facility. The inspector was informed that justification in advance was carried out by a practitioner as required by Regulation 8(8), and a record of this justification in advance was retained on the Mater PET/CT Centre's radiology information system as required by Regulation 8(15). The inspector was satisfied from reviewing a sample of records that referrals were in writing and stated the reason for the medical radiological procedure. In addition, the Mater PET/CT Centre provided risk and benefit information to service users in relation to medical radiological procedures and information leaflets were also available in the waiting area of the facility and on the MPH's website.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The Mater PET/CT Centre had a policy titled *Optimisation and Diagnostic Reference Level (DRL) Policy* which was issued in November 2022. This policy set out the responsibilities of staff in respect of DRLs and also the method for establishing and

using local DRLs. The inspector was satisfied that the Mater PET/CT Centre had established, regularly reviewed and used DRLs at the facility and these DRLs were displayed prominently in the clinical area.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at the Mater PET/CT Centre for standard radiological procedures as required by Regulation 13(1). The inspector was satisfied that information relating to patient exposure forms part of the report of the medical radiological procedure as required by Regulation 13(2). The Mater PET/CT Centre had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3).

In addition, the inspector noted a range of clinical audits which were ongoing and completed at the Mater PET/CT Centre. These audits included referrals, pregnancy policy and patient dose. Of note, the Mater PET/CT Centre had conducted a quality improvement initiative (QII) following the installation of a new PET/CT scanner in February 2022. The inspector was informed that the aim of this QII was to reduce radiation dose to service users attending the Mater PET/CT Centre for diagnostic scans while maintaining image quality. The outcome of this QII included optimising PET/CT studies, which resulted in a marked drop in administered activity and service user radiation dose while maintaining image quality. The inspector noted that the Mater PET/CT Centre viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at the Mater PET/CT Centre as required by Regulation 14(1). The Mater PET/CT Centre had a policy titled *Quality Assurance (Quality Control) Program*, the most recent version of which was issued in November 2022. This policy outlined staff responsibilities in relation to quality assurance and the quality assurance programmes for the PET/CT scanner. The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The inspector reviewed records of regular performance testing and was satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any

equipment faults or issues arising if needed. In addition, the inspector was satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The Mater PET/CT Centre had a policy titled *Policy for the Protection of the Unborn Child arising from Ionising Radiation received during Medical Diagnostic Procedures*, the most recent version of which was issued in September 2022. This policy included specific staff responsibilities, for example, the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age.

The inspector was satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, the inspector noted multiple notices in the waiting area of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector was satisfied from discussions with staff and management and a review of documents, that the Mater PET/CT Centre had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures.

The Mater PET/CT Centre had two policies titled *Incident Reporting and Management Policy*, the most recent version of which was issued in September 2022 and *Reporting of Ionising Radiation Incidents*, the most recent version of which was issued in November 2022. The inspector found that these incident reporting policies clearly outlined the process for incident reporting at the Mater PET/CT Centre. The policies also outlined HIQA's requirements for incident reporting including relevant timelines and thresholds for significant events of accidental or unintended exposures. The inspector noted that the Mater PET/CT Centre had reported one incident to HIQA since the commencement of the regulations in 2019.

Overall, the inspector was satisfied that there was a positive culture of reporting amongst staff and oversight of management who communicated the process for

reporting incidents involving, or potentially involving accidental and unintended exposures to ionising radiation.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant