



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Mater Private Northern Cross
Undertaking Name:	Mater Private Hospital
Address of Ionising Radiation Installation:	Newenham House, Malahide Road, Northern Cross, Dublin 17
Type of inspection:	Announced
Date of inspection:	14 November 2023
Medical Radiological Installation Service ID:	OSV-0007956
Fieldwork ID:	MON-0039249

## About the medical radiological installation:

Mater Private Network Northern Cross provides an outpatient diagnostic imaging service and has been in operation since 2020. The facility is located at Newenham House, Northern Cross, Dublin 17. Services provided include computed tomography (CT), magnetic resonance imaging (MRI), X-Ray, Fluoroscopy and Ultrasound imaging. The service operates 7 days a week.

The service falls under the governance of the Mater Private Network and is part of the wider Diagnostic Imaging department based at the main hospital in Eccles Street. Rapid access for advanced cardiac imaging service such as Cardiac CT and MRI is available. The diagnostic imaging department is part of the Mater Private Network at Northern Cross, where patients can avail of multiple appointments at one location in a single visit. Other services provided include Specialist Consultation, non-invasive Cardiac Testing and Healthcheck.

## 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 inspector<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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 users<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

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

<sup>4</sup> 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
Tuesday 14 November 2023	09:00hrs to 12:00hrs	Kirsten O'Brien	Lead

## Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations at Mater Private Northern Cross was carried out on the 14 November 2023. On the day, the inspector visited the general radiography (X-ray) and computed tomography (CT) rooms and spoke with staff working in each area.

Overall, the inspector was satisfied that appropriate governance and management arrangements were in place for the delivery of the radiology service at the facility on the day of inspection. In addition, the inspector noted that roles and responsibilities relating to the radiation protection of service users were carried out by appropriate individuals as recognised in the regulations. For example, only those entitled to act as a practitioner took clinical responsibility for medical exposures. In addition, the inspector was also satisfied from communication with staff and a review of relevant policies and other records, that the facility had adequate processes in place to ensure the appropriate involvement of a Medical Physics Expert (MPE) in line with radiological risk.

A dual governance structure was found to be in place which provided oversight for the conduct of medical exposures at Mater Private Northern Cross. This included line management and reporting structures in addition to committee oversight arrangements which reported up to the Mater Private Hospital's board. For example, the Radiology Service Manager (RSM) reported to the Chief Operations Officer (COO) who was the designated manager for the facility.

From the findings on the day of inspection, the inspector was assured that staff and management at Mater Private Northern Cross had processes in place to ensure the radiation protection of services users undergoing medical radiological procedures at the facility.

### Regulation 4: Referrers

On the day of inspection a sample of referrals were reviewed by the inspector who also spoke with staff working at the facility. Overall, all referrals reviewed were found to be from individuals entitled to refer as per the regulations.

Judgment: Compliant

### Regulation 5: Practitioners

From speaking with staff and reviewing documentation and other records, the inspector was satisfied that only those entitled, as per Regulation 5, to take clinical responsibility for medical exposures acted as a practitioner.

Judgment: Compliant

## Regulation 6: Undertaking

On the day of inspection, the inspector spoke with management and staff at the hospital about the governance and management structures in place for the radiology department. The Mater Private Northern Cross is a day hospital operating under the management and oversight of the Mater Private Hospital, Dublin. Overall, the inspector was satisfied that a clear allocation of responsibility for the radiation protection of service users was in place.

A dual reporting structure was found to be in place to oversee the provision of radiology services at the facility. Staff and management described the line management structure as the main mechanism for day-to-day operational oversight for radiation protection. The RSM reported to the COO and the inspector was informed that this reporting structure involved weekly meetings about the provision of radiology services. The COO of the Dublin hospitals was the designated manager for the facility inspected and had day-to-day oversight of the operational aspects of delivering the radiology service. The COO reported to the Deputy Group Chief Executive Officer (CEO) who was the undertaking representative and member of the Board of the Mater Private Hospital.

In addition to the line management structures, a committee reporting structure was also in place. A Radiation Safety Committee (RSC) was in place which reported to the Quality Using Effective Safe Treatment (QUEST) Committee. The QUEST committee in turn reported up to the Mater Private Hospital Group's Board. The inspector also found that the COO, RSM and MPE were members of both the RSC and the QUEST committee.

From reviewing documentation, a sample of patient records, and speaking with staff, the inspector was assured that only appropriate individuals, who were recognised as referrers, practitioners and MPEs, carried out these roles and responsibilities as required by the regulations. As an area for improvement, management at the facility should consider reviewing the facility's policies to ensure that they are more aligned with specific aspects of practice at the Mater Private Northern Cross to ensure that these can be clearly understood by all staff.

Overall, on the day of inspection, the inspector was satisfied that good governance and management arrangements were in place to ensure the safe delivery of medical exposures at the facility.

Judgment: Compliant

### Regulation 10: Responsibilities

On the day of inspection, the inspector found that clinical responsibility was only taken by radiologists and radiographers in the radiology department at the Mater Private Northern Cross. Both referrers and those entitled to act as practitioners were found to be involved in the justification of individual medical exposures on the day of inspection. Similarly, the inspector was satisfied that radiologists, radiographers and MPEs were appropriately involved in the optimisation of medical exposures at the facility. Additionally, from speaking with staff and management, the practical aspects of medical exposures at the facility were currently only carried out by registered radiographers.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

On the day of inspection, the inspector was satisfied that the Mater Private Hospital had appropriate measures in place to ensure the continuity of medical physics expertise at the facility.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and spoke with staff and management at the facility. From the evidence reviewed as part of this inspection, the inspector was assured that an MPE was available to act and give specialist advice on matters relating to radiation physics as required by the regulations. For example, the inspector found examples of where an MPE had taken responsibility for dosimetry as part of the analysis of an accidental or unintended medical exposure. The inspector also reviewed the records of quality assurance (QA) carried out on medical radiological equipment at the facility and was satisfied that an MPE had been involved in the definition and performance of this QA.

Judgment: Compliant

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

On the day of inspection, the inspector was assured that an MPE was appropriately involved in the radiology service at the Mater Private Northern Cross.

Judgment: Compliant

## Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Mater Hospital Northern Cross. Information about the benefits and risks associated with medical exposure to ionising radiation were available in the form of bespoke posters in waiting areas in the radiology department. Posters to raise awareness of the special protection required during pregnancy were also observed in the waiting areas.

A sample of referrals for medical exposures were also reviewed on the day of inspection. The inspector found that medical exposures were justified in advance by an individual recognised to take clinical responsibility as a practitioner. From the evidence available, the inspection was satisfied that referrals were in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Diagnostic reference levels (DRLs) were established and available for use by staff in each room. The inspector noted the inclusion of information about the rules relating to pregnancy inquiries for specific procedures were also included on the DRL poster as a memory aid. This information was displayed at the point of care and was noted as an area of good practice to promote compliance with the pregnancy policy. The inspector was also satisfied that a practitioner carried out the inquiry about patients' pregnancy status, where relevant.

On the day of inspection arrangements were found to be in place regarding the recording of events involving, or potentially involving, accidental and unintended exposures to ionising radiation.

From the evidence available on the day of inspection, the inspector was satisfied that Mater Private Northern Cross had systems in place to help ensure safe delivery of medical exposure to ionising radiation.

## Regulation 8: Justification of medical exposures



The inspector reviewed a sample of patient records, reviewed documentation and spoke with staff working at Mater Private Northern Cross. A number of bespoke notices to provide information about the radiation dose from medical exposures were observed in the waiting areas. Additional information about the risks and benefits was also available for service users on the hospital's website.

From the evidence assessed on the day of inspection, the inspector was satisfied that medical exposures conducted at the facility had referrals that were in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Staff working at the facility explained and demonstrated to the inspector how medical exposures are justified in advance of the medical exposure. All referrals reviewed on the day of inspection had a record of justification in advance by a practitioner. For CT procedures, all referrals were justified by a practitioner before an appointment was scheduled for the patient and an additional second justification in advance was also carried out on the day of the exposure by a practitioner before the exposure was conducted. Staff working in CT also demonstrated to the inspector how referrals that were not justified were returned to the referrer. Staff also demonstrated how previous medical exposures carried out by the Mater Private Hospital were available as part of each patient's record. These steps provided an assurance to the inspector that the Mater Private Northern Cross had measures in place to ensure that all CT exposures were justified in line with the principles of radiation protection.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

On the day of inspection, DRLs were observed in both the X-ray and CT rooms. These local facility DRLs were found to be regularly reviewed, compared with national levels and used in the optimisation of medical radiological procedures at the hospital.

Judgment: Compliant

### Regulation 13: Procedures

On the day of inspection, a sample of written protocols for routine examinations conducted in the radiology department at the facility were reviewed by the

inspector.

A sample of reports for X-ray and CT procedures were reviewed and information relating to patient exposure was included on all reviewed reports. The inclusion of information relating to patient exposure on all reports in these areas was facilitated through an automated electronic output of the exposure directly onto the report of each medical exposure.

Judgment: Compliant

### Regulation 14: Equipment

From speaking with staff and management and a review of documentation and records, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance. The inspector was satisfied that QA and routine performance testing programmes were implemented and maintained for each piece of medical radiological equipment at the Mater Private Northern Cross.

From a review of a sample of medical exposure records, the inspector also found that the CT equipment transferred information about the parameters to assess patient dose to the examination record at the end of the exposure.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, the inspector spoke with staff, reviewed relevant policies and a sample of patient records. At Mater Private Northern Cross, a radiographer was found to carry out the inquiry of patients' pregnancy status where relevant. In addition, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in public places such as changing rooms and waiting areas.

An area of good practice was noted by the inspector where information about procedure specific rules for carrying out an inquiry of pregnancy status was included on the DRL notice in each room. This provided an easily accessible reminder to staff to ensure compliance with the facility's policy at the point of care.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

The inspector spoke with staff and management about the systems in place to record and analysis potential or actual accidental or unintended exposures. The Mater Private Northern Cross had an electronic incident reporting system to record incidents which automatically notified relevant management. The inspector was informed that all staff had access to report incidents using this system. A weekly incident meeting is held at the hospital to discuss any incidents which occurred. This weekly incident meeting is attended by members of the radiology department who contribute as required.

From the evidence gathered during this inspection, the inspector was assured that appropriate measures were taken within this facility to minimise the probability of accidental or unintended exposures.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
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