



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Marymount University Hospital & Hospice
Undertaking Name:	Marymount University Hospital & Hospice
Address of Ionising Radiation Installation:	Curraheen Road, Curraheen, Cork
Type of inspection:	Announced
Date of inspection:	04 April 2023
Medical Radiological Installation Service ID:	OSV-0007395
Fieldwork ID:	MON-0038631

About the medical radiological installation:

Marymount University Hospital and Hospice (Marymount) has multiple services both onsite and outreach across the country. Marymount provides care for older people and Specialist Palliative Care.

Marymount has a day care unit that hosts a unique pain intervention service for patients with a cancer diagnosis. This supportive service allows easy access to complex pain management and is led by Dr. John Browne. Dr. Browne and his team collaborate with specialist palliative care senior clinicians to complement pain management for those living often with complex life limiting conditions.

This service allows patients to have enhanced management of their symptoms (pain in particular) and alleviating distress. Some of the procedures are x-ray guided using a mobile fluoroscopy unit in a dedicated treatment room. The x-ray guided service operates one afternoon a week, as required. This allows for patients and their families to live a more fulfilled life, despite their diagnosis. The collaborative care provided in the pain service is not only unique but is patient centred, efficient and effective, having an invaluable outcome for service users.

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
Tuesday 4 April 2023	11:00hrs to 13:48hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

An inspection was carried out at Marymount University Hospital and Hospice on 4 April 2023 by an inspector to assess compliance with the regulations. Marymount University Hospital and Hospice delivers a specialised pain medicine clinic that utilises X-ray guided fluoroscopy as part of some pain management procedures delivered there. The inspector found that a relatively low level of medical exposures involving ionising radiation were conducted annually within this service.

From discussions with staff with responsibility for the fluoroscopy imaging service and hospital management, the inspector found that Marymount University Hospital and Hospice demonstrated compliance with all the regulations assessed as part of this inspection.

The inspector was satisfied that governance arrangements for medical radiological procedures were effective and provided assurance that there was appropriate oversight by management at the hospital to ensure the radiation protection of service users. There was a clear allocation of responsibilities as per Regulation 6(3) which was evident following the review of documentation and discussions with staff. The inspector found that referrals for medical radiological exposures were only accepted from individuals entitled to refer, namely, the pain medicine consultant. Similarly, only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures. In addition, the inspector was satisfied that the undertaking had the necessary arrangements in place to ensure the continuity of medical physics expertise for this installation as per Regulation 19(9) and medical physics expert (MPE) involvement was proportionate to the radiological risk posed by the service.

Staff at the hospital described measures taken to improve regulatory compliance to the inspector. The actions taken addressed gaps in compliance and demonstrated the commitment by staff and management at the hospital to ensuring the radiation safety of service users and compliance with regulations.

Regulation 4: Referrers

The inspector was informed that the pain medicine clinic provided by Marymount University Hospital and Hospice was led by one pain medicine consultant who was the sole referrer for medical radiological procedures performed there. A sample of referrals for medical radiological procedures viewed by the inspector verified that referrals were written by this physician who was a recognised referrer as per this regulation.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from the day-to-day practice described by staff and the documentation viewed, that the pain medicine consultant and the radiographer were recognised as practitioners for this medical radiological facility thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

The allocation of responsibilities for the radiation protection of services users undergoing medical exposures at this facility was clearly documented and viewed by the inspector. Radiology governance structures and clinical oversight were detailed in the document *Radiation Safety Procedures* and these arrangements and allocation of responsibilities were confirmed by staff who spoke with the inspector.

The hospital had a Radiation Safety Committee (RSC) with responsibility for overseeing radiation protection and monitoring compliance with the regulations. There was evidence in the minutes and terms of reference viewed that this committee was multidisciplinary. The chair person was the Chief Executive Officer and also the designated manager for this medical radiological facility. Organisational structures viewed detailed the reporting lines of communication from the RSC via the Risk Committee and Quality and Safety Committee up to the Board of Directors and undertaking.

Overall, the inspector was satisfied that the undertaking, Marymount University Hospital and Hospice, had effective governance and management structures in place to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector reviewed radiation safety procedures and documentation provided in advance of this inspection. A review of patient records relating to medical exposures and discussions with staff confirmed that all medial exposures took place under the clinical responsibility of a practitioner as per Regulation 10(1). The inspector was informed by staff that the pain medicine consultant had overall clinical responsibility

for each medical exposure performed within this facility.

The inspector was assured that the justification of each medical exposures involved the practitioner and the referrer. Similarly, practical aspects of medical exposures were only carried out by a radiographer and the optimisation process involved the practitioner and the MPE.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector spoke with the MPE and reviewed formalised arrangements and was satisfied that these arrangements ensured the continuity of medical physics expertise at Marymount University Hospital and Hospice.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed up-to-date professional registration certificates of the MPEs providing specialist advice on matters relating to radiation physics. MPE responsibilities were detailed in the hospital radiation safety procedures and the service level agreement viewed by the inspector which aligned with regulatory requirements.

MPE roles and involvement were clearly articulated by staff who worked at the facility to the inspector. The inspector saw evidence of MPE contribution to the quality assurance of the fluoroscopy equipment and involvement in optimisation of medical radiological procedures and diagnostic reference levels (DRLs). There was also evidence to show MPE involvement in the development and approval of the hospital radiation safety procedures document. RSC minutes showed that the MPE attended all the meetings held since August 2022. The inspector was informed that the MPE contributed to staff training on matters relating to the radiation protection of services users and if required would contribute to the analysis of any accidental and unintended exposure should one occur.

Judgment: Compliant

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

From discussions with the staff and management and documentation viewed, the

inspector found that level of involvement of the MPE at Marymount University Hospital and Hospice was appropriate and proportionate to the radiological risk posed by the fluoroscopy guided procedures undertaken at this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

Systems and processes in place to ensure the protection of service users undergoing medical exposures at Marymount University Hospital and Hospice were reviewed by the inspector during this inspection. Discussions with staff and management and documentation reviewed, demonstrated to the inspector that the staff working in this service had a strong commitment and local ownership for the radiation protection of the service user.

Staff utilised a patient pathway document for each pain medicine procedure involving a medical exposure. This meant that the written referral, pregnancy inquiry record, record of justification in advance, information relating to the patient exposure and outcome of the procedure were contained in one document. The records viewed provided a seamless collation of information in relation to medical radiological procedures delivered in this specialised service and evidence of compliance with regulations.

The inspector was satisfied following review of documentation and discussion with staff that an appropriate quality assurance programme was implemented and maintained in accordance with documented time frames detailed in local policy.

Regulation 8: Justification of medical exposures

The processes for referring and justifying individual medical radiological procedures was documented in the hospital *Radiation Safety Procedures* which was consistent with the day-to-day practice described by staff to the inspector.

The inspector reviewed a sample of the patient pathway documentation containing records relating to each medical exposure conducted as part of a pain medicine procedure. These records confirmed that the referral for each procedure was documented as part of the consent process, stated the reason for the request and included sufficient clinical data to inform the justification of the procedure. The pain medicine consultant and the radiographer were jointly responsible for justifying each medical exposure which was co-signed by both as verification that justification in advance had been carried out.

Information for service users on the risks and benefits associated with exposure to

ionising radiation from X-rays were displayed in recovery area for service users.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs for fluoroscopy procedures were established as per Regulation 11(5). These local DRLs were established from data gathered in a patient dose audit from January 2020 to November 2021 and were displayed in the fluoroscopy procedure room. The inspector noted that data was limited for some procedures due to low levels of activity but there was sufficient data to establish a local DRL for lumbar epidural and facet joints procedures within that period. The inspector was informed that staff were currently collating data to review and update current facility DRLs.

Judgment: Compliant

Regulation 13: Procedures

From documentation viewed and discussions with staff, the inspector found that the undertaking met the requirements set out in Regulation 13. For example, protocols for all fluoroscopy procedures carried out in this practice were established as per Regulation 13(1). Information relating to the patient exposure was contained in the each of the patient pathway documentation viewed. There was sufficient documentary evidence to show that regular clinical audit was undertaken with high levels of compliance evident in reports viewed by the inspector.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided to the inspector as requested in advance of the inspection. Documentation viewed by the inspector provided evidence that quality assurance testing of the medical radiological equipment by a MPE had been completed in January 2023. Service reports viewed also demonstrated that regular servicing and maintenance of equipment by an engineer was carried out. In-house quality assurance was conducted by radiography staff every six to eight weeks depending on activity levels

Overall, the inspector was satisfied that equipment was maintained in satisfactory working order and fit for clinical use. The evidence gathered demonstrated that

medical radiological equipment at Marymount University Hospital and Hospice was kept under strict surveillance as per Regulation 14(1)

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector was informed that this regulation rarely applied to service users attending the pain medicine clinic as most were not of child bearing age. However measures were implemented by staff to ensure compliance with this regulation. For example, the inspector observed posters relating to pregnancy in the recovery area for service users. Staff described the process in place for establishing the pregnancy status of relevant service users. The process described aligned with the hospital standard operating procedure for ruling out pregnancy contained in the document *Radiation Safety Procedures* which was provided in advance of this inspection and viewed by the inspector. The inspector viewed a sample of relevant patient pathway records and found that the record of the pregnancy status assessment was evident for relevant service users.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following review of documentation and discussion with staff, the inspector was satisfied that there was a system in place to record all radiation safety incidents or near misses should one occur. Staff described the potential for error to occur as extremely low given the nature of the specialised service provided.

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