



**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

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| Name of Medical Radiological Installation: | Mercy Urgent Care Centre |
| Undertaking Name: | Mercy University Hospital |
| Address of Ionising Radiation Installation: | St Mary's Health Campus, Gurrabraher, Cork |
| Type of inspection: | Announced |
| Date of inspection: | 09 November 2023 |
| Medical Radiological Installation Service ID: | OSV-0007404 |
| Fieldwork ID: | MON-0041414 |

About the medical radiological installation:

The Mercy Local Injury Unit (also known as the Mercy Urgent Care Centre) at St. Mary's Health Campus, Cork, offers service users assessment and treatment of minor injuries, for example, suspected broken bones, minor burns and scalds or cuts, and operates between the hours of 8am-6pm 7 days a week. The centre is led by a consultant in emergency medicine and is under the operational governance of Mercy University Hospital, Cork, CLG (MUH).

The Mercy Local Injury Unit has a dedicated digital general x-ray room which provides on-site diagnostic radiographic imaging for patients attending the unit.

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 |
|--------------------------|----------------------|------------|------|
| Thursday 9 November 2023 | 09:25hrs to 13:21hrs | Kay Sugrue | Lead |

Governance and management arrangements for medical exposures

An inspection was carried out at Mercy Urgent Care Centre (MUCC) on 9 November 2023. From documentation reviewed and speaking with staff and management, the inspector was satisfied that the hospital had a clear allocation of responsibility for the protection of service users undergoing medical exposures at the facility.

Documented radiology governance arrangements viewed detailed that Mercy University Hospital (MUH) was the undertaking and had overall responsibility for the radiation protection of service users at MUCC. Reporting structures from staff working in MUCC to the MUH Radiology Department and up to the undertaking were well defined and were consistently articulated by staff to the inspector during the inspection.

Following discussions with staff and a review of documents and records, the inspector was assured that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. In addition, the inspector found that the undertaking had ensured that a medical physics expert (MPE) was involved in medical radiological practices which was evident in documentation reviewed and in discussions with staff.

Overall, the inspector was satisfied that there were effective management structures in place at MUCC to ensure the radiation protection of service users attending for X-ray at this facility.

Regulation 4: Referrers

The inspector was satisfied that referrals reviewed were from referrers as defined in the regulations. The inspector was informed that all referrals for X-rays at this facility were written by referrers working there. This meant that referrers were easily recognisable to practitioners and contactable by staff should the need arise.

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 a practitioner as per Regulation 5 took clinical

responsibility for medical exposures at MUCC.

Judgment: Compliant

Regulation 6: Undertaking

Documented radiology governance structures were reviewed as part of this inspection and showed clear lines of communication within corporate and clinical governance structures outlined. A radiation safety committee (RSC) was in place with responsibility for overseeing radiation protection and monitoring compliance with the regulations. A radiation safety action group (RSAG) was the operational sub-committee of the RSC. The designated manager for MUCC was also the operations director and undertaking representative for radiology services provided at MUH and MUCC and attended both the RSC and RSAG meetings. The minutes reviewed by the inspector demonstrated that there was an effective communication of MUCC radiation protection matters up to the chief executive officer of the MUH and the 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, thereby, meeting the requirements of this regulation.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The inspector was satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. There was also evidence to show that practitioners and the MPE were involved in the optimisation process as per the requirements of this regulation.

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 MUCC.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records and documentation reviewed by the inspector demonstrated that an MPE provided specialist advice at MUCC as per Regulation 20. Evidence gathered during the inspection demonstrated that an MPE carried out annual quality assurance (QA) testing, the most recent of which was completed in January 2023. The inspector saw evidence that acceptance testing was completed for medical radiological equipment before its first clinical use in 2021. Documentation viewed and discussions with staff provided evidence that an MPE took responsibility for optimisation and the collation of data to establish and review facility diagnostic reference levels (DRLs). RSC minutes showed that the MPE attended all the meetings held since February 2022. There was also evidence to demonstrate MPE involvement in the development and approval of radiation safety procedures, policies and protocols and analysis of any accidental and unintended exposures. From training records reviewed, the inspector was satisfied that an MPE contributed and delivered training to staff on various aspects of radiation protection, as required by the regulations.

Judgment: Compliant

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

The inspector was satisfied that an MPE was appropriately involved at MUCC, with the level of involvement proportionate to the radiological risk posed by the radiological practice as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector spoke with staff and management, reviewed documentation and visited the X-ray department during this inspection to assess the processes in place for the radiation protection of service users attending MUCC for medical radiological procedures.

From the evidence gathered, the inspector was satisfied that justification in advance was undertaken by a practitioner before each medical exposure which was recorded on the radiology information system (RIS). Facility DRLs for 2023 were displayed in

the X-ray control room and were reviewed each year by the MPE. Records viewed demonstrated that medical radiological equipment in use was kept under strict surveillance as required under Regulation 14.

The inspector found examples of good practice regarding clinical audit which were focused on improving justification and optimisation of commonly performed medical radiological procedures. There was also an effective system to manage radiation safety incidents. Staff informed the inspector that communication and training relating to an update to the process for managing radiation incidents had led to improvements in the reporting of near misses. In addition, staff explained how the learning from the analysis of incidents and near misses reported between November 2022 and October 2023 had resulted in the overall reduction of unjustified referrals.

Notwithstanding the good practices identified, the inspector found that action was needed to improve compliance with Regulation 13. While protocols for adult procedures were evident, consideration should be given to the development of paediatric protocols for X-rays performed on children 10 years or older at this facility. From a sample of medical radiological procedure reports reviewed, the inspector noted that the interim measure implemented at the time of the inspection did not go far enough to meet the requirements of Regulation 13(2). Management informed the inspector that actions had been taken to address this issue, including a recent upgrade to the RIS completed in early 2023. This upgrade was required before the application of a new software programme that once in place, should enable the transfer of information relating to the patient exposure onto the report of the examination and address this gap in compliance. Improvements were also required to ensure that up-to-date referral guidelines were available to staff as required under Regulation 13(3) which was not evident during the inspection.

Regulation 8: Justification of medical exposures

The processes for referring and justifying individual medical radiological procedures was documented in the facility policy and procedure for justification of exposure to ionising radiation which was consistent with the day-to-day practice described by staff to the inspector. From a sample of referrals reviewed, the inspector was satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data to inform the process of justification. A record demonstrating that justification by a practitioner had taken place was retained on the RIS and viewed by the inspector.

Information for service users on the risks and benefits associated with exposure to ionising radiation from X-rays were displayed in service user waiting areas visited.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector found that DRLs for adult and paediatric medical radiological procedures were established and staff described how they were referenced and used in practice. A DRL policy underpinned the process for the establishment, use and review of facility DRLs which was viewed by the inspector.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for adult standard radiological procedures provided at MUCC were available and viewed by the inspector. Staff informed the inspector that small numbers of paediatric X-rays were provided to children 10 years or over, however paediatric protocols were not available to view on the day of the inspection. Protocols relevant to this category of service users should be developed and made available to radiology staff as per the regulations.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. The inspector viewed a sample of patient records and found that while an interim measure had been implemented at this facility, it did not meet the requirements of this regulation. Management informed the inspector that there had been a recent upgrade to the RIS which was the first step required before a software solution could be implemented to address the gap identified. Improvements were also required to ensure that up-to-date referral guidelines were available to staff as required under Regulation 13(3) which was not evident on the day.

Areas of good practice were identified by the inspector in relation to clinical audit. Reports viewed demonstrated that staff at this facility were committed to improving the justification and optimisation of medical radiological procedures. For example, an audit carried out in March 2023 assessed the appropriateness of duplicate shoulder and clavicle imaging referrals and found that nine out of the 18 angled views reviewed were not needed. This issue was highlighted to referrers and a follow up audit in April found the rate of inappropriate referrals fell significantly. In addition, reject analysis audits reviewed the reasons why images were frequently rejected with an aim to minimise patient exposure to radiation and improve image quality. The results of these audits were shared with radiography staff via short tutorials and reminders and tips were communicated using a staff phone messaging application.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided as requested in advance of the inspection which was verified by the inspector on the day. 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. Acceptance testing and performance testing including maintenance and quality control checks of the equipment had been completed in line with Regulation 14(3). Therefore, the inspector was satisfied that the medical radiological equipment at this facility was kept under strict surveillance as per Regulation 14(1).

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following documentation review and discussion with staff, the inspector was satisfied that there was a system in place to record all radiation safety incidents. There was also evidence in minutes of meetings viewed to show that radiation incidents were regularly discussed at committees within the radiology and hospital governance structures. The inspector was informed that a recent update to the procedure for reporting and recording radiation incidents along with staff training on these changes had resulted in improvements in the levels of reporting of potential incidents at this facility. A summary of the incidents reported at the MUCC between 1 November 2022 and 24 October 2023 included the analysis of near misses. The majority of incidents were categorised as near misses and were related to referral errors such as laterality issues, incorrect anatomy or procedure or incorrect clinical information. The inspector noted from documentation viewed that the learning from the analysis and trending of radiation incidents and near misses gleaned from the data gathered was shared among staff including referrers which the inspector considered to be evidence of good practice for the radiation protection of service users.

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 | Not Compliant |
| Regulation 14: Equipment | Compliant |
| Regulation 17: Accidental and unintended exposures and significant events | Compliant |

Compliance Plan for Mercy Urgent Care Centre OSV-0007404

Inspection ID: MON-0041414

Date of inspection: 09/11/2023

Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking’s responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

| Regulation Heading | Judgment |
|--|---------------|
| Regulation 13: Procedures | Not Compliant |
| <p>Outline how you are going to come into compliance with Regulation 13: Procedures: Action 1 – Specific protocols to be established for paediatric patients presenting to the Mercy Local Injury Unit. Once the written protocols are completed and approved, information sessions and training will be provided to all radiographers by the MUCC CSR and RPO. To be completed by 30th June 2024.</p> <p>Action 2 –The following footer and link will be added to the report template for all radiology reports as an interim measure by 31st March 2024 “This patient has had a medical exposure to ionising radiation. Information relating to this exposure can be found at (https://www.hse.ie/eng/about/who/acute-hospitals-division/radiation-protection/radiation-doses-received-during-medical-procedures/). The patient / doctor can also contact the department where the procedure was carried out for the specific radiation dose associated with the procedure. Ionising Radiation is not used in ultrasound or MRI examinations”.</p> <p>Action 3 - Undertaking to seek/approve funding for purchase of appropriate electronic dose-management system compatible with existing RIS/PACS environment to enable information relating to patient exposure to form part of the report of the medical radiological procedure. The undertaking will implement the appropriate system once funding has been sanctioned from the HSE.</p> <p>Action 4 - As of 6/12/2023, the latest electronic version of the iRefer Guidelines was made available to all MUH-based referrers via electronic link on the radiology ordering system, and access verified. A hospital-wide communication was sent out on 21/12/2023 confirming that the imaging referral guidelines had been re-activated and were available for all referrers at the point of ordering.</p> | |



Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

| Regulation | Regulatory requirement | Judgment | Risk rating | Date to be complied with |
|------------------|--|-------------------------|-------------|--------------------------|
| Regulation 13(1) | An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients. | Substantially Compliant | Yellow | 30/06/2024 |
| Regulation 13(2) | An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure. | Not Compliant | Orange | 31/03/2024 |
| Regulation 13(3) | An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers. | Not Compliant | Orange | 21/12/2023 |