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:	Mercy University Hospital
Undertaking Name:	Mercy University Hospital
Address of Ionising Radiation Installation:	Glenville Place, Cork
Type of inspection:	Announced
Date of inspection:	14 August 2024
Medical Radiological Installation Service ID:	OSV-0007403
Fieldwork ID:	MON-0042863

About the medical radiological installation (the following information was provided by the undertaking):

The Mercy University Hospital Radiology Department provides an extensive range of radiological services comprising of both diagnostic imaging and interventional procedures. The Radiology Department performs 65,000 examinations annually, and provides imaging services for inpatients, outpatient, and emergency referrals. Out-of-hours emergency imaging provision is available 24 hours a day, 7 days a week.

The Radiology Department participates in clinical multi-disciplinary team meetings for Vascular Surgery, General Surgery/GI and Urology, General Medicine, Geriatrics, Oncology, and Neurology, and we are an approved training site for the National Diagnostic Radiology training programme.

Imaging services currently provided include:
-Plain-film digital radiographic imaging, including mobile radiography.
-Dedicated Vascular imaging in a Hybrid Theatre.
-Computed tomography (CT) scanning.
-Nuclear Medicine.
-Interventional Radiology.
-Ultrasound services.

The Mercy University Hospital Radiology Department performs approximately 43,000 examinations involving medical exposure to ionising radiation each year, and an additional 17,000 examinations in the off-site Mercy Injury 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, as amended. 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[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] 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] 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.

1. Governance and management arrangements for medical exposures:

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
Wednesday 14 August 2024	09:30hrs to 14:55hrs	Noelle Neville	Lead
Wednesday 14 August 2024	09:30hrs to 14:55hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

An inspection of Mercy University Hospital was carried out on 14 August 2024 by inspectors to assess compliance with the regulations at the hospital. As part of this inspection, inspectors followed up on the compliance plan from the previous inspection in August 2022 and noted that the actions set out had been completed. Inspectors visited the computed tomography (CT), general X-ray and nuclear medicine units, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking, Mercy University Hospital, demonstrated compliance during this inspection with Regulations 4, 5, 6, 8, 10, 11, 14, 16, 17, 19, 20 and 21 and substantial compliance with Regulation 13.

The undertaking, Mercy University Hospital, had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. Inspectors noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the hospital across a range of responsibilities. Inspectors were 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.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Mercy University Hospital and clear and effective management structures were in place for medical exposures to ensure the radiation protection of service users.

Regulation 4: Referrers

A document titled *Policy and Procedure for the Justification of Exposure to Ionising Radiation in Mercy University Hospital and the Mercy Injury Unit*, the most recent version of which was published in May 2024, was in place at Mercy University Hospital. This document outlined who was entitled to make a referral for a medical radiological exposure at the hospital. Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were 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 Mercy University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation including governance structure organograms (organisational chart that shows the structures and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Mercy University Hospital. Inspectors noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the hospital across a range of responsibilities. Inspectors 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) for the medical exposures carried out at Mercy University Hospital.

A radiation safety committee (RSC) was in place at Mercy University Hospital and this committee met twice a year. Inspectors reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership. This membership included the operations director who also acted as designated manager for the facility, radiologists, an MPE, a radiation protection adviser (RPA), a radiographic service manager (RSM) and a radiation protection officer (RPO). Inspectors noted that the committee had a standing agenda and items such as equipment, training, incidents and clinical audit were discussed. The committee was incorporated into local governance structures, chaired by a radiologist and reported to the hospital's clinical quality and safety governance committee which in turn reported to the undertaking. Inspectors were informed that there was also a radiation safety action group (RSAG) in place at the hospital. This group was a sub-group of the RSC and was responsible for operational issues relating to radiation protection. Its membership included the operations director, a radiologist, RPO, RSM, MPE and RPA.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Mercy University Hospital and clear and effective management structures were in place for medical exposures to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological exposures were only carried out at the hospital by individuals entitled to act as practitioner in the regulations. The undertaking, Mercy University Hospital, had retained the presence of radiographers in areas where medical exposures were conducted outside of the radiology department, for example theatre. In the absence of new training requirements being implemented as per Regulation 22, this was viewed as good practice to ensure the radiation protection of service users at the hospital. Practitioners and the MPE were found to be involved in the optimisation of medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure continuity of medical physics expertise at Mercy University Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Mercy University Hospital and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted MPE involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at the hospital. The MPE was a member of the radiation safety committee and radiation safety action group in place at the hospital. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relevant aspects of radiation protection. Inspectors noted that the MPE liaised with the hospital's radiation protection adviser

and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, inspectors were satisfied that the level of MPE involvement at the hospital was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the CT, general X-ray and nuclear medicine units at Mercy University Hospital, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the hospital. Inspectors noted compliance with each regulation reviewed with the exception of Regulation 13.

For example, there was evidence showing that each medical exposure was justified in advance as required by Regulation 8. Facility DRLs were established, regularly reviewed and used for each modality at the hospital. Staff at the facility ensured that medical radiological equipment was kept under strict surveillance as required by Regulation 14. In relation to Regulation 16, records of pregnancy inquiries for relevant service users were seen by inspectors. In addition, there was a process for identification, management, reporting, analysis and trending of radiation incidents and potential incidents as required by Regulation 17.

Inspectors noted that improvements had been made since the previous inspection in August 2022 in relation to meeting the requirement of Regulation 13(2). A technical solution had been implemented at Mercy University Hospital to meet compliance with Regulation 13(2). Inspectors reviewed a sample of reports for CT, general X-ray, nuclear medicine and theatre and found that information relating to the patient exposure formed part of the report for these modalities.

In relation to Regulation 13(4), inspectors noted that there was scope for improvement in aligning clinical audit to HIQA's national procedures, published in November 2023. For example, the development of an overarching clinical audit strategy, which should identify how clinical audit is prioritised, including based on risk and information from incidents or near misses. In addition, inspectors noted that further work was required in auditing the full clinical pathway of the service user, which should also be addressed in the clinical audit strategy.

Overall, noting that improvements were required to bring Regulation 13 into compliance, inspectors were satisfied that systems and processes were in place at the hospital to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users and displayed on posters throughout the facility.

A document titled *Policy and Procedure for the Justification of Exposure to Ionising Radiation in Mercy University Hospital and the Mercy Injury Unit*, the most recent version of which was published in May 2024, was in place at Mercy University Hospital. This document outlined the justification procedure in place at the hospital for each modality. Inspectors reviewed a sample of records for CT, general X-ray, nuclear medicine and theatre and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

A document titled *Policy and Procedure for the Use of Diagnostic Reference Levels (DRLs) and Patient Dose Audit*, the most recent version of which was published in May 2024, was in place at Mercy University Hospital. This document set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. Inspectors found that considerable work had been completed since the previous inspection in August 2022 in relation to establishing, regularly reviewing and using both adult and paediatric DRLs. Inspectors noted that facility DRLs were displayed prominently in the facility as a reference for staff.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Mercy University Hospital for standard radiological

procedures as required by Regulation 13(1). Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. Since the previous inspection in August 2022, inspectors noted that improvements had been made in relation to meeting the requirements of Regulation 13(2). A technical solution had been implemented at Mercy University Hospital to meet compliance with Regulation 13(2). Inspectors reviewed a sample of reports for CT, general X-ray, nuclear medicine and theatre and found that information relating to the patient exposure formed part of the report for these modalities. Referral guidelines were adopted at the hospital and were available to staff as required by Regulation 13(3).

Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's national procedures document, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). Inspectors reviewed a sample of audits carried out at the facility including audits of compliance with checks for pregnancy and breastfeeding status of female patients in nuclear medicine, evaluating CT KUB technique to ensure limitation of scan range and clinical information details provided on request for fluoroscopy screening. However, inspectors were informed that the current approach to clinical audit was ad-hoc and discussions were underway with regard to aligning to HIQA's national procedures. While inspectors noted that some work had been carried out in relation to clinical audit, there was scope for improvement in aligning to HIQA's national procedures. For example, the development of an overarching clinical audit strategy, which should identify how clinical audit is prioritised, including based on risk and information from incidents or near misses. In addition, inspectors noted that further work was required in auditing the full clinical pathway of the service user, which should also be addressed in the clinical audit strategy.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Mercy University Hospital as required by Regulation 14(1). Inspectors 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). There was a document titled *Radiation Safety Procedures*, which set out the quality assurance tests required and the frequency of tests for each modality in use. Inspectors reviewed records of regular performance testing and were 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, inspectors were 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

A document titled *Policy and Procedure for the protection of the unborn child arising from ionising radiation received during medical diagnostic procedure*, the most recent version of which was published in April 2024, was in place at Mercy University Hospital. This policy included information on the pregnancy procedures in place at the hospital including 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. From a sample of records reviewed, inspectors were satisfied that a referrer or practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing.

Inspectors also noted improvements since the previous inspection in August 2022 in relation to checking the breastfeeding status of relevant service users undergoing nuclear medicine procedures. A pregnancy and breastfeeding declaration form was in place for nuclear medicine procedures and from a sample of forms reviewed inspectors were satisfied that breastfeeding status was checked for relevant service users. In addition, inspectors noted multiple notices in the waiting areas 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

Inspectors were satisfied from discussions with staff and management and a review of documents that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended exposures was implemented at Mercy University Hospital. The incident management process in place at the hospital was outlined in a document titled *SOP for the Management of Radiation Incidents involving Service Users*, the most recent version of which was published in February 2022. This document included information on the requirement to notify HIQA of certain notifiable incidents and the timeframe for completing same. Inspectors noted that 11 incidents were reported to HIQA within the required timelines since the commencement of the regulations in 2019 and aligned to the procedure in place at the facility. Inspectors noted that a new form for reporting incidents and near misses was introduced at Mercy University Hospital with the aim of increasing reporting and efficiency of reporting for staff. Inspectors noted that

near misses and incidents had been tracked and trended since the introduction of the new form and this was viewed as an example of good practice to increase reporting at the hospital.
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, as amended. 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	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mercy University Hospital OSV-0007403

Inspection ID: MON-0042863

Date of inspection: 14/08/2024

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, as amended.

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	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: To ensure compliance with Regulation 13(4), whereby clinical audits are carried out in accordance with national procedures, MUH will: • Formally table the requirement at the Radiation Safety Committee (November 2024) where action points/timeframes will be finalised for implementation and subsequently managed through the radiation safety action group (RSAG) to ensure that the compliance date is met, • Identify a stakeholder group in order to develop a Clinical Audit Strategy in line with the HIQA 'National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation' document, • Ensure the strategy accounts for the full clinical pathway, • Fully implement the HIQA audit template	

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(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	31/03/2025