



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Our Lady's Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Manorhamilton, Leitrim
Type of inspection:	Announced
Date of inspection:	04 December 2024
Medical Radiological Installation Service ID:	OSV-0008718
Fieldwork ID:	MON-0043770

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

OLHM Radiology Department provides a broad range of general x-ray imaging to our (predominantly adult) patients in a digital environment. It includes both scheduled care for outpatient and GP patients and occasional unscheduled care for inpatients. The department comprises of 1 x general X-ray room. Adjacent to the Radiology Department is the Rheumatology Department where there is a DXA scan room. The DXA scanner provides bone densitometry scans for adult patients.

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 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 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 4 December 2024	09:30hrs to 15:30hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation, visited the X-ray and DXA scanning departments and spoke with staff and management.

The Health Service Executive (HSE) was identified as the undertaking. The Hospital Manager of Sligo University Hospital was identified to the inspector as the person with overall responsibility for the radiation protection of service users at Our Lady's Hospital. Our Lady's Hospital and Sligo University Hospital shared many radiation safety structures including a Radiation Safety Committee (RSC) and a Quality and Safety Executive Committee (QualSEC), they used the same National Integrated Medical Imaging System (NIMIS) and many practitioner staff members such as radiographers and radiologists served both sites. The inspector was also informed that radiation safety documentation pertained to both Our Lady's Hospital and Sligo University Hospital.

Some work was required by the undertaking in the version control and recording of updating and ratifying radiation safety related Policies, Procedures, Protocols and Guidelines (PPPG). Also, information relating to patient exposure did not consistently form part of the reports reviewed. This non compliance was previously identified in a related service, however, management was not aware of the lack of progress on this matter on the day of inspection. This must be addressed by the undertaking to come into compliance in relation to Regulation 13(2).

Following a review of documents and records, and speaking with staff, the inspector was assured that systems and processes were in place to ensure 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.

After speaking to staff and reviewing radiation safety related documentation and records, the inspector was assured that the responsibilities, advice and contributions of the Medical Physics Expert (MPE) were commensurate with the services provided at Our Lady's Hospital and satisfied the requirements of the regulations.

Overall, despite a few areas needing the attention of the undertaking to meet and maintain regulatory compliance the inspector was satisfied that staff at Our Lady's Hospital had implemented effective governance and management arrangements for the radiation protection of service users.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Our Lady's Hospital only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals were considered practitioners at Our Lady's Hospital.

Judgment: Compliant

Regulation 6: Undertaking

The HSE was identified as the undertaking and the Hospital Manager of Sligo University Hospital was identified to the inspector as the person with overall responsibility for the radiation protection of service users at Our Lady's Hospital. The inspector was informed that Our Lady's Hospital operated within the radiation safety architecture of Sligo University Hospital which meant that radiation safety related committees, a Radiology Information System (RIS) and Picture Archiving and Communication System (PACS) as well as radiation protection Policies PPPG were shared by both sites. The inspector reviewed minutes from the RSC and QualSEC committees and was satisfied that Our Lady's Hospital staff were well represented on these committees. The associated relevant platforms, responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection.

It was noted by the inspector that a number of PPPGs, relating to the radiation safety practice at Our Lady's Hospital, required update and ratification post inspection of a related service in December 2023. The associated compliance plan suggested that the Radiation Safety Procedures (RSPs), Terms of Reference of the RSC, the Diagnostic Reference Levels (DRLs) policy document and the special protection during pregnancy and breastfeeding policy document would be updated and ratified at the Hospitals RSC to be held in March 2024.

The inspector reviewed updated RSPs and TOR for the RSC. The RSPs were signed off in July of 2024 but were not mentioned or ratified according to the August RSC minutes reviewed. The inspector was informed that the TOR were also signed off after the related service inspection, the updated TOR were reviewed by the

inspector and the contents did align with this information. However, no date was recorded on this document nor was a record of its discussion or ratification included in the March or August RSC meeting minutes.

The DRL and special protection during pregnancy and breastfeeding PPPGs reviewed displayed approval dates in March of 2024 (14 and 15 March). However, records that these documents were discussed or ratified in the March RSC held on 30 March 2024 were not available in the minutes reviewed by the inspector. They were however noted in the August RSC meeting minutes as being updated.

The inspector noted the need to improve the radiation protection PPPG document version control as well as the recording of the formal discussion and ratification of these PPPGs in order to ensure the clear allocation of responsibility for the effective protection of service users.

The inspector also reviewed a number of DXA and X-ray imaging reports during the inspection. All DXA procedure reports had information relating to patient exposure forming part of the report. However, for the X-ray reports reviewed, some did not have any information relating to patient exposure. When information relating to patient exposure did form part of the X-ray report, Our Lady's Hospital used information developed by the HSE to differing degrees and some adapted reports reviewed only provided digital links to information. Therefore, despite having previously highlighting this issue to the undertaking, information relating to patient exposure remains absent from a number of reports reviewed.

Notwithstanding the gaps in compliance under Regulation 6, the inspector was informed that the RSC had recently increased resourcing around the minuting of the RSC proceedings and had added an action log to the meeting minutes. The inspector was supplied with draft minutes from the November RSC meeting which included the discussed additions which may aid the undertaking in the allocation of responsibility for, and oversight of, ongoing regulatory required actions. However, given the shared structures discussed, Our Lady's Hospital had failed to implement compliance plan actions provided to HIQA following the inspection of a related service which affected radiation safety PPPG and X-ray reports generated for Our Lady's Hospital. In addition, on the day of inspection, senior management at Our Lady's Hospital were unaware that the associated compliance plan actions in relation to X-ray reports had not been implemented as detailed and therefore the oversight of radiation protection matters needs to be improved.

Judgment: Not Compliant

Regulation 10: Responsibilities

Following the review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and

management, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner.

Similarly, the inspector was assured that the optimisation process involved the practitioner and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer at Our Lady's Hospital.

For the DXA service operated at Our Lady's Hospital, practical aspects of medical radiological procedures were delegated to individuals registered with the Nursing and Midwifery Board of Ireland. The associated professional registration, radiation safety training records and record of delegation were reviewed as part of the inspection process and were found to satisfy the requirements of Regulation 10(4) and 10(5).

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to the inspector by staff and management. All evidence supplied satisfied the inspector that Our Lady's Hospital had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, the inspector was satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was

both appropriate for the service and commensurate with the risk associated with the service provided at Our Lady's Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this hospital. Following a review of a sample of referrals for general X-ray and DXA scanning the inspector was satisfied that Our Lady's Hospital had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. The inspector was also satisfied that DRLs were established, used and reviewed.

An area noted as not meeting the requirements of the regulations on this occasion was related to Regulation 13(2), namely that information relating to patient exposure did not form part of all patients' reports reviewed on the day of inspection.

The inspector reviewed Our Lady's Hospital's approach to clinical audit and was not assured that current systems and processes surrounding clinical audit met the requirements of Regulation 13(4). While some work had commenced to come into compliance, the undertaking must address this non-compliance with the regulations.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. All records reviewed detailed that all testing was up to date and any issues identified were appropriately followed up or closed off as required. The inspector was provided with an up-to-date inventory which was verified on site.

Overall, despite some areas noted for the attention of the undertaking, the inspector was satisfied that systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users in Our Lady's Hospital.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. In line with Regulation 8, all referrals reviewed by the inspector were available 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.

The inspector visited the clinical area and observed multiple posters which provided service users with information relating to the benefits and risks associated with the radiation dose from X-ray procedures. The inspector was also informed that this information was available in pamphlet format.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRL information, the inspector was satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. The inspector visited the clinical areas and observed local facility DRLs displayed in the clinical areas.

The inspector was informed of a DRL review initiated after a local facility DRL exceeded the national DRL for one DXA procedure. The inspector was satisfied that the appropriate multidisciplinary investigation, implementation of corrective actions and subsequent patient dose review enabled Our Lady's Hospital to reduce the patient dose associated with this DXA procedure. This was seen as a positive use of information gained through DRL review to reduce patient dose, optimise the service provided and enhance service user outcomes.

Judgment: Compliant

Regulation 13: Procedures

Regulation 13(2) states that an undertaking shall ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector spoke with staff and reviewed a sample of imaging reports from X-ray and DXA procedures on the day of inspection. The inspector noted that medical imaging reports generated for DXA procedures all included information relating to patient exposure. However, of the eight X-ray reports reviewed, two had no information relating to patient exposure, three included patient exposure information as developed by the HSE and three reports had adapted the HSE information and subsequently only provided digital links to information relating to patient exposure, and therefore were not compliant with the regulations.

The inspector reviewed documentation and spoke to staff and management about Our Lady's Hospital approach to clinical audit. The inspector was informed that the role of Clinical Audit Coordinator had remained unfilled for a protracted period of

time which affected the Hospital's ability to align the Hospital's approach to clinical audit with HIQA's national procedures. Clinical Audit documentation reviewed as part of this inspection predated HIQA's publication of national procedures. The inspector noted that some work had commenced on developing an overarching strategy to better align with the national procedures, namely the development of a draft clinical audit guidance document. However, work was still required to align this document with national procedures, finalise and ratify this document and incorporate this approach to clinical audit into the day-to-day practice at Our Lady's Hospital.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory which was verified on site.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and imaging records reviewed satisfied the inspector that Our Lady's Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

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	Not 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

Compliance Plan for Our Lady's Hospital OSV-0008718

Inspection ID: MON-0043770

Date of inspection: 04/12/2024

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 6: Undertaking	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: (3) Radiation Safety document version controls have been updated to reflect their previous ratification by the RSC. Evidence & date of separate document ratification will be documented at upcoming RSC meeting scheduled for March 2025.</p> <p>A new Action Log has been developed to assist RSC members allocate responsibilities and associated timelines in completing tasks actioned at RSC meetings.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: (2) RSC Chair has already confirmed that all radiologists now have information relating to patient exposure on their radiological reports. RSC Chair will aim to have consensus on ‘wording’ of same by next RSC meeting in March 2025. RPA suggested to audit our compliance with section 13(2), which the RPO agreed to facilitate and provide evidence of same from mid 2025 onwards.</p> <p>(4) SUH Clinical Audit Support Team has been contacted regarding development of a strategy to comply with national procedures. A Clinical Audit Strategy document for radiological procedures involving ionising radiation to be ratified at next RSC Meeting in March 2025. This will include a first draft of an Audit schedule, regulatory & non-regulatory for further development and input as required.</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 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	07/03/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Substantially Compliant	Yellow	07/03/2025

	radiological procedure.			
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	07/03/2025