



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	St. Joseph's Care Centre
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Dublin Road, Longford, Longford
Type of inspection:	Announced
Date of inspection:	21 May 2024
Medical Radiological Installation Service ID:	OSV-0008323
Fieldwork ID:	MON-0042299

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

The X-ray department at St. Joseph's Care Centre, Longford, is a satellite unit under the governance of Regional Hospital Mullingar. It was refurbished in November 2023 to comprise of a digital X-ray system. It is located 42km from Mullingar and offers diagnostic imaging to all patients from the surrounding community. Patients can access the service by appointment from the surrounding GPs or via a walk-in service from the GP Minor Injury Treatment Centre which is located on site at the St Joseph's Campus.

On average, between 6000-7000 studies are performed annually. All types of general X-ray examinations are carried out including chest, abdomen, pelvis, spine and all extremity X-rays. The X-ray images are sent via NIMIS (National Integrated Medical Imaging System) to the radiology department at Regional Hospital Mullingar where they are reported remotely. This allows for rapid assessment and hot reporting if required for trauma patients from the treatment centre.

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
Tuesday 21 May 2024	10:00hrs to 13:15hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of the X-ray facility at St Joseph's Care Centre was carried out by an inspector on the 21 May 2024 to assess compliance with the regulations. The X-ray facility is under the management of Regional Hospital Mullingar and is located on the Health Service Executive (HSE) St Joseph's Care Centre campus along with a number of other services. The X-ray facility consists of one general radiography (X-ray) room.

The governance and management arrangements in place to ensure the safe delivery of medical exposures were reviewed on the day of inspection. The designated manager with responsibility for the radiation protection of service users was the general manager of Regional Hospital Mullingar. The designated manager was also the chair of the radiation safety committee (RSC). In addition, line management structures were reviewed and the inspector was satisfied that appropriate oversight measures were in place.

The inspector reviewed a sample of referrals and spoke with staff and management at the facility on the day of inspection. From the evidence reviewed the inspector was satisfied that only referrals for medical radiological procedures from those who were entitled to refer had been carried out. Similarly, only those entitled to act as a practitioner had taken clinical responsibility for medical exposures. The facility was also found to have appropriate medical physics involvement in line with the level of radiological risk.

Overall, the inspector was satisfied that there was a clear allocation of responsibility for the radiation protection of service users in place at the X-ray facility on the day of inspection which resulted in a high level of compliance with the regulations assessed during this inspection.

Regulation 4: Referrers

The inspector reviewed a sample of referrals for medical exposures that had been carried out and spoke with staff working at the facility. The inspector found that referrals were only accepted at the X-ray facility from those entitled to refer in line with Regulation 4. The main source of referrals were from local general practitioners (GPs) or from the GP Minor Injury Treatment Centre, which was also located at the St Joseph's Care Centre campus.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed. The inspector also spoke with staff working at the facility and found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The inspector spoke with staff and management working at the X-ray facility, and reviewed documentation and other records, to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures. The inspector found that the X-ray facility at St Joseph's Care Centre was under the governance and management of Regional Hospital Mullingar. The designated manager for the X-ray facility was the general manager of Regional Hospital Mullingar, and St Joseph's Care Centre X-ray facility was integrated into the radiation protection oversight arrangements that Regional Hospital Mullingar had in place which included its off-site radiology facilities.

A RSC was in place which included representation from the St Joseph's Care Centre X-ray facility. The inspector reviewed the terms of reference and minutes for the RSC and found that the designated manager is the chair of the RSC. From a review of line management structures, the inspector also found that the designated manager had oversight of the delivery of medical exposures as the clinical director and radiography services manager both reported directly to the designated manager. The RSC reported to the Health and Safety Committee.

The inspector was also satisfied that there was a clear allocation of responsibility to individuals, as defined in the regulations. For example, where responsibility for justification may be allocated to different professional groups, such as radiographers, this was documented in policies and communicated to the inspector by staff.

As part of the inspection, the implementation status of a clinical audit strategy and other requirements as specified in the *National Procedures for Clinical Audit of Radiological Procedures Involving Medical Exposure to Ionising Radiation*, were discussed. Staff communicated the steps that had been taken in conjunction with the lead for clinical audit at Regional Hospital Mullingar, to update documentation and integrate the radiology department into the hospital's existing clinical audit structures. While it is important that management at the facility prioritise development of a clinical audit strategy for medical exposures in line with regulatory requirements published in November 2023, the steps taken to date were noted by the inspector as positive action taken by staff in this facility. Clinical audits

completed in this facility were also reviewed and provided good examples of the benefits of clinical audit in supporting optimisation as described under Regulation 9.

Overall the inspector was satisfied that governance and management arrangements were in place to ensure the safe delivery of medical radiological procedures at the X-ray facility at St Joseph's Care Centre on the day of inspection.

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. Similarly, practitioners and a medical physics expert (MPE) were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. The practical aspects of medical radiological procedures were also found to be only carried out by radiographers at the facility.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from communicating with staff, and a review of documentation, that adequate processes were in place to ensure the continuity of medical physics expertise at the facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and spoke with staff at the hospital and was satisfied that arrangements were in place to ensure that the involvement and contribution of a medical physicist was in line with the requirements of Regulation 20. For example, medical physicists were found to be involved in quality assurance (QA) programmes, acceptance testing and staff training.

Judgment: Compliant

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

On the day of inspection, the inspector was satisfied from the evidence reviewed that a medical physicist was appropriately involved at the X-ray facility in line with the radiological risk.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at the St Joseph's Care Centre X-ray facility.

Signage in the form of posters containing information about the benefits and risks associated with medical exposure to ionising radiation and to raise awareness of pregnancy were observed in the waiting area. The inspector was satisfied that a practitioner carried out an inquiry as to the pregnancy status of service users, where appropriate, and this inquiry was recorded in writing.

Information relating to patient exposure was included on all of the reports of medical radiological procedures reviewed on the day of inspection. Written protocols were available for standard medical radiological procedures and diagnostic reference levels (DRLs) were found to be established for medical radiological procedures and were available for use by radiographers in the control area.

All referrals reviewed as part of the inspection were in writing and accompanied by sufficient information. Staff working at the facility informed the inspector that a practitioner justified all medical exposures in advance. However, a record of justification in advance by a practitioner was not found on all records reviewed on the day of inspection.

In addition, arrangements were found to be in place regarding recording incidents involving, or potentially involving accidental and unintended exposures to ionising radiation. However, while the facility was found to be compliant with the requirements of Regulation 17 that were assessed as part of the inspection, efforts to promote the importance of a good reporting culture should be taken to ensure that all staff are aware of the importance of reporting all actual or potential incidents so that these are available for analysis and trending.

The inspector reviewed documentation and records relating to the X-ray equipment at the facility and was assured that it was kept under strict surveillance with regards to radiation protection. The X-ray equipment had recently been upgraded to a new

digital unit and a quality assurance (QA) programme, which included performance testing had been established and was found to be maintained. An up-to-date inventory was provided in advance of the inspection.

Regulation 8: Justification of medical exposures

The inspector observed information about the benefits and risks associated with the radiation dose from medical exposures available to patients in the form of posters and information leaflets in the X-ray waiting area. A sample of referrals were reviewed by the inspector who found that these 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.

On the day of inspection, the inspector spoke with practitioners who explained how medical exposures were justified in advance and how this justification was recorded. The facility's *Policy for the Justification of Medical Exposures* was also reviewed by the inspector as part of this inspection. However, a record of justification in advance by a practitioner was not available for all medical radiological procedures reviewed over the course of the inspection. In order to ensure full compliance with the regulations, a record of justification in advance by a practitioner is available for each individual medical radiological procedure.

Judgment: Substantially Compliant

Regulation 9: Optimisation

The optimisation of medical exposures was discussed with staff on the day of inspection. Documentation and other records, such as policies and clinical audit reports, were also reviewed.

Staff described how they would optimise paediatric procedures to ensure the adequate production of diagnostic information to obtain the required diagnostic information. Staff also communicated the results and outcomes of a recent clinical audit which aimed to optimise paediatric patient doses through the introduction of extra beam filtration. Other clinical audits reviewed by the inspector and discussed with staff on the day focused on the appropriate use of grids for shoulder imaging to ensure that the as low as reasonably achievable (ALARA) radiation protection principal was adhered to. These examples of using clinical audit to facilitate optimisation were identified as good practice and emphasised the benefit of clinical audit as part of quality improvement.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation submitted in advance of the inspection and also spoke with staff and management, to determine how DRLs were established, used and reviewed at the X-ray facility at St Joseph's Care Centre. The inspector also observed DRLs were available for use in the control area of the X-ray room on the day of inspection.

Judgment: Compliant

Regulation 13: Procedures

The inspector reviewed a sample of medical radiological procedures and found that information relating to patient exposure formed part of the report of these medical radiological procedures as required by Regulation 13(2). The inspector also found that written protocols were established for standard medical radiological procedures.

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that an appropriate QA programme was in place to ensure that medical radiological equipment was kept under strict surveillance. An up-to-date inventory was also provided in advance of the inspection. The inspector noted that the equipment had been recently installed and acceptance testing had been completed by a medical physicist before first clinical use.

A QA programme, which included an annual QA assessment by an MPE, was implemented and maintained. Documentation reviewed on the day of inspection demonstrated that quality control was also routinely performed. This provided an assurance to the inspector that the medical radiological equipment at the facility is maintained in good working condition.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the X-ray waiting area at the facility. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations. Inspectors reviewed a sample of referral records and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing. Adherence of staff to the facility's pregnancy policy was also found to be audited.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

St Joseph's Care Centre X-ray facility was found to have a system in place to facilitate the reporting and recording of actual or potential accidental or unintentional exposures. The inspector spoke with staff and management about the process for reporting and was informed that no actual or potential accidental or unintended exposures have been reported recently at the facility.

While found to be compliant with the requirements of the regulations on the day of inspection, management at the facility should increase awareness and encourage a good reporting culture and assure themselves that all incidents, especially potential accidental and unintended exposures, are captured at the facility.

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	Substantially Compliant
Regulation 9: Optimisation	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

Compliance Plan for St. Joseph's Care Centre OSV-0008323

Inspection ID: MON-0042299

Date of inspection: 21/05/2024

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 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <ul style="list-style-type: none">• CPD session for staff to remind staff to adhere to Radiation Safety policies and procedures• Audits will continue to be carried out to ensure adherence to justification of ionising radiation examination policy• Results to be analysed and non-compliance addressed with individual staff members	

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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	30/09/2024
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	30/09/2024