



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 Hospital
Undertaking Name:	Beaumont Hospital
Address of Ionising Radiation Installation:	Springdale Road, Raheny, Dublin 5
Type of inspection:	Announced
Date of inspection:	03 April 2024
Medical Radiological Installation Service ID:	OSV-0007306
Fieldwork ID:	MON-0038628

About the medical radiological installation:

Beaumont Hospital incorporating St. Joseph's Hospital Raheny, is a large academic teaching hospital facility situated north of Dublin City centre. Diagnostic facilities specifically in St Joseph's Hospital's Radiology Department include: 1 Computed tomography (CT) scanner 1 X-Ray room, 1 portable X-ray unit, 1 Theatre C-arm, 1 DXA Scanner. In 2023 St. Joseph's Hospital performed approximately 10,245 radiology exams.

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
Wednesday 3 April 2024	09:00hrs to 17:00hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

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

St. Joseph's Hospital operates under the management of Beaumont Hospital which itself operates within a larger Hospital Group as an independent undertaking. The staff at St. Joseph's Hospital, with Beaumont Hospital, use a shared radiation safety committee (RSC) appointed by the undertaking to monitor and oversee the radiation protection of patients. A shared radiation protection unit (RPU) was also employed by staff at St. Joseph's Hospital as an operational radiation safety resource which reported into the RSC. The inspector was informed that local responsibility for the radiation protection of service users lay with the Beaumont Hospital Chief Executive Officer (CEO). The integration and involvement of senior management at St. Joseph's Hospital in the radiation safety structures of Beaumont Hospital were clearly articulated to the inspector on the day of inspection.

Following a review of documents and records, and after 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. The inspector was also satisfied that where practical aspects of medical radiological DXA procedures were delegated, the associated professional registration records, radiation safety training records and record of delegation were available and met the requirements of Regulations 10(4) and 10(5).

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 St. Joseph's Hospital and satisfied the requirements of the regulations.

Overall the inspector was satisfied that on this inspection, effective governance, leadership and management arrangements were in place with a clear and understood allocation of responsibility for the protection of service users undergoing medical exposures at St. Joseph's Hospital.

Regulation 4: Referrers

Following a review of referral documentation and a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was assured that

St. Joseph's Hospital had systems and processes in place to ensure that only referrals from appropriately recognised referrers were accepted.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of radiation safety procedure documentation and a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures at St. Joseph's Hospital.

Judgment: Compliant

Regulation 6: Undertaking

The inspector was informed that St. Joseph's Hospital was under the management of Beaumont Hospital which operated in the RCSI Hospital Group but Beaumont Hospital was an independent undertaking within this group. Therefore, Beaumont Hospital was identified as the undertaking with overall responsibility for the radiation protection of service users at St. Joseph's Hospital.

The staff at St. Joseph's Hospital and Beaumont used a joint RSC and RPU to ensure effective oversight, management and communication of all issues relating to the radiation protection of service users at St. Joseph's Hospital. The RSC reported to the Beaumont Hospital Board via Beaumont Hospital's CEO. St. Joseph's Hospital CEO was represented at the RSC meeting by the Clinical Services Director but also had direct lines of communication with the dual site Radiography Service and Business Manager. The inspector was also informed that the Director of Nursing (DON) at St. Joseph's Hospital attended RSC meetings as required and also reported into the clinical governance committee (CGC) which provided another pathway of communication with the Board and senior management at St. Joseph's Hospital.

The inspector was also informed that the RSC and RPU covered practice at both Beaumont Hospital and St. Joseph's Hospital and many members of both the RSC and RPU including radiology and medical physics staff maintained a presence at both facilities giving further assurances that all operational radiation safety issues could be considered by the relevant parties and escalated as necessary through multiple pathways described.

St. Joseph's Hospital employed a bespoke online digital platform which delivered radiation safety training for referrers and practitioners as well as an information

sharing platform which made all relevant radiation safety information, policies, procedures and guidance readily available to all staff. This platform was also used to clearly identify all relevant staff involved in the delivery of the ionising radiation service including referrers, practitioners, persons delegated the practical aspects of medical radiological procedures and MPEs. The inspector noted that learning from previous inspections at Beaumont Hospital had been applied at St. Joseph's Hospital, which helped to improve document version control and clear allocation of responsibility for the protection of service users at St. Joseph's Hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Following 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 staff at St. Joseph's Hospital ensured that all medical exposures took place under the clinical responsibility of a practitioner.

The inspector was assured that the optimisation process involved the practitioner and the MPE in all aspects of optimisation. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff.

The inspector was informed that aspects of medical radiological procedures were delegated by a practitioner to individuals, registered with the Nursing and Midwifery Board of Ireland, in the DXA scanning unit at St. Joseph's Hospital. Records of the delegation and associated professional registration were available and reviewed as part of the inspection.

The inspector was assured by the training records supplied that St. Joseph's Hospital had a system in place to ensure that all training requirements, as specified by the Nursing and Midwifery Board of Ireland, were satisfied. Training records were well maintained by the undertaking and staff and included initial training records and records in relation to continuing education after qualification.

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 and all evidence

supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at St. Joseph's Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. 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 and the training of practitioners. The inspector noted that the medical physics staff played an important role in the content and delivery of bespoke online and in person practitioner training at St. Joseph's Hospital.

The inspector was assured that the involvement and contribution of MPEs at St. Joseph's Hospital was in line with the requirements of Regulation 20.

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 St. Joseph's Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure the safe delivery of medical exposures to service users at this hospital.

Following a review of a sample of referrals from all areas providing medical exposures the inspector was satisfied that all referrals were accompanied by the

relevant information, justified in advance by a practitioner and that practitioner justification was recorded.

The inspector was satisfied that the undertaking employed a systematic approach to ensure the special protection during pregnancy of the relevant service users. The inspector was also assured that DRLs were established, used and reviewed at St. Joseph's Hospital. Similarly, records of acceptance and performance testing for all radiological equipment at the hospital satisfied the inspector that the undertaking had kept all medical radiological equipment under strict surveillance.

One area identified as not meeting the requirements of the regulations from their transposition in 2019 was the inclusion of information relating to patient exposure consistently forming part of the report. However, the inspector was satisfied that processes had been implemented at the time of inspection to address this area of non-compliance.

The inspector was satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures. Good practice in relation to the training of referrers was observed which was noted as having the potential to reduce the amount of incidents associated with procedure referrals.

Overall, the inspector was satisfied that the area of non compliance identified did not pose a risk in relation to the safe delivery of medical exposures at St. Joseph's Hospital .

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals from a number of clinical areas on the day of inspection. The inspector was satisfied that the sample of referrals for X-rays, DXA, CT and fluoroscopic procedures were in writing, stated the reason for requesting the procedure and were accompanied by sufficient medical data to satisfy the practitioner that the procedure was justified. Evidence reviewed also 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.

The undertaking at St. Joseph's Hospital developed and provided bespoke training for referrers and all staff involved in the provision of ionising radiation. The inspector noted that this training was a two-tier system with tier one providing a component aimed predominantly at referrers. The inspector was also informed that non consultant hospital doctors (NCHDs) were not given access to medical radiological procedure referral rights until they demonstrated proof of completion of tier one training. This was seen as a positive initiative which could improve the

quality of subsequent referrals at St. Joseph's Hospital through elimination of inadequate, incorrect or inappropriate referrals.

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 a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation and records pertaining to DRLs and spoke with staff. St Joseph's Hospital had established DRLs across all imaging modalities and had compared these local facility DRLs to national DRLs as required by the regulations. The inspector was assured that in all cases where local facility DRLs exceeded nationally established DRLs the appropriate multidisciplinary investigations had taken place satisfying all requirements of Regulation 11. The inspector also visited the clinical area and observed multiple examples of local facility DRLs displayed in the general X-ray department, DXA department and CT department.

Judgment: Compliant

Regulation 13: Procedures

The inspector reviewed written protocols for every type of standard medical procedure for each type of equipment and relevant patient categories. The inspector noted that learning from a previous inspection at Beaumont Hospital and associated improvements in document stewardship had been applied to written protocols at St. Joseph's Hospital and that all protocols reviewed on the day included approval dates, review dates, document owners and document reviewer records.

The inspector noted that the inclusion of information relating to patient exposure on every report, as communicated from the HSE, had been discussed by the RSC in September 2023 via the radiation protection advisor's report. The inspector reviewed a sample of reports for DXA, general X-ray, CT and fluoroscopic medical radiological procedures and observed that records generated before February 2024 did not routinely include information relating to patient exposure. The inspector was subsequently informed that interim solutions presented in September were adopted by all relevant staff after internal review, discussion and subsequent staff communication in February 2024. The inspector was assured that information relating to the patient exposure formed part of the report for all reports generated since February 2024. The undertaking is responsible for ensuring that any person employed or engaged by it complies with the regulations and it is essential that the

undertaking ensures that the processes in place to meet the requirements of Regulation 13(2) are maintained in this hospital.

Judgment: Substantially Compliant

Regulation 14: Equipment

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 appropriately followed up or closed off as required. The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Following documentation and imaging record review and after speaking with staff, the inspector was satisfied that St. Joseph's Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status and the answer recorded. Radiation safety documentation clearly identified the procedures for which appropriate service user questioning and records were required. As part of the inspection, records of pregnancy questioning were reviewed for procedures carried out in general X-ray, CT and theatre and all records satisfied the requirements of Regulation 16.

Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing diagnostic medical exposures in this facility. The inspector was satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or

unintended medical exposures had been implemented and maintained by St. Joseph's Hospital.

The inspector also noted that the good practice in relation to the training of referrers as discussed under Regulation 8 may, in part, account for the low number of reportable, non reportable and near miss incidents in relation to inadequate, incorrect or inappropriate referrals for medical exposures at St. Joseph's 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 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	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 St Joseph's Hospital OSV-0007306

Inspection ID: MON-0038628

Date of inspection: 03/04/2024

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 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	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The inclusion of patient dose information on radiology reports was discussed at the RSC in September 2023 and agreed we need to engage with the Radiologist grouping and automate the process. Following a number of engagements it was agreed to add the information into all reporting templates for the Radiologists by our interim PACS manager in January 2024. This was completed and as mentioned in this report the inspector was assured the information formed part of the report for all reports since February 2024. In order to maintain compliance with this regulation a clinical audit has been added to the department clinical audit template each quarter to ensure the information is on all reports.	

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(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	29/02/2024