



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	The Rotunda Hospital
Undertaking Name:	The Rotunda Hospital for Poor Lying In Women
Address of Ionising Radiation Installation:	Parnell Square, Dublin 1
Type of inspection:	Announced
Date of inspection:	25 September 2024
Medical Radiological Installation Service ID:	OSV-0007725
Fieldwork ID:	MON-0043623

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

The Rotunda Hospital is a Voluntary Hospital located in the North Inner City. The Rotunda Hospital is part of the Royal College of Surgeons Ireland (RCSI) Hospital Group ensuring it remains committed to the aim of the RCSI group. Rotunda Hospital is a major teaching hospital and its academic partner is the RCSI. The Rotunda Hospital provides obstetric, gynaecological and neonatal care for the catchment area. This care is delivered in day care, inpatient, outpatient, diagnostic and support services. A service level agreement exists between Beaumont Hospital and Rotunda Hospital to supply Medical Physics Services. The Radiology Department provides diagnostic imaging for: In-patients - Adult and Neonatal, Out-patients –Adults and Neonatal, Emergency Department, Ambulatory Gynae Unit (AGU), Neo Natal Intensive Care Unit (NICU), High Dependency Unit (HDU) Adult and Neonatal. The department provides 24/7, 365 days emergency diagnostic service for the hospital. The department has four Consultant Radiologists shared between Connolly Hospital and CHI at Temple Street. The department has one general room comprising of ceiling mounted x-ray tube and fluoroscopy table, two mobile radiography machines both which are direct digital.

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 25 September 2024	10:00hrs to 15:00hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation, visited the X-ray department and spoke with staff and management. On this inspection, the inspector found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures.

The Rotunda Hospital operated within a larger Hospital Group but operated as a separate undertaking within this group. Local responsibility for the radiation protection of service users lay with the Hospital Board and Hospital General Manager (GM). The Rotunda Hospital used a Radiation Safety Committee (RSC) to ensure regulatory compliance but also employed alternate platforms within the governance structure to ensure that radiation safety related issues could be considered and escalated appropriately.

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 The Rotunda Hospital and satisfied the requirements of the regulations.

Overall, the inspector was satisfied that the undertaking had implemented and maintained effective governance and management arrangements through the clear and effective allocation of responsibility for the radiation protection of service users at The Rotunda Hospital.

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 The Rotunda Hospital only accepted referrals from appropriately recognised referrers. In line with the regulations, advanced nurse practitioners were also considered referrers in this facility and the specific circumstances in which they could act as referrers were clearly articulated to the inspector by staff.

Judgment: Compliant

Regulation 5: Practitioners

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 had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all medical exposures carried out at The Rotunda Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by the undertaking at The Rotunda Hospital. The Rotunda Hospital for Poor Lying in Women was identified as the body corporate undertaking for The Rotunda Hospital. The undertaking's Board of Governors delegated operational running of the hospital to the Executive Management Team (EMT) while retaining overall responsibility for the radiation protection of patients. The Rotunda Hospital is part of the Royal College of Surgeons Ireland (RCSI) Hospital Group, however, it operates as a separate undertaking within this group.

The GM was identified as the individual with responsibility for the radiation protection of patients and this role was supported, as necessary, by the Master and Chief Executive Officer (CEO) of the hospital. The Rotunda Hospital used a RSC and both the GM and Master were members of this committee with the Master as sitting Chair. This committee reported directly to the Board but the inspector was also informed that the Quality and Safety Committee provided an alternate platform for consideration of radiation safety issues as required. Documents reviewed and staff spoken with on the day of inspection demonstrated the multiple formal and informal pathways within the Hospital's governance structures for the consideration and escalation of all radiation safety issues.

The 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 and based on the evidence gathered as part of this inspection, the inspector was assured that the undertaking had provided a clear allocation of responsibility for the protection of service users from medical exposures to ionising radiation.

Judgment: Compliant

Regulation 10: Responsibilities

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 ensured that all medical exposures took place under the clinical responsibility of a practitioner and that the optimisation process involved the practitioner and the MPE. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer at The Rotunda Hospital.

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 the details were available in a service level agreement (SLA) reviewed as part of this inspection. All evidence supplied satisfied the inspector that the undertaking 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. The inspector noted that the medical physics staff played an important role in the content and delivery of face-to-face and virtual practitioner training at The Rotunda Hospital.

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 The Rotunda 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 review of a sample of referrals for general X-ray, fluoroscopy and mobile radiography the inspector was satisfied that The Rotunda 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 satisfied that DRLs were established, used and reviewed. The inspector also noted that DRL reviews were used by The Rotunda Hospital to appropriately investigate low patient doses which, in one case, subsequently led to the standardisation of good radiation safety practice. Staff spoken to also articulated plans to share this information with other Hospital Group sites which was considered a positive use of patient dose optimisation information.

One area of improvement identified by the inspector related to Regulation 13(2), namely that the information relating to patient exposure did not consistently form part of all patients' reports as required. However, it was noted that nationally developed solutions had been incorporated into some reports reviewed on the day but some gaps were identified in adapted versions of the national solution used by The Rotunda Hospital.

The inspector reviewed The Rotunda Hospital's approach to clinical audit and was satisfied that the undertaking had ensured that clinical audits were carried out in accordance with the national procedures for clinical audit established by HIQA in 2023. The inspector noted good practice in relation to the development and implementation of a robust clinical audit strategy which fully incorporated radiation safety related clinical audits. The undertaking had also an effective system for the dissemination of relevant clinical audits to all staff at The Rotunda Hospital.

The inspector reviewed documentation and records of accidental and unintended exposures and significant event near misses and was assured that the undertaking had employed measures to minimise the probability and magnitude of accidental or unintended exposures of service users. Records reviewed also satisfied the inspector

that the appropriate systems were implemented at The Rotunda Hospital for the record keeping and analysis of such events.

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, the inspector was assured that The Rotunda Hospital had appropriate systems in place to support the safe delivery of medical exposures.

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, bespoke for The Rotunda Hospital, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. These posters also used QR (quick response) codes, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures at The Rotunda Hospital. Pamphlet versions of these posters were also available to service users throughout the radiology department and the combination of formats in which the benefits and risks associated with a range of medical exposures was available was seen as a comprehensive approach to risk-benefit communication.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRLs, 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 hospital. In the clinical area multiple examples of local facility DRLs were displayed for staff.

The inspector spoke to staff in relation to the review of patient dose for the Histosalpinogram (HSG) procedure. Staff informed the inspector that when compared to National DRLs, produced by HIQA, it was noted that the associated dose at The Rotunda Hospital was particularly low. Staff informed the inspector that this initiated a multidisciplinary review to ensure the adequacy of the associated image quality. The investigation determined that image quality was sufficiently diagnostic and low patient dose was due to operator expertise combined with good radiation safety practice. This was seen as a positive use of regulatory required dose reviews to promote good radiation safety practice and patient dose optimisation. Staff indicated that work was currently being considered to disseminate the relevant information to other Hospital Group sites to help facilitate patient dose optimisation elsewhere.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for all medical radiological procedures. A sample of these were reviewed by the inspector. Staff spoken with in the clinical areas clearly articulated how these protocols were made available to them.

The inspector reviewed documentation and spoke to staff and management about The Rotunda Hospital's approach to clinical audit and was satisfied that clinical audits were carried out in accordance with national procedures established by HIQA. The Rotunda Hospital employed a robust approach to clinical audit and radiation safety related audits were very well integrated into this corporate system. The Hospital's audit system included a registration and approval process, established action plans for completed audits and had a mechanism to identify and escalate serious concerns to the EMT. The Rotunda Hospital also ensured the dissemination of all relevant audit information through monthly clinical audit reports, quarterly clinical audit results meetings and biannual clinical audit and research meetings. Documents reviewed also highlighted an internally developed *'10 steps to success'* for clinical audit in The Rotunda Hospital which provided staff with a useful resource helping include all staff in the clinical audit process. The inspector noted that the strong corporate approach to clinical audit encouraged and supported all staff in the clinical audit process as well as satisfying all regulatory requirements in relation to clinical audit of radiological procedures involving medical exposure to ionising radiation.

The inspector spoke with staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. The inspector noted that medical imaging reports generated for The Rotunda Hospital used information relating to patient exposure information developed by the HSE. While all reports reviewed based the subsequent information relating to patient exposure on those developed by the HSE, some adapted reports reviewed only provided digital links to

information. Therefore, gaps were identified in these adapted versions of the national solution used by The Rotunda Hospital. This was seen as an area for improvement that must be addressed to ensure compliance with Regulation 13(2).

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. Evidence was also available to show that any issues identified as part of the equipment QA had been followed up in a timely manner and the inspector noted the quality and availability of equipment specific records reviewed on the day.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and imaging records reviewed satisfied the inspector that The Rotunda 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

Regulation 17: Accidental and unintended exposures and significant events

From speaking with staff and reviewing local incident records and associated documentation, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at the RSC and other quality and safety platforms, thus the undertaking had oversight of incidents in this Hospital. The inspector was also 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 The Rotunda Hospital. However, the inspector noted that the document *Radiation Safety Incident Reporting* could have more information for staff on categorisation of radiation incidents, while this was not considered a non-compliance in this instance, it was noted as an area for improvement.

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 The Rotunda Hospital OSV-0007725

Inspection ID: MON-0043623

Date of inspection: 25/09/2024

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: The medical imaging reports have now been updated to reflect the HSE recommendation more accurately. The dose report was updated and implemented by RPO/PACS Manager on 25th September and approved by the Radiation Safety Committee on 7th November 2024.	

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	25/09/2024