Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Roscommon University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Athlone Road, Ardsallagh More, Roscommon
Type of inspection:	Announced
Date of inspection:	25 August 2022
Medical Radiological Installation Service ID:	OSV-0007372
Fieldwork ID:	MON-0036810

About the medical radiological installation:

Roscommon University Hospital is a model 2 hospital under the Acute Medicine Programme which provides general, computed tomography (CT) and ultrasound services. The Hospital has 63 inpatient beds, a Medical Assessment Unit and Injury Unit as well as extensive day and endoscopy services. The Radiology Department consists of two general rooms, one orthopantomogram (OPG) machine, one mobile machine, one CT scanner and one Ultrasound machine. Staffing includes two Radiologists, with one on site at a time, one Radiology Services Manager (RSM), one Clinical Specialist in CT, one Clinical Specialist in Ultrasound and just over five whole time equivalent Senior Radiographers. The Radiology Department provides a service to in patients, out patients and GP referrals.

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 inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. 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
Thursday 25 August 2022	09:30hrs to 16:00hrs	Lee O'Hora	Lead
Thursday 25 August 2022	09:30hrs to 16:00hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the computed tomography (CT) and general radiography departments and spoke with staff and management. On this inspection, inspectors found effective governance, leadership and management arrangements in place with a clear allocation of responsibility for the protection of service users undergoing medical exposures. Roscommon University Hospital operated within the Saolta Hospital Group and the Health Service Executive (HSE) was the undertaking with overall responsibility for the radiation protection of service users.

Local responsibility for the radiation protection of service users lay with the hospital General Manager (GM) who communicated upwards through the Saolta Group to the HSE. Roscommon University Hospital used a Radiation Safety Committee (RSC) to direct and enforce radiation safety policy locally but also employed alternate platforms within the governance structure to ensure that radiation safety related issues could be considered and escalated appropriately.

While inspectors were satisfied that the allocation of responsibility was clear as articulated by staff and management and observed throughout the inspection, documentation in relation to the allocation of responsibility for the protection of service users must be reviewed and updated to align with both the current regulatory language and reflect day-to-day practice at Roscommon University Hospital.

Following review of documents and records, and speaking with staff, inspectors were 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, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

Inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, inspectors were assured that the level of involvement of MPEs was proportionate to the level of radiological risk at the installation and that MPEs took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations. However, the HSE should ensure that MPE arrangements are formalised to ensure the continuity of medical physics expertise at Roscommon University Hospital.

Overall, despite some areas for improvement, inspectors were satisfied that the allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at Roscommon University Hospital.

Regulation 4: Referrers

Following review of documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were assured that Roscommon University Hospital only accepted referrals from appropriately recognised referrers.

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 during the inspection, inspectors were satisfied that this facility had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Senior management who spoke with inspectors during the inspection outlined a clear allocation of responsibility for the radiation protection of service users by the HSE operating at Roscommon University Hospital. Internal and external responsibilities and lines of communication regarding the effective protection of service users were clearly articulated to the inspectors during the course of the inspection.

The HSE was the undertaking with overall responsibility for the radiation protection of service users. Roscommon University Hospital operated within the Saolta Hospital Group and the GM of the hospital reported to the undertaking via the Chief Operations Officer (COO) and Chief Executive Officer (CEO) of the Saolta group.

Roscommon University Hospital employed a RSC, to direct and enforce radiation safety policy in line with all relevant laws and regulations, and best management practices. The GM was a member of the RSC and was identified to inspectors as the person with responsibility for the radiation protection of service users at Roscommon University Hospital. Inspectors were informed that other platforms were used within the governance structure of Roscommon University Hospital to ensure radiation safety related issues could be considered, for example the GM also attended monthly Quality and Safety meetings as well as Directorate meetings which took place three times per year.

However, while the document *Radiation Safety Procedures Including Standard Operating Procedures* incorrectly assigned the GM as the undertaking, inspectors were satisfied after speaking with staff and management that this document did not accurately reflect the understanding of the hierarchy of responsibility or day-to-day practice at Roscommon University Hospital.

The document *Radiation Safety Procedures Including Standard Operating Procedures* also incorrectly detailed who was responsible for the justification of practices and included the concept of accepting referrals from non referrers. These concepts are not based on current regulations and documentation needs to be updated to reflect current regulations. This being said inspectors were satisfied that referrals were only accepted from referrers entitled by the regulations as noted under Regulation 4.

While inspectors were satisfied that the allocation of responsibility was clear as articulated by staff and management and observed throughout the inspection, documentation in relation to the allocation of responsibility needs to be reviewed and updated to ensure it aligns with current Regulations and reflects day-to-day practice at Roscommon University Hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From speaking with staff and management and reviewing the radiation safety procedure documentation and a sample of referrals for medical radiological procedures, inspectors were satisfied that the undertaking had ensured that all medical exposures took place under the clinical responsibility of a practitioner. Similarly, inspectors were 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.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, inspectors were informed that MPE services were supplied to Roscommon University Hospital by the medical physics department from another Saolta Hospital Group hospital. The mechanisms in place to provide continuity of MPE expertise at the hospital were described to inspectors by staff and management who spoke with inspectors on the day of inspection. Staff who spoke with inspectors reported that they had adequate access to medical physics expertise, however inspectors were informed that a formalised arrangement for the provision of MPE

services was not in place at the time of inspection. Formalising the arrangements in place between Roscommon University Hospital and the hospital whose medical physics department provide the MPE service would provide the undertaking and Roscommon University Hospital with assurance that the current MPE service will be maintained and assure the undertaking of the contingencies to guarantee the continuity of MPE service provision.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors were 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. Inspectors were assured that the involvement and contribution of MPEs at Roscommon University 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, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Roscommon University Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by Roscommon University Hospital ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals from a range of departments, inspectors were assured that the 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. Service user information on radiation risks was available throughout the radiology department on the day of inspection. The additional use of quick response (QR) codes and associated online radiation risk benefit information was seen as a positive use of Saolta Group resources to improve the amount and type of information relating to the risks and benefits of medical radiation doses available to service users.

DRLs were established, used and reviewed. For example, when doses were identified as above national figures for one particular procedure, Roscommon University Hospital investigated appropriately and implemented corrective actions subsequently reducing patient dose. Inspectors were satisfied that the undertaking had also 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. This system was overseen by the GM and facilitated by the Quality and Safety team in conjunction with the Radiology Department. Records reviewed highlighted this comprehensive approach of the hospital to the analysis and mitigation of accidental and unintended exposures and significant events.

Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the hospital had implemented a quality assurance program and kept its radiology equipment under strict surveillance. Inspectors were also satisfied that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded however, the associated policy documentation must be reviewed and updated to align with current regulations and day-to-day practice. Another area of improvement, noted by inspectors, related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of patients' reports as required by the regulations.

Overall, inspectors were assured that Roscommon University Hospital had effective systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors spoke with staff and management who explained how medical exposures are justified in advance of the medical exposure. All referrals reviewed by inspectors on the day of inspection 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 record of justification of medical radiological procedures that was recorded by a practitioner in advance of the procedure was also available for all medical radiological procedures reviewed. The undertaking employed a radiology information system (RIS) and picture archiving and communication system (PACS) which was independent of the national integrated medical imaging system (NIMIS) but shared with a larger hospital within the Saolta Hospital Group. Although not connected to the NIMIS, inspectors were satisfied that previous diagnostic information was sought where practicable as staff consistently articulated the methods used at Roscommon University Hospital to obtain previous diagnostic information.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from general radiography and CT. Roscommon University Hospital also used a novel method to provide service users with information relating to the benefits and risks of medical exposures to ionising radiation by displaying QR codes in poster format throughout the radiology department. Once the QR code is scanned using a smart phone or similar device the service user is directed to an online video explaining patient radiation dose.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of documentation and records, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed examples of local facility DRLs displayed in the CT control room.

Where local facility DRLs exceeded national values, the records of investigation outcomes and corrective actions were available for review. Inspectors were assured that for a single CT procedure, when the local facility DRLs exceeded national values a multidisciplinary team implemented the necessary corrective actions and subsequently lowered the patient dose through protocol review and scan range reduction.

This use of local DRL review to closely monitor, and in certain cases, optimise service user radiation doses was seen as a positive use of regulatory required reviews to optimise service user outcomes.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for standard radiological procedures carried out at Roscommon University Hospital were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff in the clinical areas who spoke with inspectors clearly articulated how these protocols were made available to them and were able to access these on request.

Inspectors spoke to staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. Inspectors observed and were informed by staff and management that information relating to patient exposure did not form part of the report for medical imaging procedures carried out at Roscommon University Hospital. Although the HSE has proposed measures for facilities using the NIMIS to come into compliance with Regulation 13(2), these were not available to Roscommon University Hospital as they operate on a separate PACS that is not part of NIMIS. To ensure compliance with Regulation 13(2) the HSE and Roscommon University Hospital must consider a solution for Roscommon University Hospital to come into compliance with this regulation.

The specific referral guidelines used in this facility were documented in radiation safety documentation supplied in advance of this inspection and inspectors were informed and observed that these referral guidelines were made available digitally for the relevant staff on the hospital's intranet system.

Documentation and records reviewed satisfied inspectors that Roscommon University Hospital routinely audited various aspects of radiation safety practice including medical procedure justification, protocol compliance, pregnancy policy compliance, triple ID check compliance and patient dose.

Judgment: Substantially Compliant

Regulation 14: Equipment

Information relating to equipment including policies and procedures, MPE quality assurance records, MPE acceptance testing records, radiographer's monthly, weekly and daily checks were reviewed by inspectors. From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. From the inventory of equipment provided to inspectors, further documentation reviewed on site and after speaking with staff, inspectors were assured that all QA was up to date at the time of inspection.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Processes observed and records reviewed on site satisfied inspectors that the undertaking had systems in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with regulatory requirements.

Multilingual posters were observed throughout the department. Inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

However, the document *Policy for the Protection of the Unborn Child arising from Ionising Radiation received during Medical Diagnostic Procedures in RUH* used the term prescriber as opposed to referrer and the associated definition was based on no longer current regulations. This document did not include Radiographers in its definition of practitioners, while staff and management consistently articulated that Roscommon University Hospital aligned with current regulations and considered Radiographers as practitioners. Finally, this document allowed for staff other than practitioners to inquire and record pregnancy status, while staff and management consistently articulated that Roscommon University Hospital aligned with current regulations and only practitioners inquired and recorded pregnancy status. The undertaking must ensure that all documentation is updated to align with current regulations and day-to-day practice at Roscommon University Hospital.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, incident records and speaking with staff inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Inspectors were 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. Minutes of the RSC were reviewed by inspectors and detailed that accidental and unintended exposures and significant events were a standing agenda point.

Staff who spoke with inspectors consistently articulated the process used locally for the reporting and recording of accidental and unintended exposures and significant events. Inspectors were assured that Roscommon University Hospital took a multidisciplinary approach to the investigation and close out of all incidents, with good oversight by the GM and the effective use of the Risk Manager and Quality and

Safety team.

Roscommon University Hospital's approach to the management of accidental or unintended medical exposures and significant events was considered comprehensive and enhanced the facility's ability to deliver a safe and effective medical imaging service.

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	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Substantially 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	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Roscommon University Hospital OSV-0007372

Inspection ID: MON-0036810

Date of inspection: 25/08/2022

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiation safety procedures including standard operating procedures have been updated to reflect the HSE as the Undertaking and to clarify the justification and referral process according to the latest legislation. The updated document will be brought to the Radiation Safety Committee and Quality and Safety Committee for approval. Time frame: November 2022	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: A Service Level Agreement is being prepared by the General Manager for the provision of Medical Physics Expert Services to Roscommon University Hospital by the Medical Physics and Clinical Engineering Department at Galway University Hospital. This will be approved by the Radiation Safety Committee. Time frame: November 2022	
Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: Discussions are underway with our PACS provider in order to find a solution in order to comply with this Regulation. An initial meeting was held on 11th October 2022. Time frame: December 2022	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: The Standard Operating Procedure for the Protection of the Unborn Child arising from Ionising Radiation received during Medical Diagnostic Procedures in RUH has been updated to align with current regulations and day-to-day practice. The updated document will be brought to the Radiation Safety Committee and Quality and Safety Committee for approval. Time frame: November 2022	

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.	Substantially Compliant	Yellow	14/11/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	31/12/2022

	procedure.			
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	14/11/2022
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	14/11/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this	Substantially Compliant	Yellow	31/12/2022

	Regulation.			