

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:	17 June 2026
Medical Radiological Installation Service ID:	OSV-0007372
Fieldwork ID:	MON-0049578

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

Roscommon University Hospital is a model 2 hospital under the Acute Medicine Programme. We provide general and CT and ultrasound for Roscommon University Hospital. The Hospital has 66 inpatient beds, a Medical Assessment Unit and Injury Unit as well as extensive day and endoscopy services. GPs can refer in for X-ray. The Radiology Department consists of 2 general rooms, 1 OPG machine, 1 mobile machine, 1 CT scanner and 1 Ultrasound machine. Staffing includes Radiologists, an RSM1, Clinical Specialist Radiographers and Senior Radiographers. We carry general x-rays, CT scans and Ultrasound scans on both in and out patients, including 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, 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 17 June 2026	09:30hrs to 15:00hrs	Lee O'Hora	Lead
Wednesday 17 June 2026	09:30hrs to 15:00hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

The inspectors completed an inspection of the radiological service at Roscommon University Hospital to follow up on the compliance plan from the previous inspection in August 2022 and to monitor the service's ongoing compliance with the regulations. The inspectors noted that all of the compliance plan actions from the previous inspection in August 2022 had been sufficiently addressed at the time of this inspection.

As part of this inspection, the inspectors reviewed documentation and visited the general X-ray and computed tomography (CT) departments and spoke with staff and management. Inspectors also reviewed imaging records from general radiography and CT.

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 regulatory requirements and to reflect day-to-day practice at Roscommon University Hospital. Also, some work was required to establish formal processes around certain regulatory requirements as discussed in detail under Regulation 6.

Inspectors were assured 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 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 medical physicists was proportionate to the level of radiological risk at the installation and that medical physicists took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, despite some areas noted for improvement, inspectors were satisfied that the allocation of responsibility for the protection of service users was nonetheless sufficient to ensure the safe conduct of medical exposures at Roscommon University Hospital at the time of inspection.

Regulation 4: Referrers

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

In line with the regulations, radiographers and nurses meeting the requirements of Regulation 4 were also considered referrers in this facility. Staff information posters were observed in the clinical area with information on individual nurse referrers and their respective scope of practice. The specific circumstances in which radiographers could act as referrers were clearly and unambiguously outlined in local policies and articulated to inspectors by staff.

Judgment: Compliant

Regulation 5: Practitioners

Similarly, following review of relevant documentation, referral records and staff communication, inspectors were satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures at Roscommon University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Senior management staff who spoke with inspectors during the inspection outlined the 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 radiation protection of service users were articulated to the inspectors and documented in radiation safety procedure organograms reviewed 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 HSE West and Northwest Healthcare Group and the General Manager (GM) of the hospital reported to the undertaking via the Integrated Healthcare Area Manager and Regional Executive Officer of the group respectively.

Roscommon University Hospital employed a Radiation Safety Committee (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 the person identified to inspectors 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 Quality and Safety meetings as well as Radiology Directorate Committee meetings. Inspectors were assured that the Hospital utilised multiple, multi-disciplinary platforms for the consideration and escalation of all radiation safety related issues.

However, inspectors did note that some documentation needed to be updated to align the allocation of responsibility with day to day practice and regulatory requirements. The document *Radiation Safety Procedures Including Standard Operating Procedures* had assigned responsibility for approval of the justification of new practices to incorrect external parties. This document also incorrectly assigned approval of medical research projects to internal hospital committees namely the RSC and Quality and Safety Committee. The regulations assign responsibility for approval of the justification of new practices to HIQA and approval of medical research projects is addressed in the amendment S.I. 29 of 2023. After discussion with senior radiation safety representatives and management, the inspectors were assured that Roscommon University Hospital had informal, ad hoc, processes to review and ensure any potential new practices or medical research involving ionising radiation could be considered in a manner satisfying regulatory requirements. However, as mentioned, related radiation safety documentation must be updated and all associated processes must be formalised and documented.

Similarly, inspectors reviewed RSC minutes which noted that this committee had briefly discussed medical radiological procedures on asymptomatic individuals, performed for the early detection of disease. However, no formal procedures for the consideration and ongoing review of the imaging of asymptomatic individuals was available. To ensure a clear allocation of responsibility for the systematic review, discussion and consideration of imaging of asymptomatic individuals at Roscommon University Hospital some work is required on the part of the undertaking.

Finally, inspectors reviewed the document *Standard Operating Procedures for the Protection of the Unborn Child arising from Ionising Radiation*. This document used regulatory terms such as 'referrer' and 'practitioner' interchangeably with professional titles such as 'radiographer' and 'radiologist'. Inspectors noted that this caused some ambiguity in the allocation of responsibility. For example, the document noted radiographers as practitioners but went on to mention that the radiographer may seek advice from the practitioner, thus suggesting that the radiographer was not the practitioner in certain cases. The designation and role of all staff in all procedures should be made abundantly clear by the undertaking to ensure compliance with Regulation 6.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspectors reviewed radiation safety procedure documentation, a sample of referrals for medical radiological procedures and spoke with staff and were satisfied that all medical exposures at Roscommon University Hospital took place under the clinical responsibility of a practitioner. The inspectors were also assured that the optimisation process involved the practitioner and the medical physicist and that the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that arrangements in place secured the continuity of medical physics involvement and contribution at Roscommon University Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The undertaking engaged persons with up-to-date medical physics expert (MPE) voluntary professional certification with the Irish College of Physicists in Medicine (ICPM). In the absence of a statutory Register of Medical Physics Experts, as per Regulation 19, this ensured that the undertaking had engaged medical physicists with appropriate knowledge, skills and competencies to act or give specialist advice in relation to medical radiological practices.

Inspectors saw evidence that showed medical physicists took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners.

Judgment: Compliant

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

From the evidence gathered during the course of this inspection, inspectors were satisfied that the level of medical physicists involvement was appropriate and

proportionate to the radiological risk associated with medical radiological practices at Roscommon University Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this service and noted areas of good practice in relation to this. Following a review of a sample of referrals for a number of areas, the inspectors were satisfied that Roscommon University Hospital had reliable and consistently applied 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 inspectors were satisfied that DRLs were established, used and reviewed to ensure patient dose optimisation in conjunction with the Hospital's audit processes. Records of acceptance and performance testing for radiological equipment at the hospital satisfied the inspectors that the undertaking had implemented and maintained an appropriate QA programme and ensured that all radiological equipment was kept under strict surveillance.

Inspectors were satisfied that Roscommon University Hospital took a comprehensive approach to the identification, recording and analysis of accidental and unintended exposures which ensured that the likelihood of incidents for service users undergoing medical exposures in this facility were minimised.

Despite one area for improvement in relation to paediatric protocols, inspectors found that radiation protection processes implemented by Roscommon University Hospital ensured the safe and effective delivery of medical exposures.

Regulation 8: Justification of medical exposures

The inspectors spoke with staff and reviewed a sample of referrals for all clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure that 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 inspectors 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 risks of the medical exposure.

Staff who spoke with inspectors consistently informed them that previous diagnostic information was routinely sought to avoid unnecessary exposure. This was seen as an area of good practice at Roscommon University Hospital and staff prioritised the review of previous imaging on multiple platforms, outside of the local Radiology Information System, as well as referrer interaction as required, to ensure that unnecessary medical imaging was avoided.

The inspectors 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

Following a review of DRLs, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at Roscommon University Hospital. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the clinical areas.

The inspectors reviewed multi-disciplinary dose audits commenced as a result of DRL reviews and noted subsequent protocol changes which facilitated lower patient doses while maintaining image quality. This was seen as a positive use of information gained through DRL review to reduce patient dose, optimise the service provided and enhance service user outcomes.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors found that written protocols were established for standard medical radiological procedures in adult general X-ray and CT. However, some work was required to ensure that protocols for all paediatric general X-ray medical exposures are documented and available to all staff.

The inspectors spoke with staff and reviewed a sample of imaging reports from all clinical areas on the day of inspection. The inspectors observed that information relating to patient exposure formed part of all reports reviewed, satisfying the requirements of Regulation 13(2).

Inspectors reviewed information relating to clinical audit via documents supplied, examples of clinical audits, both ongoing and completed, and by speaking with staff and management. Inspectors were assured that Roscommon University Hospital's approach to clinical audit was in accordance with the national procedures established by HIQA. Inspectors were informed that work on extra resourcing for a local clinical audit committee was underway and likely to be introduced in the near future. Inspectors were satisfied that regulatory requirements related to Regulation 13(4) were currently being met, but acknowledged that the corporate and hospital approach to radiology clinical audit could be reinforced and enhanced by the proposed increased hospital resources dedicated to clinical audit.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspectors were provided with an up-to-date inventory which was verified on site. From the evidence available, the inspectors were satisfied that all medical radiological equipment was kept under strict surveillance at Roscommon University Hospital. The process to ensure this included the implementation and maintenance of a QA programme. This included appropriate acceptance testing before clinical use, regular radiographer and medical physicist led performance testing as well as manufacturer suggested equipment service. All QA records were available and up to date on the day of inspection.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and imaging records reviewed satisfied the inspectors that Roscommon University 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.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, inspectors were 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 multiple committees namely: radiation safety, quality and risk and departmental committees within the hospital. Thus hospital management had oversight of incidents in this facility. The 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 by at Roscommon University 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, 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	Substantially 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 Roscommon University Hospital OSV-0007372

Inspection ID: MON-0049578

Date of inspection: 17/06/2026

Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: 1. Revise Radiation Safety Procedures Including Standard Operating Procedures to include correctly assigned responsibilities for approval of justification of new practices and approval of medical research projects to appropriate parties/committees. 2. Put in place 3 new SOP's, a. Volunteers in Medical or Bio-medical Research b. New practices c. Asymptomatic individuals 3. Revise "Standard Operating Procedures for the Protection of the Unborn Child arising from Ionising Radiation" in relation to the terminology used. 4. All new SOP's and two existing SOP's will be ratified by appropriate governance committees. 5. To have in place by 31/12/2026	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: 1. Revise all protocols for all paediatric general X-Ray exposures and fully document them in the SOP for General Radiography 2. This updated SOP be ratified by appropriate governance committees. 3. To have in place by 31/12/2026	

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	31/12/2026
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are	Substantially Compliant	Yellow	31/12/2026

	established for each type of equipment for relevant categories of patients.			
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