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:	University Hospital Galway
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Newcastle Road, Galway
Type of inspection:	Announced
Date of inspection:	06 August 2025
Medical Radiological Installation Service ID:	OSV-0007356
Fieldwork ID:	MON-0045776

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

University Hospital Galway is a Model 4 teaching hospital servicing a catchment area of over 1 million people (adult and paediatric). It is a supra-regional cancer centre as well as providing 24/7 acute surgery, acute medicine and critical care.

UHG Radiology provides an extensive service for planned and acute care including:

• Plain film, portable and dental radiography, including Dental CBCT

• CT service for both diagnostic and interventional procedures

• IR across two dedicated suites with cone-beam capability

• Fluoroscopy suite for barium studies, VFSS, HSG and tube checks

• Nuclear Medicine studies provided by SPECT/CT scanner

• Mammography examinations are provided by two mammography units with tomosynthesis capability ans ultrasound. Biopsy services are also provided as well as specimen imaging.

• MRI and US imaging

• PACS support

Cardiology cases are performed across two dedicated cardiac catheterisation labs whilst Vascular procedures are carried out in a hybrid theatre with cone-beam capability.

Lithotripsy, Rhizolysis and ERCP procedures are fluoroscopically-guided by a range of C-arms.

Orthopedics, Urology and Plastics also have access to C-arms for screening during procedures. Orthopedics also have access to an O-arm for navigation of complex spinal cases.

The Radiation Oncology Department at University Hospital Galway is located in the Saolta Radiation Oncology Centre (SROC) on the UHG campus. This is a purpose built facility which was officially opened in October 2023.

The department comprises of four Elekta Versa-HD linear Accelerators, one Womed Superficial kV Therapy unit, one Varian Bravos HDR brachytherapy unit and two Siemens Go-Sim CT-simulators.

The department provides radiotherapy services to the West North West Regional Health Area which serves the population of counties Galway, Mayo, Roscommon,

Donegal, Leitrim, Sligo and West Cavan with a population of approximately 800,000 people.

The Radiotherapy services include External Beam Radiotherapy including stereotactic radiosurgery (SRS), Superficial-kV skin treatments, HDR Gynaecological brachytherapy treatments, HDR Prostate brachytherapy treatments and LDR Prostate seed brachytherapy implantation.

The department also provides systemic radiation therapy to patients which are prescribed by radiation oncologists and delivered within the Nuclear Medicine department.

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 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] 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 6 August 2025	09:00hrs to 16:30hrs	Lee O'Hora	Lead
Wednesday 6 August 2025	09:00hrs to 16:30hrs	Margaret Keaveney	Support
Wednesday 6 August 2025	09:00hrs to 16:30hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiology and radiation therapy services at University Hospital Galway on 6 August 2025 to follow up on the compliance plan from the previous inspection in May 2023 and to monitor the service's ongoing compliance with the regulations. Inspectors noted that most of the compliance plan actions from the previous inspection had been completed. However, work on the clear allocation of responsibility for the radiation protection of service users was still ongoing through a review of the hospital's radiation safety documentation system. Inspectors noted that this review was comprehensive in nature and was being monitored by hospital management through the appropriate channels.

During this inspection, inspectors visited the radiotherapy, general X-ray, nuclear medicine and interventional cardiology departments, spoke with staff and management and reviewed radiation safety related documentation and records. Inspectors were satisfied that staff at University Hospital Galway employed a number of appropriate radiation safety platforms and communication channels to ensure that all radiation safety issues could be considered, discussed, and when necessary, escalated to hospital management and the undertaking as required.

On the day of inspection in both the radiotherapy and radiology departments, systems and processes were in place to ensure that medical exposures were only carried out when referred by a person entitled to refer as per Regulation 4. Similarly, inspectors were assured that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

The inspectors reviewed documentation and spoke with medical physics staff and senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and following staff communication, the inspectors were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall, notwithstanding the area for improvement in relation to the ongoing document version control review and update, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at University Hospital Galway.

Regulation 4: Referrers

Following a review of radiology and radiotherapy referral documentation, a sample of referrals for a range of medical radiological procedures and by speaking with

staff, the inspectors were satisfied that University Hospital Galway only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed a sample of referrals, associated justification documentation and records of clinical evaluation of the outcome for a range of medical radiological procedures. Inspectors also discussed the processes and practice surrounding practitioners in University Hospital Galway with staff in the radiology and radiotherapy departments. Subsequently, inspectors were satisfied that University Hospital Galway had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures in both the radiology and radiotherapy departments.

Judgment: Compliant

Regulation 6: Undertaking

The Health Service Executive (HSE) was identified to inspectors as the undertaking with overall responsibility for the radiation protection of service users at the hospital. University Hospital Galway operated within the HSE West/Northwest regional area and inspectors were informed that, at the time of inspection, the General Manager (GM) was the person with responsibility for the protection of service users at University Hospital Galway. The GM reported externally through the Integrated Healthcare Area (IHA) group meetings and the Regional Executive Officer (REO) to the HSE.

Inspectors noted from documentation and were informed that staff at University Hospital Galway used a radiation safety committee (RSC), which met quarterly and a radiation protection unit (RPU), which met monthly to achieve compliance with licensing conditions and regulatory requirements. The GM was represented by their deputy at the RSC meetings and the hospital also had a quality and patient safety (QPS) committee which met quarterly and considered relevant radiation safety issues such as audit and incidents. At a departmental level, inspectors were informed that monthly radiology QPS meetings and radiotherapy management meetings also provided platforms for the consideration of all relevant issues.

Since the last inspection, key roles relating to radiation safety had been strengthened through formal role resourcing and inspectors were assured that the associated responsibilities could now be completed as required, independent of staff shortages or resource levels. Inspectors also noted the increased inclusion of

departments using fluoroscopy and interventional radiology outside of the radiology department at the RSC meetings, helping to ensure that radiation safety issues are regularly and routinely communicated to all areas conducting medical exposures in the hospital.

However, inspectors noted that work was required in the area of radiation safety documentation and formal version control of this documentation to ensure the clear allocation of responsibility for the protection of service users from medical exposure to ionising radiation. In particular, in May 2023, inspectors highlighted that the document *Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures* needed to be updated. While this document had subsequently been updated in 2024 to reflect relevant regulatory language and day-to-day practice, the process for the review and ratification of all radiation safety related documents as well as the designation of platforms where the updated formal documents would be available to staff was only partially complete. Additionally, the corporate approach to the consideration, ratification and review of radiation safety related document was not formally documented at the time of inspection. Inspectors were assured that this process was ongoing and overseen by hospital management. Notwithstanding the work completed, this was highlighted as an area that needed to be completed in a timely manner to satisfy the requirements of Regulation 6. Inspectors also noted that the clear allocation of responsibility and associated process regarding the justification of practices at University Hospital Galway needs to be documented, agreed and ratified.

Finally, the clear allocation of responsibility for clinical audit at University Hospital Galway as highlighted in clinical audit documentation was not reflected in the day-to day-practice of proposing, reviewing, agreeing, completing and communicating radiation therapy clinical audits in the hospital. To ensure no ambiguity in the clear allocation of responsibility for clinical audit, day-to-day practice must align with hospital documentation, which must also satisfy the requirements of the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

During the inspection of the radiotherapy department, inspectors were informed that only radiation oncologists and radiation therapists were entitled to act as practitioners, carry out the practical aspects of, and take clinical responsibility for, the medical radiological procedures. Similarly, in the radiology department inspectors were satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner as defined in the Regulations.

Inspectors also noted that practitioners and MPEs were involved in the optimisation process for medical exposures to ionising radiation, and that referrers and

practitioners were involved in the justification process for individual medical exposures in both the radiology and radiotherapy departments.

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 inspectors by staff and management and the details were available in documents reviewed as part of this inspection. All evidence supplied satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise for both radiology and radiotherapy services at University Hospital Galway.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Professional registration certificates from the Irish College of Physicists in Medicine (ICPM) were reviewed by inspectors and were up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that the undertaking had arrangements in place to ensure the involvement and contribution of MPEs was in line with the requirements of Regulation 20. For example, inspectors were assured 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.

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 MPEs was both appropriate for the service and commensurate with the risk associated with all radiological services provided at University Hospital Galway.

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 University Hospital Galway and noted many areas of good practice which, in this case, helped to ensure high levels of compliance with the regulations reviewed on the day of inspection.

Inspectors reviewed a sample of referrals for a number of areas across the radiology and radiotherapy departments. The inspectors were satisfied that University Hospital Galway had reliable, consistently applied and internally audited 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.

Inspectors were satisfied that DRLs were established, used and reviewed. Evidence of patient dose optimisation through the use of DRLs and patient dose reviews were noted in both the radiology and radiotherapy departments which resulted in patient dose reductions, where appropriate, and enhanced service user outcomes at University Hospital Galway.

Records of acceptance and performance testing for all radiological equipment at the hospital satisfied the inspectors that the undertaking had implemented and maintained an appropriate QA programme and kept all radiology equipment under strict surveillance.

The undertaking had employed robust multidisciplinary systems and platforms for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice. These processes were consistently articulated by staff who spoke with inspectors and were used to actively improve service user outcomes. However, some work is required by the undertaking to ensure that HIQA is notified of the occurrence of any significant event within three days of its discovery.

The inspectors were assured that University Hospital Galway had appropriate systems in place to support the safe delivery of medical exposures and staff demonstrated a commitment to the continual improvement of radiology and radiotherapy services provided.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referrals from a number of clinical areas on the day of inspection using the hospital's radiology picture archiving

and communications system (PACS) and the cardiology department's newly installed cardiovascular information system (CVIS). From the records reviewed, the inspectors were assured that the undertaking had employed systems and processes in the radiology service to ensure that procedures were justified in advance by a practitioner and that this justification was recorded across all records reviewed. All records reviewed consistently included sufficient clinical information to satisfy all requirements of Regulation 8(10) and inspectors were further assured that non-compliance noted in the previous inspection in relation to the inclusion of clinically relevant information had been addressed and was routinely audited to maintain compliance.

Similarly, in the radiotherapy department, inspectors were informed that the radiation oncologist justified, in advance, each patient's planning scan by signing the treatment booking form. Inspectors were also informed that, by reviewing and electronically approving the final treatment plan, the radiation oncologist justified the radiotherapy treatment course in advance. A sample of patient records and treatment plans were reviewed and inspectors saw that this practice was followed for each record. Inspectors noted that referrals were available in writing and stated the reason for the request. Inspectors also saw that sufficient medical data, such as diagnostic imaging and pathology reports, accompanied each referral. Also, the process for radiation therapy justification and recording of justification, highlighted in the previous inspection as lacking, had been formally documented in the document *Policy of justification of medical ionising exposures in radiation oncology department* which was reviewed by inspectors as part of this inspection.

Inspectors also observed that information leaflets were available to inform patients of the benefits and risks associated with their particular radiotherapy treatment course. In the radiology department, inspectors observed multiple posters, both general and hospital specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. University Hospital Galway also provided service users with information relating to the benefits and risks of medical exposures to ionising radiation by displaying quick response (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 9: Optimisation

Inspectors were informed that University Hospital Galway had a Chief Academic Office which provided training in optimisation and quality tools which both the radiology and radiotherapy department had utilised. This was seen as a positive use of a resource to optimise patient radiation dose in both the radiology and radiotherapy departments.

Inspectors noted that there was a strong multidisciplinary approach to optimisation of radiation doses in the radiotherapy department. For example, inspectors were informed of a quality improvement project that involved radiation therapists, radiation oncologists and nursing staff, and which aimed to improve the pre-treatment preparation and consequently reduce organ motion during CT planning and treatment delivery for one cohort of patients. Evaluation of the project outcomes showed that organ motion had decreased for these patients, resulting in a lower overall radiation dose as fewer verification images were required to assess the accuracy of treatment delivery.

The radiotherapy management team had also developed a policy which outlined the imaging type and frequency to be followed by radiation therapists when verifying the radiotherapy treatment for different treatment sites, such as for prostate and breast treatment. Inspectors were also informed that the management team had a system in place which ensured that the radiation oncologist was informed of any necessary deviations from this policy during a treatment fraction. This system ensured that additional imaging doses were appropriately justified by a multidisciplinary team. Inspectors were also informed that radiation therapists completed and recorded a time-out check before each treatment fraction was delivered.

Additionally, the radiotherapy department employed a structured process that was followed prior to the introduction of a change of practice that may have resulted from treatment technique developments or from incident learning**.** Inspectors were informed that an assigned staff member, the change lead**,** would document the change, which was then reviewed and approved by a multidisciplinary radiotherapy team before education sessions were held for all relevant staff. This was identified as an area of good practice in the service.

Similarly, the radiology department had utilised wider corporate academic and quality improvement structures and resources to monitor, address and improve paediatric patient dose optimisation as discussed further under Regulation 11.

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 this hospital throughout the diagnostic service but also in the radiotherapy CT planning and radiotherapy CBCT services.

Inspectors were informed that the RPU platform was used to monitor ongoing operational optimisation plans in relation to DRLs. Where local facility DRLs exceeded national values, the records of associated ongoing corrective actions were available for review and managed by the RPO. Inspectors were informed that for

paediatric radiography procedures, staff had utilised hospital quality improvement resources available through the hospital's academic office which had helped to improve the approach to paediatric patient dose optimisation. This was seen as a positive use of a corporate resource to reduce, where possible, service user radiation dose while maintaining the diagnostic quality of images.

DRLs had been established in the radiotherapy department for both CT planning and CBCT verification imaging. This local data had been compared to international data as national data for radiotherpay is not yet available. Inspectors were also informed that further reviews were planned to improve the doses and image quality associated with these medical exposures. This was seen as a good example of the undertakings proactive approach to patient dose optimisation and radiation protection in the radiotherapy department.

Inspectors also visited the radiology department and observed multiple examples of local facility DRLs displayed in the clinical areas.

Judgment: Compliant

Regulation 13: Procedures

In both the radiotherapy and radiology departments, the inspectors were satisfied that written protocols for every type of standard medical radiological procedure were available, satisfying, in this case, the regulatory requirements of Regulation 13(1). However, the potential for improvements in protocol version control in line with those discussed under Regulation 6 was highlighted to staff and management on the day of inspection.

From a review of patient records, inspectors saw that the planned radiotherapy dose, received by the patient, was included in a radiotherapy summary letter. This letter was generated for each patient on completion of their treatment course. In the radiology department, information relating to patient exposure was included on all radiology and cardiology reports reviewed on the hospital PACS and CVIS systems.

Inspectors were informed that University Hospital Galway used a hospital Audit Committee managed through a Clinical Audit Co-ordinator's office. After discussing this with staff and reviewing audit documentation and records, inspectors were satisfied that University Hospital Galway had sufficiently incorporated HIQA's *national procedures for clinical audit* to ensure that the processes employed satisfied the requirements of Regulation 13(4). Inspectors were informed that the radiology RPO and a radiation oncologist sat on the hospital’s audit committee. Inspectors reviewed a list of current audits being carried out or recently completed by the radiation therapy department and radiology department. The inspectors were informed that while all radiology audits were reviewed and approved by the hospital audit committee, the audits carried out by the radiotherapy department were still

proposed, agreed and completed outside of these corporate structures. While satisfying the requirements of regulation 13(4) in this case, management at University Hospital Galway should ensure that all radiotherapy audit practices align with hospital policy as specified under Regulation 6.

Judgment: Compliant

Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This included the implementation and maintenance of QA and assessment of dose and verification of administered activity programmes including acceptance and regular performance testing.

Judgment: Compliant

Regulation 15: Special practices

Inspectors reviewed policies and procedures utilised in the interventional radiology departments, including the cardiovascular, general interventional and theatre vascular suites, to identify potential high skin doses in patients undergoing such procedures. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses that may result in tissue reactions. Records of patients who reached substantial radiation dose levels, details of their their skin dose investigations and subsequent decision making and communication processes were reviewed. Inspectors were assured that University Hospital Galway had a well defined and multidisciplinary approach to the identification and subsequent management of service users who may develop tissue reactions as a result of justified and optimised interventional procedures.

The management team in the radiotherapy department at University Hospital Galway had a number of appropriate measures in place to ensure that patients receiving high dose medical exposures were appropriately protected. From example, from discussions with staff, inspectors were informed that for a newly introduced high dose radiotherapy treatment technique, additional peer review checks were performed at various stages along the patient's pre-treatment pathway to ensure that the treatment plan was appropriately optimised before any radiation treatment dose was delivered. In other cases, additional mechanical checks were performed on the radiotherapy treatment units to ensure that complex plans were deliverable before any radiation dose was received by the patient.

Inspectors were satisfied that University Hospital Galway demonstrated many areas of good practice and had multiple systems and processes in place to ensure service users undergoing medical exposures involving high radiation doses, and where high doses were a possible outcome of a procedure, were appropriately protected.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The management team had developed and implemented a policy to ascertain pregnancy status of women undergoing radiotherapy, which guided and supported staff on the process for enquiring about and recording pregnancy status for relevant patients. Inspectors also reviewed a number of patient records and found that this enquiry had been documented prior to the planning CT scan by the Information and Support Radiation Therapist and was rechecked with the patient at the time of their CT scan and documented on the first day of treatment by the treating radiation therapists. Inspectors were also informed that relevant patients were again asked about their pregnancy status at intervals over their radiotherapy course.

Similarly, processes observed and records reviewed in the radiology department satisfied the 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. A sample of referrals reviewed by the inspectors verified the consistent recording of the relevant information in line with regulatory requirements.

Multilingual posters were observed throughout the radiotherapy and radiology departments. The inspectors were assured that measures had been taken 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, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing radiotherapeutic, diagnostic and interventional medical exposures in this hospital.

Evidence was available to show that incidents were discussed at the appropriate committee levels within the radiotherapy and radiology departments, as well as audit and quality assurance platforms used by staff at the hospital. All radiation

incidents were also considered by the RPU and reported to the RSC, thus ensuring the undertaking had oversight of incidents in this service.

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 University Hospital Galway. Inspectors were consistently informed of the process that the undertaking employed to inform HIQA of accidental and unintended exposures and significant events, which relied upon each department's RPO to access the relevant HIQA portal once it had been determined locally that the incident was reportable. However, consistent failures to meet time lines required by Regulation 17(1)(e), namely three days from discovery of the incident, were noted by inspectors as an area requiring the immediate attention of the undertaking to meet regulatory requirements.

Judgment: Substantially 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 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for University Hospital Galway OSV-0007356

Inspection ID: MON-0045776

Date of inspection: 06/08/2025

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: Outline how you are going to come into compliance with Regulation 6: Undertaking: · Develop and Finalise SOP on the Justification of New Ionising Radiation Practices in GUH (Target: Q1 2026) · Develop and Finalise SOP on Review & Ratification of GUH Radiation Protection PPPGs (Target: Q1 2026) · Upload outstanding Local Rules SOPs to Q-Pulse (Target: Q1 2026) · Upload outstanding Radiology imaging protocols to Q-Pulse with author, owner, approver and revision dates (Target: Q1 2026)	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: Distribute signage in Radiology to encourage early reporting of radiation incidents (Target: Q4 2025) · Regular reminders at radiology staff meetings regarding regulatory requirement to report within 72 hours (Monthly)	

Request addition of sub-users to HIQA portal to ensure timely reporting during times of leave (Target: Q4 2025)

Add more users to NIMS dashboards to ensure timely reporting during times of leave (Target: Q4 2025)

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	31/03/2026
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event,	Not Compliant	Orange	31/12/2025

	as defined by the Authority in guidelines issued for that purpose, and			