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:	16 May 2023
Medical Radiological Installation Service ID:	OSV-0007356
Fieldwork ID:	MON-0035037

About the medical radiological installation:

Galway University Hospital is a Level 4 Teaching Hospital, which provides an extensive range of Radiology Services for all inpatients/outpatients and GP patients including plain Films, fluoroscopy, Ultrasound, Interventional Radiology, Cone Beam CT, Mammography, DAT Scans, Nuclear Medicine, & MRI. We aim to deliver this service in a timely manner following best practice policies and procedures. The Radiation Oncology Department at GUH is now on 2 sites since going clinical with 2 Elekta Versa linear accelerators on 18/04/2023 in the new NPRO Radiation Oncology Building. The department now comprises of 3 Siemens and 2 Elekta Linear Accelerators, a Cannon CT Simulator, a Womed Orthovoltage Unit and a Varian HDR unit. A further 2 Elekta Versa linear accelerators, a Siemens CT Simulator, a Philips MRI Simulator and a Brachytherapy Suite with a new Varian HDR unit will become operational in the new building within the next year. As the Ekekta becomes operational the Siemens units will be de-commisioned. The department provides radiotherapy services to the Saolta region which serves the population of counties Galway, Donegal, Leitrim, Sligo, Mayo, Roscommon and adjoining areas. These services include External Beam Radiotherapy, Orthovoltage treatments, HDR Gynacological treatments, HDR Prostate treatments and Prostate seeds implantation. The department also provides systemic radiation therapy to patients via 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 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
Tuesday 16 May 2023	09:30hrs to 16:30hrs	Lee O'Hora	Lead
Tuesday 16 May 2023	09:30hrs to 16:30hrs	Agnella Craig	Support
Tuesday 16 May 2023	09:30hrs to 16:30hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the radiotherapy and radiology departments at Galway University Hospital was carried out on the 16 May 2023 to assess compliance with the regulations. On the day of inspection, inspectors reviewed documentation and records and spoke with staff working in both of these departments.

Galway University Hospital operated within the Health Service Executive (HSE) Saolta Hospital Group and the 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 through the hospital group's Chief Operations Officer (COO) to the HSE. Staff at Galway University Hospital used a radiation safety committee (RSC) to direct and enforce radiation safety policy in line with all relevant regulations and best management practices. Inspectors were also informed that Galway University Hospital utilised many alternate platforms and communication pathways for the consideration and discussion of the radiation protection of service users.

While the relevant responsibilities and lines of communication regarding the protection of service users was consistently articulated during the course of the inspection some work was required to ensure that radiation safety documentation satisfied all regulatory requirements, used current regulatory language and reflected day-to-day practice at Galway University Hospital. Also inspectors noted that systems could be improved to ensure key radiation safety roles as identified by local policy are protected. The undertaking should also ensure that all areas using ionising radiation are represented within the radiation safety platforms and communication pathways used by Galway University Hospital.

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 senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, 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 areas for improvement identified over the course of the inspection, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at Galway University Hospital.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for a range of medical radiological procedures and by speaking with staff, inspectors were satisfied that Galway University Hospital only accepted referrals from appropriately recognised referrers, in both the radiology and radiotherapy departments.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that Galway University Hospital had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Galway University Hospital operated as part of the wider HSE Saolta Hospital Group. Inspectors were informed that the GM was the person with overall responsibility for the protection of service users at Galway University Hospital and reported via the COO of the Saolta Group to the HSE. Inspectors noted from documentation that staff at Galway University Hospital used a RSC to direct and enforce radiation safety policy in line with relevant laws and regulations. Inspectors were informed that a radiation protection unit (RPU) was also used as a more operational platform within the radiation safety structure of the hospital.

Radiology directorate meetings and radiotherapy management team meetings also provided a more frequent opportunity for staff to discuss radiation protection and related issues as required. Inspectors were also informed that the hospital's Quality and Patient Safety Committee served as another platform for the consideration of radiation safety issues as necessary.

However, while the inspectors were satisfied that Galway University Hospital had the appropriate radiation safety platforms and lines of communication in place, some work was required in radiation safety documentation and stewardship of this documentation to ensure the clear allocation of responsibility for the protection of service users from medical exposure to ionising radiation. For example, the document *Policies, Procedures and Guidelines for the Safe Use and Application of*

Ionising Radiation including Standard Operating Procedures needed to be updated to satisfy regulatory requirements and mirror current regulatory language and reflect day-to-day practice. In many cases documentation did not reflect the current practices which had to be established via staff communication as described further under Regulations 8, 10 and 16.

Radiation safety document version control was another area highlighted as needing action to ensure a clear allocation of responsibility. Many documents reviewed did not have authors, ratification details or revision dates as detailed in Regulation 13, making it difficult to establish who had the responsibility for creating, updating and approving documented policies, procedures and protocols. The undertaking is responsible for ensuring that staff and those engaged by the undertaking understand local systems and processes and are supported in carrying out their individual roles through the provision of regularly reviewed and ratified documented procedures, policies, protocols and guidelines.

Inspectors were informed on the day that key radiation safety roles in both the radiotherapy and radiology departments had been supplied with an element of good will. Inspectors were informed that certain key radiation safety responsibilities were being provided in staff members own time due to ongoing staff shortages and current lack of formal role resourcing. The undertaking must ensure that key roles as identified locally are appropriately resourced to ensure that the associated responsibilities can be completed as required independent of staff shortages or resource levels. The undertaking must ensure that a robust system is put in place to guarantee the delivery of the allocated responsibilities as described in local radiation safety documentation for all key radiation safety personnel identified.

Finally, formalising communication pathways to include departments using fluoroscopy and interventional radiology outside of the diagnostic imaging department would ensure radiation safety issues are considered in all areas conducting medical exposures in the hospital. The clear allocation of responsibility and appropriate lines of communication are of particular relevance in areas such as interventional cardiology and vascular surgery where patient radiation doses could potentially be high.

While inspectors had no concerns with the radiation safety practice at Galway University Hospital or the commitment and good will of staff, some action was required on the part of the undertaking to ensure that said practice is accurately and clearly reflected in up-to-date and regularly reviewed radiation safety documentation. Also, inspectors noted that ensuring that all relevant departments are appropriately represented in the radiation safety architecture of the hospital and that essential radiation safety roles are maintained and protected are areas that once addressed could improve the undertaking's ability to improve the protection of service users.

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, and carried out the practical aspects of and took clinical responsibility for the medical radiological procedures. 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.

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, the optimisation process involved the practitioner and the medical physics expert (MPE) and that the justification process for individual medical exposures involved the practitioner and the referrer.

However, in relation to the radiology department, while inspectors were assured that practice satisfied the requirements of the regulations, some work was required to ensure radiation safety documentation reflected day-to-day practice in relation to the individuals considered practitioners in diagnostic medical exposures. For example, those defined as practitioners in the document *Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation* did not align with that of the document *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures.*

Similarly, in relation to the radiotherapy department, documentation must be updated to clearly define the process outlining the responsibilities of appropriate persons with regard to the delivery of radiotherapeutic medical exposures, as mentioned, inspectors were informed that only radiation oncologists and radiation therapists were entitled to act as practitioners, and carried out the practical aspects of and took clinical responsibility for the medical radiological procedures, however these responsibilities were not clearly defined in the document *Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation*.

Judgment: Substantially 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 radiotherapy and diagnostic imaging services at Galway University Hospital.

Judgment: 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 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 the services provided at Galway University Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors were satisfied that Galway University Hospital had multiple systems and processes in place to ensure patients undergoing medical exposure involving high radiation doses, such as those delivered in radiotherapy, and where high doses were a possible outcome of a procedure, such as interventional cardiology and radiology, were appropriately protected.

Inspectors were assured that all medical exposures in the radiotherapy and radiology departments were justified in advance, however some work was required to ensure documentation reflected the process for justification in the radiotherapy department. Despite this, inspectors saw good practice in relation to the justification process in the radiotherapy department namely the weekly multidisciplinary approach to the justification of patient treatments. Also, inspectors noted that some

radiology records reviewed lacked reasons for requesting the particular procedure and sufficient medical data. In order to maintain regulatory compliance the undertaking must ensure that all medical exposure procedure referrals are accompanied by the regulatory required information with no exceptions.

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 facility. Similarly, from the evidence available, inspectors were assured that all medical radiological equipment was kept under strict surveillance by the undertaking.

Although, the inspectors were satisfied that only recognised practitioners inquired and recorded pregnancy status for the relevant service users, some work was required by the undertaking to ensure that the associated documentation reflects both the regulatory requirements and day-to-day practice at Galway University Hospital.

The inspectors were satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures.

Although a number of areas required improvement to ensure regulatory compliance, inspectors were satisfied that these did not pose an immediate risk to the safety, health or welfare of service users.

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. Documentation reviewed detailed the process by which the undertaking recorded practitioner justification for each area delivering diagnostic and interventional medical exposures. The inspectors noted that general X-ray procedures were justified by the performing radiographer just before imaging. Inspectors were informed that this was due to current staff shortages not facilitating practitioner justification at an earlier point in the referral process. While satisfying the regulations, this was noted as an area that could be improved to enhance the service delivered and, in some instances, prevent unnecessary patient journeys.

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. They 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. However, inspectors noted that the undertaking's *Radiation Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation* did not clearly outline how medical exposures completed during the course of radiotherapy planning and treatment delivery are justified, and how or where justification is recorded. While this gap in the documentation must be addressed by the undertaking it was noted that the radiotherapy management team held a weekly patient planning meeting, which was attended by radiation oncologists, radiation therapists and medical physics experts, to discuss all and justify radiotherapy treatment plans in advance of patients starting their treatment. This multi-disciplinary approach and discussion of justification in advance was acknowledged as an area of good practice by Galway University Hospital.

A sample of radiology records were also reviewed, and inspectors noted that for a small number of fluoroscopic procedures carried out outside the radiology department, namely endoscopic retrograde cholangiopancreatography (ERCP - used for imaging parts of the digestive system), the reason for requesting the particular procedure or sufficient medical data to enable the practitioner to carry out a justification assessment was not routinely included on the referral. This must be addressed by the undertaking to ensure that all referrals to a practitioner for a medical radiological procedures meet the criteria laid out in Regulation 8(10).

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. Galway 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: Substantially 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.

Where local facility DRLs exceeded national values, the records of associated audits and corrective actions were available for review. Inspectors were assured that for a number of paediatric radiography procedures, when the local facility DRLs exceeded

national values a multidisciplinary team were involved in the associated investigation and the implementation of corrective actions. At the time of inspection the undertaking had implemented corrective actions and inspectors were informed that data collection was ongoing but establishment of associated updated paediatric DRLs was delayed by low procedure numbers.

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

Judgment: Compliant

Regulation 13: Procedures

Inspectors noted that clinical audit was a standing agenda point of the RSC. A sample of clinical audits conducted in the radiotherapy department were reviewed by inspectors. Inspectors saw that image quality audits were completed by the radiotherapy Imaging Specialist Team, to provide assurances that the images obtained during treatment verification provided adequate information to ensure that the treatment dose was being accurately delivered to the target site. Similarly, inspectors reviewed examples of radiation safety related clinical audits completed by the radiology department. These included justification audits, reject analysis, DRL audits, incident trending audits and pregnancy policy compliance audits.

Inspectors noted that a number of written policies and procedures specific to the radiotherapy service were available to staff, and staff spoken with demonstrated how they accessed these documents on the hospital's intranet system. Similarly, written protocols for medical radiological procedures in the radiology department were available on a radiology shared drive and in paper format. However, the undertaking did not have a robust governance system in place for the management of these written policies, procedures and protocols. For example, from the sample of documents reviewed, inspectors noted that many radiology protocols did not contain details of who had responsibility for creating them or dates indicating when or who had approved them, or when they were due for review. Therefore, inspectors were not assured that protocols were up to date and regularly reviewed and this omission in documentation version control must be addressed in a timely manner.

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. However, no such system was available to ensure that information relating to patient exposure formed part of the report of the medical procedure in the radiology service. Inspectors were informed that a plan was being progressed with management in order to come into compliance with Regulation 13(2) but no such system was available at the time of inspection despite being raised at the RSC meeting in September and subsequently discussed at the December RSC meeting of 2022. This non compliance must be prioritised by the undertaking to ensure

measures identified to ensure regulatory compliance are progressed in a timely manner.

Judgment: Not 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 had included the implementation and maintenance of quality assurance and assessment of dose and verification of administered activity programmes including acceptance and regular performance testing.

Judgment: Compliant

Regulation 15: Special practices

Inspectors observed that the management team in the radiotherapy department at Galway University Hospital had in place a number of appropriate measures to ensure that patients receiving high dose medical exposures were appropriately protected, with careful consideration given to dose optimisation for patients. For example, at CT the dose delivered to the patient was recorded and compared to national and internationally published data, to ensure that it was optimal**.** Again at CT, patient immobilisation and scanning margins were carefully considered to ensure that only relevant areas were scanned. Inspectors were informed that some patients underwent specific preparation to reduce organ motion prior to the CT planning scan, to ensure that target doses to target organs were achieved. In the CT console area, inspectors observed a 'Paused and Checked' poster which had been developed as a result of lessons learnt from the review of incidents. The poster reminded staff to recheck key elements of the patient set-up before proceeding with the CT planning scan, with the aim of reducing the need for re-scans and the associated re-scan dose. Inspectors also observed that the management team had implemented an electronic patient record system, that forced key tasks on the patient radiotherapy work flow to be completed before the next key task was available to complete. This work flow was designed to ensure that checks and tasks on each radiotherapy treatment plan were completed by appropriate personnel, before medical exposures were delivered, and therefore ensured that patients were receiving high quality and safe courses of radiotherapy treatments.

The radiotherapy management team had also allocated a radiation therapist to the role of Information and Support Radiation Therapist (ISRT), who met with each patient before they received their initial dose of ionising radiation. The ISRT provided patients with information leaflets on the benefits and risks associated with

receiving a course of ionising radiation to their particular treatment site, and provided them with an opportunity to adequately discuss this information before proceeding with radiotherapy planning and treatment. The ISRT also ensured that CT staff were informed of any specific patient issues prior to the CT scan, which allowed CT staff to optimise the scanning procedure and therefore ensure doses delivered during the scan and treatment course were as low as achievable.

During the course of the inspection, inspectors also spoke with treatment planning staff in the radiotherapy department, who informed inspectors that specific planning protocols were used for each treatment site to ensure the doses to normal tissue is kept as low as possible while delivering the optimal treatment dose to the target area.

Inspectors also reviewed policies and procedures utilised in the interventional radiology departments to identify potential high skin doses in patients undergoing cardiac and general interventional 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. Staff spoken with clearly articulated the practical application of these policies in clinical practice and informed inspectors that, at the time of inspection, four patients had reached the predetermined threshold for follow up, had been followed up and had not reported any tissue reactions associated with high skin doses.

Inspectors were satisfied that Galway University Hospital had multiple systems and processes in place to ensure patients undergoing medical exposure 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 undergoing radiotherapy. Inspectors also reviewed a number of patient records and found that this enquiry had been documented prior to the planning CT scan by the ISRT and was rechecked with the patient at CT 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. Staff articulated the process clearly to the inspectors on

the day of inspection and sample referrals reviewed by the inspectors verified the consistent recording of the relevant information in line with regulatory requirements.

Although, the inspectors were satisfied that only recognised practitioners inquired and recorded pregnancy status, the document *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* included the provision for a person other than a practitioner to inquire and record the answer to whether an individual subject to the medical exposure is pregnant or breastfeeding. This document also used the now superseded term 'prescriber' throughout and did not include radiographers or radiation therapists in its definition of practitioners, and was therefore inconsistent with other radiation safety documentation. As the regulations specify that the inquiry and recording of pregnancy and breastfeeding status can only be done by appropriately recognised referrers and practitioners and day-to-day practice predominantly relied on radiographers and radiation therapist to both inquire and record service users answers, the undertaking must update the relevant documentation to ensure it reflects both the regulatory requirements and day-to-day practice at Galway University Hospital.

Multilingual posters were observed throughout the radiotherapy and diagnostic imaging departments. The inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Substantially 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 facility.

Evidence was available to show that incidents were discussed at the appropriate committee levels within the hospital and subsequently reported to the RSC, thus the undertaking had oversight of incidents 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 by Galway 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 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	Substantially 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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for University Hospital Galway OSV-0007356

Inspection ID: MON-0035037

Date of inspection: 16/05/2023

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:
Time lines below have been developed, with all relevant stakeholder input, namely hospital management, radiology, radiotherapy and Medical physics/Clinical engineering. The target dates have been established within the context of current staffing levels within the departments. The compliance plan and actions will be reviewed on a monthly basis, through the RPU and RSC by use of a tracker tool developed.
1. Improve radiation protection document stewardship
(a) Compile a list of controlled versus uncontrolled documents pertaining to radiation protection in GUH.
(b) Decide and formalise responsibilities for (i) creation, (ii) approval and (iii) update/review of controlled documents.
(c) Feedback responsibilities to relevant responsible staff.
(d) Explore IT solution for Document Control System (Q-pulse) module specific for radiation protection
ACTION: RPU Target date: Q3-4 2023
(e) Convert all controlled documents to a standard format (author(s), version, review date, etc.) as per the HSE National Framework for Developing PPPGs (2016).
(f) Upload all standardised controlled documents to Q-Pulse.
(g) Relevant responsible staff to ensure all hardcopies; and softcopies in circulation on shared drive; are most recent Q-Pulse version.
(h) Relevant responsible staff to remove all out-of-date hardcopies and softcopies from circulation.
(i) Audit document stewardship in a selection of areas annually.
ACTION: Author of each controlled document Target date: Q2 2024

2. Formalise communication to other departments using fluoroscopy
(a) Write to relevant parties to ensure representation from each department at RSC level.
ACTION: RSC Chair Target date: Q3 2023
(b) Identify any possible changes to RSC schedule that could be implemented to help

ensure regular attendance
(c) Update RSC TOR to formalise follow-up of consistent absenteeism
ACTION: RPU Target date: Q3 2023
3. Update the document Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures to satisfy regulatory requirements and reflect current legislative language.
ACTION: RPU Target date: Q4 2023
4. Ensure key roles are appropriately resourced such that a robust system exists that guarantees allocated responsibilities can be met regardless of staff shortages
(a) Risk Assessment for Radiology and Radiotherapy in relation to staff shortages, detailing control measures and staff responsibilities in context of staffing shortage
Action: RSM in Radiology and Radiotherapy Target date: September 2023
(b) GUH actively recruiting into vacant Radiography and Radiotherapist posts in order to have sufficient staffing levels to allow RSO scheduled regular protected time for radiation protection. Due to current staffing levels, RSO can be re-deployed to clinical service due to patient care needs
Action: RSM in Radiology and Radiotherapy & HR, GUH Target date: Ongoing
(c) Submit business case for RSO posts for Radiography and Radiotherapist through NCCP
Action: RSM in Radiology and Radiotherapy Q4 2023

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
Time lines below have been developed, with all relevant stakeholder input, namely hospital management, radiology, radiotherapy and Medical physics/Clinical engineering. The target dates have been established within the context of current staffing levels within the departments. The compliance plan and actions will be reviewed on a monthly basis, through the RPU and RSC by use of a tracker tool developed.
1. Update the document Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures to satisfy regulatory requirements and reflect current legislative language.
ACTION: RPU Target Date: Q4 2023
2. Update the document Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures to satisfy regulatory requirements and reflect current legislative language.
ACTION: Radiology and RT RSOs Target Date: Q4 2023

Regulation 8: Justification of medical	Substantially Compliant

exposures	

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Time lines below have been developed, with all relevant stakeholder input, namely hospital management, radiology, radiotherapy and Medical physics/Clinical engineering. The target dates have been established within the context of current staffing levels within the departments. The compliance plan and actions will be reviewed on a monthly basis, through the RPU and RSC by use of a tracker tool developed.
RADIOTHERAPY
1. (i)Ensure clinical information on all radiological examinations performed satisfies regulation 8(10):
(a) Develop a department policy on justification processes across the patient pathway clearly outlining roles and responsibilities across the MDT at each point.
(b) Include justification recording within the end of process quality checklist along the patient pathway as evidence of justification within the electronic patient record.
(c) Integrate the electronic paper record to capture noncompliance within the referral pathway, which can be used as a source for ongoing audit.
(d) Ensure referral audit data is presented to management meeting and quarterly at the radiation safety meeting and quality initiatives implemented as result of findings.
ACTION: Radiotherapy RSO Target Date: Q4 2023

RADIOLOGY
1. (ii) Ensure clinical information on all radiological examinations performed satisfies regulation 8(10):
(a) Audit a sample of performed and cancelled radiological procedures to determine what referrers are consistently ordering with insufficient clinical information.
(b) Feedback inspection findings to practitioners engaged in justification, endoscopy team and any other offending referrers.
(c) Highlight importance of ensuring compliance to practitioners engaged in justification process.
(d) Re-audit of justification of radiological procedures to measure compliance.
ACTION: Radiology RSO Target Date: Q4 2023

2. Update the document Standard Operating Procedure for the Justification of Radiological Procedures Utilising Ionising Radiation in GUH to satisfy regulatory requirements.
ACTION: Radiology RSO Target Date: Q4 2023

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Time lines below have been developed, with all relevant stakeholder input, namely hospital management, radiology, radiotherapy and Medical physics/Clinical engineering.

The target dates have been established within the context of current staffing levels within the departments. The compliance plan and actions will be reviewed on a monthly basis, through the RPU and RSC by use of a tracker tool developed.
1. Improve radiation protection document stewardship
(a) Compile a list of controlled versus uncontrolled documents pertaining to radiation protection in GUH.
(b) Decide and formalise responsibilities for (i) creation, (ii) approval and (iii) update/review of controlled documents.
(c) Feedback responsibilities to relevant responsible staff.
ACTION: RPU Target date: Q3 2023
(d) Convert all controlled documents to a standard format (author(s), version, review date, etc.) as per the HSE National Framework for Developing PPPGs (2016).
(e) Upload all standardised controlled documents to Q-Pulse.
(f) Relevant responsible staff to ensure all hardcopies; and softcopies in circulation on shared drive; are most recent Q-Pulse version.
(g) Relevant responsible staff to remove all out-of-date hardcopies and softcopies from circulation.
(h) Audit document stewardship in a selection of areas annually.
ACTION: Author of each controlled document Target date: Q2 2024
2. Update the document Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures to satisfy regulatory requirements and reflect current legislative language.
ACTION: RPU Target Date: Q4 2023
3. Dose on Report
(a) Identify vendors with software capable of automating individual patient dose on each report.
(b) Carry out tender process
ACTION: MPCE Target Date: Q1 2024
(c) Integrate solution with existing system
ACTION: Multidisciplinary team including at a minimum Vendor Rep, Equipment Service Engineers, RIS/PACS Administrator, IT rep, MPCE rep, Radiology Rep. Target Date: Q1 2024

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:
Time lines below have been developed, with all relevant stakeholder input, namely hospital management, radiology, radiotherapy and Medical physics/Clinical engineering. The target dates have been established within the context of current staffing levels within the departments. The compliance plan and actions will be reviewed on a monthly basis, through the RPU and RSC by use of a tracker tool developed.
1. Update the document Policy for the protection of the unborn child arising from ionising

radiation received during medical diagnostic or therapeutic procedures to satisfy regulatory requirements and reflect current legislative language.
ACTION: Radiology and RT RSOs Target Date: Q3 2023

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	31/12/2023
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	31/12/2023

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Orange	31/12/2023
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Orange	31/12/2023
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	31/12/2023
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	31/12/2023

Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/12/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/03/2024
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	30/09/2023
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)	Substantially Compliant	Yellow	30/09/2023

	in writing, retain such record for a period of five years and provide such records to the Authority on request.			