



**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:	Cork University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Model Farm Road, Wilton, Cork
Type of inspection:	Announced
Date of inspection:	03 July 2025
Medical Radiological Installation Service ID:	OSV-0007353
Fieldwork ID:	MON-0044112

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

Cork University Hospital (CUH) is Ireland's largest statutory/HSE hospital and the only Model 4 Specialist Academic Teaching Hospital in the state, integrating all acute surgical and medical specialties, including Adults, Paediatrics, Maternity, and Mental Health, on a single campus. As one of the busiest Model 4 hospitals nationally, CUH serves as a regional and supra-regional centre for secondary and tertiary care, covering a catchment population of approximately 1.1 million across counties Cork, Kerry, Limerick, Clare, Tipperary, Waterford, Kilkenny, Wexford, Carlow, and Laois. CUH is nationally designated as one of two Level 1 trauma centres, one of two 24/7 neurosurgical and stroke thrombectomy centres, one of five 24/7 PPCI centres, one of four cardiothoracic surgical centres, and one of two comprehensive coagulation and haemophilia centres. It is also a cystic fibrosis centre and one of eight NCCP designated Cancer Centres, the only one offering all tumour pathways, diagnostics, modalities, and treatments under a single provider. Radiotherapy Services are delivered through the state-of-the-art NPRO Radiation Oncology building, opened in November 2019. The department features five Linear Accelerators, two CT simulators, a superficial therapy unit, and a brachytherapy unit. It provides advanced radiotherapeutic treatments including external beam radiotherapy, superficial therapy, HDR gynaecological treatments, prostate seed implantation, and radioisotope therapies using Iodine-131 and Radium-223. These services support patients from Cork, Kerry, Limerick, Waterford, and South Tipperary. Radiology Services at CUH offer comprehensive, high-quality imaging and image-guided procedures on a 24/7 basis. The department supports in-patient, out-patient, emergency, and GP-referred cases. Sub-specialty imaging includes CT, Vascular, Paediatric, Interventional, Fluoroscopy, Nuclear Medicine, Ultrasound, Breast Imaging, Neuro-radiology, Cath Lab, Chest, Abdominal, Musculoskeletal, and Oncology Imaging. All imaging equipment is digital and integrated into the RIS/PACS system, ensuring seamless access and reporting. Together, the Radiotherapy and Radiology departments at CUH play a critical role in supporting the hospital's regional and national responsibilities, delivering cutting-edge diagnostic and therapeutic services to a broad and diverse patient population.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 3 July 2025	09:00hrs to 16:00hrs	Kay Sugrue	Lead
Thursday 3 July 2025	09:00hrs to 16:00hrs	Margaret Keaveney	Support
Thursday 3 July 2025	09:00hrs to 16:00hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Cork University Hospital (CUH) was inspected by HIQA inspectors on 3 July 2025, to assess compliance with the regulations at the hospital. Both the radiotherapy and radiology departments at the hospital were inspected on the day and inspectors reviewed documentation and records and spoke with staff working in both of these departments.

Compliance plans from inspections carried out on 20 August 2020 and 23 October 2023 were followed up and discussed with hospital management during this inspection. While measures had been implemented to address the findings of these previous inspections, not all achieved improvement in compliance. The findings from this inspection identified that compliance, overall, had reduced since 2023, therefore, the undertaking must ensure that effective measures are now implemented to achieve compliance with Regulations 4, 5, 6, 8, 10, 14, 17, 20 and 21, and to support staff working in the radiology service to implement the improvements required to effect the necessary changes.

From the evidence gathered on the day of inspection, inspectors found that the allocation of responsibilities for radiotherapy practices aligned with the regulations. This meant that in this department, medical radiological procedures involved recognised referrers and practitioners. In the radiology department, medical exposures were predominantly conducted by a practitioner, based on a referral from a practitioner, with some exceptions. Greater assurances however, must be provided by the undertaking to ensure that all medical radiological procedures are only carried out on the basis of referrals from persons entitled to act as referrers under the regulations, to comply with Regulation 4. Following this inspection, management at Cork University Hospital was required to submit an urgent compliance plan to address the non-compliances identified in relation to Regulation 4. The undertaking's response provided an assurance that the risk was adequately addressed. Also, clinical evaluation of the outcome, an aspect of clinical responsibility, for some fluoroscopy procedures, was taken by individuals not recognised as a practitioner under Regulation 5, therefore, this issue must be addressed by the undertaking.

Furthermore, as outlined under Regulation 6, other aspects in relation to the allocation of responsibilities also required action by the undertaking. For example, in the radiology department, the scope for nurse referrers to refer for medical exposures should be clearly defined within the areas they work in. Improvements were also required in other areas such as clinical audit of medical radiological procedures to ensure alignment with the national procedures. In addition, the allocation of responsibilities needs to be clear and the process outlined in documentation to ensure that the introduction of a new type of practice is managed in line with Regulation 7.

Discussions with staff delivering medical exposures in both radiology and radiotherapy departments at CUH provided assurance that there was a strong

commitment by staff in relation to the radiation protection of service users. Overall, as discussed under Regulation 6, the management arrangements need to be strengthened to improve the two-way communication pathways between hospital management and staff, and greater support provided to staff to effectively implement the changes needed to improve regulatory compliance.

Regulation 4: Referrers

In the radiotherapy department, referrals were only accepted from appropriately registered medical practitioners, and from radiation therapists for image guided radiation therapy (IGRT) exposures. These roles were clearly allocated in *Policy for the Communication, Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital*.

Inspectors viewed referrals from a range of modalities in the diagnostic imaging department and found that in the majority of areas, the individual referring was a recognised referrer, in line with regulatory requirements and hospital policy. However, in a sub-set speciality area, inspectors saw evidence of non-compliance with this regulation where the following non compliant referring practices were identified:

- A blanket system for referring patients for medical radiological procedures in the orthopaedic out-patient department was applied in which inspectors viewed significant numbers of pre-signed blank referral cards.
- In addition, inspectors saw evidence where these pre-signed cards were completed by individuals not recognised as referrers within the hospital. In discussions with staff working in this department, it was clear that this issue was ongoing for several years and attempts to change legacy referral practices in this service were unsuccessful to date.
- The referral system for medical radiological procedures in the theatre department requires the referrer to raise an order (which is the referral) on the radiology information system (RIS) in advance of carrying out the procedure. Inspectors found that orders were not placed by a referrer on RIS and were informed by staff that practitioners entered the procedures on the system for these procedures retrospectively. This meant that medical radiological procedures were carried out in the absence of a referral from a recognised referrer.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 5: Practitioners

From a review of documentation and speaking with staff and management, the inspectors were satisfied that the undertaking had systems in place to ensure that only appropriate individuals, as per Regulation 5, acted as practitioners in the radiotherapy department at Cork University Hospital.

Inspectors were satisfied from a review of documentation and speaking with staff, that for the majority of medical exposures delivered at the hospital, only individuals entitled to act as practitioner, as per Regulation 5, took clinical responsibility for the procedure with some exceptions. For example, reports from some fluoroscopy procedures showed evidence that the clinical evaluation of the outcome, which is an aspect of clinical responsibility, was completed by an individual not recognised as a practitioner under this regulation. Therefore, the undertaking must take action to ensure that all aspects of clinical responsibility is allocated to a practitioner as per Regulation 10(1).

Judgment: Substantially Compliant

Regulation 6: Undertaking

Cork University Hospital provides both a diagnostic imaging service and a radiotherapy service that are located in different areas of the hospital. Each of these departments had separate local management arrangements that included multidisciplinary forums responsible for the day-to-day operations of each of these departments. For example, each department had a radiation protection unit (RPU) that reported in to a single overarching radiation safety committee (RSC). There were additional sub-committees in each department with responsibility for reviewing clinical audits and radiation incidents relevant to each department. Inspectors were informed that any issues arising from these meetings were escalated to the RSC. The RSC reported to the quality, safety and risk committee and upwards to the executive management team (EMT). The RSC was responsible for ensuring regulatory compliance and overseeing the radiation protection of service users. Overall responsibility for the radiation protection of service users rested with the designated manager, who was the chief executive officer (CEO) for CUH, and also chaired the EMT. Inspectors were informed that upward communication to the undertaking, the Health Services Executive (HSE), was via the Intergrated Healthcare Area (IHA) reporting structure in the Southwest region.

Minutes reviewed from radiology governance forums in each department indicated that there were regular meetings held to discuss matters relating to day-to-day operations, radiation incidents, clinical audits, radiation safety training, quality assurance of medical radiological equipment and to support radiation protection measures across both departments. The evidence gathered demonstrated that there was multidisciplinary awareness and input into radiation protection matters and

issues arising within each department, which were communicated up to the RSC. However, from the composite of findings from this inspection, and outstanding gaps not fully addressed from previous inspections carried out in 2020 and 2023, inspectors found once again, reporting pathways from the RSC to hospital management and overarching oversight of regulatory compliance needs to be strengthened. For example, inspectors found from discussions with staff, that there had been a significant delay, by hospital management, in informing staff in both the radiology and radiotherapy departments of this announced inspection. Consequently, this led to a delay in the submission of documents requested by HIQA in advance of the inspection and did not provide sufficient assurance to inspectors that that communication pathways between senior hospital management and staff in both departments were as effective as they should be. In addition, the undertaking had not notified HIQA of the change of the designated manager in a timely way, in line with HIQA guidance. This change only came to light following the inspection announcement. The undertaking should notify HIQA when there is a change of designated manager or if the contact details of the current designated manager have changed to facilitate communications between HIQA and the undertaking and facility.

In relation to the clear allocation of responsibilities in the radiotherapy department, inspectors were satisfied that referrals and clinical responsibility for medical exposures for radiotherapy planning and treatments were allocated to individuals entitled, under the regulations, to act as referrers and practitioners. This was also the case for the majority of medical exposures carried out in the radiology department. However, within this department, inspectors identified several gaps in compliance in which action was required by the undertaking to ensure that:

- all referrals are provided by a recognised referrer, as per the regulations
- medical radiological procedures are only carried out by a practitioner based on a referral from a recognised referrer
- the scope for nurse referrers to refer should be clearly defined and monitored within the speciality they work in
- all aspects of clinical responsibility, particularly, the clinical evaluation of the outcome of a medical exposure must only be taken by an individual entitled to as a practitioner
- the allocation of responsibilities for the oversight, management and approval pathway for applications of new types of practice for submission to HIQA is formalised and reflected in local documentation, and a review of all current practices should be completed to provide assurance of compliance with Regulation 7 requirements
- an overarching clinical audit strategy for medical radiological procedures carried out at the hospital is developed in accordance with the national procedures
- greater assurance that as per hospital policy, referrers allocated with the responsibility for making the pregnancy enquiry and providing the relevant information to the practitioner comply with hospital policy.

Since the 2020 and 2023 inspections, inspectors found that action was taken to improve the document quality management systems for the radiology service. This

was evident in the review and update of several procedures and policies developed to guide and support staff in the radiation protection of service users, in both the radiotherapy and radiology departments of Cork University Hospital. However, this was not the case for all documents reviewed where inspectors found that some documents were in draft format, some were not reviewed within defined time frames, and others needed to be updated to accurately reflect day-to-day practices. For example, as outlined in the compliance plan following the 2023 inspection, a corrective action to revise the RSC terms of reference (TOR), last updated in August 2020, had not been addressed. This was despite changes to the hospital governance arrangements and reporting pathways to the undertaking.

The undertaking is responsible for ensuring that there are appropriate governance, leadership and management systems in place to ensure that individuals allocated with the responsibilities for carrying out medical exposures at Cork University Hospital comply with the regulations. Overall, inspectors found established governance and management arrangements, including the communication pathways, need to be strengthened at the hospital, to ensure greater oversight of medical radiological practices and assurances of consistent compliance with the regulations.

Judgment: Not Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures performed in the radiotherapy departments took place under the clinical responsibility of a practitioner, as defined in the regulations. In relation to diagnostic imaging, a practitioner took clinical responsibility and was present for all medical exposures conducted at the hospital. However, from discussions with staff and a review of records, inspectors found that the clinical responsibility for the clinical evaluation of the outcome, which is an aspect of clinical responsibility, was completed by professionals not recognised under Regulation 5 for a sub-set of some fluoroscopy procedures. This must be addressed by the undertaking to ensure compliance with Regulation 10(1).

The evidence gathered demonstrated that practitioners and MPEs were involved in the optimisation process for medical exposure to ionising radiation. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual radiotherapy medical exposures and for the majority of medical radiological procedures carried out in diagnostic imaging, with the exception of those medical exposures that were not appropriately referred and already discussed under Regulation 4. This finding meant that corrective measures must be implemented by the undertaking to provide assurance that the justification process of individual medical exposures involves the referrer to comply with Regulation 10(3)(b).

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

The evidence supplied during this inspection satisfied the inspectors that Cork University Hospital had the necessary arrangements in place to ensure the continuity of MPE expertise in both the radiotherapy and radiology departments.

While meeting the requirements of this regulation during this inspection, inspectors noted that MPE resource deficiencies departments remained an ongoing issue since the 2020 inspection. The effects of these deficiencies were more notable in the radiology department where MPE advice was provided both to CUH and multiple external facilities in the Southwest region. Inspectors were informed that medical physics department resources had increased since the last inspection, however, had fallen again and were below the whole time equivalent levels required for the service provided. Inspectors noted that staff recruitment was ongoing which should remain a priority to ensure there is stability in the continuity arrangements for MPE services and to meet the demands of an expanding radiology service at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Current MPE professional certification records were viewed by inspectors and found that all but one were up to date. Inspectors were satisfied that a team of MPEs were involved and contributed to radiological practices and the radiation protection of services users in both the diagnostic imaging and radiotherapy departments at the hospital.

From a review of documentation and discussions with the undertaking's management team and the medical physicists, inspectors were satisfied that a team of MPEs completed a range of responsibilities as per Regulation 20(2). For example, in both the radiotherapy and radiology departments, inspectors noted that the MPEs contributed to the optimisation of the radiation protection of patients, were responsible for dosimetry and advised on the dose calculations for radiation incidents. MPE involvement in the review and establishment of facility diagnostic reference levels (DRLs) was also evident in both departments. Inspectors saw evidence of MPE involvement in clinical audits to review procedures that consistently exceeded national DRIs. They were also involved in the quality assurance (QA) and acceptance testing of medical radiological equipment and had inputted into on-line training modules available to staff. A review of meeting minutes also showed that there was MPE representation on the RSC, and other departmental committees tasked with the radiation protection of service users. MPEs at Cork University

Hospital also liaised with radiation protection advisors (RPAs) assigned to the hospital, therefore satisfying the requirements of Regulation 20(3).

While QA timelines, as specified in the QA programme, were met in the radiotherapy department, the QA for three units in the radiology service was behind schedule. Staff informed inspectors that every effort was made to ensure MPE responsibilities were met, however, access to equipment, staff deficiencies and competing demands on MPE resources proved challenging, particularly following through on day-to-day issues as they arose. Staff also said that improved resources would allow for additional MPE involvement in optimisation and training of practitioners for the benefit of the radiation protection of service users.

Judgment: Substantially Compliant

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

Inspectors noted that there was MPE involvement across the range of medical radiological practices at CUH. While MPE involvement was commensurate with the radiological risk posed by the medical radiological practices in the radiotherapy department at Cork University Hospital, as discussed under Regulation 20, there was scope to further improve MPE involvement and contribution in the radiology department in this regard.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors were assured from speaking with staff involved in the delivery of medical radiological procedures across both departments at CUH that there was a multidisciplinary approach taken to ensure the radiation protection of service users. In the radiotherapy department, inspectors found good compliance with the regulations while compliance levels in the radiology department needed to improve.

Good practices were seen across both services in relation to Regulation 11, DRLs. For example, facility DRLs for CT planning scans were established and used by radiation therapists to monitor scan doses to ensure that any high dose scans were identified and investigated. In the radiology department, evidence provided to inspectors showed that optimisation projects were initiated, with some ongoing at the time of the inspection, to review facility DRLs that consistently exceeded national DRLs. Compliance was also found in relation to Regulation 16 regarding the special protection during pregnancy and breastfeeding.

Inspectors noted good practices in the radiation protection of patients undergoing high dose procedures in radiotherapy medical exposures and interventional cardiology procedures which are discussed under Regulation 15. In addition, examples of clinical audits of medical exposures showed the optimisation of patient doses was a topic prioritised for audits undertaken in both departments. Inspectors found that work was in progress to establish a clinical audit strategy that fully incorporates the principles and criteria of the national procedures, to align fully with Regulation 13(4) and to integrate clinical audit of medical radiological procedures into a hospital wide co-ordinated approach to clinical audit.

Inspectors reviewed a sample of referrals in both the radiology and radiotherapy departments and found that all referrals viewed in the radiotherapy department were in writing and contained the reason for the requests and sufficient medical data to inform the justification process, with some exceptions identified in the radiology service. These exceptions related to gaps in compliance previously outlined under Regulation 4. Furthermore, for some medical radiological procedures conducted in the theatre department, inspectors were not fully assured that clinical information relating to the patient was documented in the referral in all cases. Inspectors saw that there were defined processes for documenting justification in advance for medical exposures carried out across both departments, however, records for justification in advance of medical exposures delivered in the interventional cardiology department were not clearly evident in patient records viewed. Therefore, the undertaking's management team must address the gaps in compliance outlined to ensure compliance with Regulations 8.

Pregnancy declaration forms were viewed by inspectors for a sample of medical exposures, which demonstrated that the pregnancy enquiry was completed by a practitioner in advance of carrying out each medical exposure.

Inspectors found there were appropriate quality assurance (QA) programmes in place in both the radiology and radiotherapy departments with evidence to show that medical radiological equipment was subject to regular performance testing and annual QA by an MPE. Time lines for annual QA of equipment outlined in the QA programmes were met in both departments with the exception of a small number in the radiology department which were overdue. This was attributed by staff to accessing the equipment in a busy environment, with high activity levels, and competing demands on available MPE resources. Therefore, the undertaking must ensure that staff are adequately supported to carry out MPE responsibilities to fully comply with Regulation 14(1).

In both departments, a system was in place for recording and reviewing incidents involving, or potentially involving, accidental or unintended exposures to ionising radiation in both departments. Inspectors noted that significant events were reported within time lines outlined in HIQA guidance. While improving compliance with Regulation 17 since the previous inspection, greater assurance is needed in relation to the identification, reporting and management of potential incidents and near misses across the service.

Overall, inspectors were satisfied that there were systems in place to support the safe delivery of medical exposures at Cork University Hospital, however, improvements were required to strengthen the systems and processes in the radiology department to support staff in achieving full compliance with the regulations.

Regulation 8: Justification of medical exposures

The undertaking's radiotherapy management team had developed a policy titled *Policy for Communication Justification Optimisation in Radiotherapy* which outlined the justification process, and associated roles and responsibilities, along the radiotherapy patient's pathway. On the day of the inspection, inspectors reviewed a sample of referrals in the radiotherapy department and saw that they were available in writing and stated the reason for the request. From this review, inspectors were also assured that sufficient medical data, including diagnostic imaging and histology reports, were available to enable the practitioner to adequately consider if the referral was justified. Inspectors were also informed that, during the initial consultation with the radiation oncologist, enquiries were made to determine if a patient had completed previous radiotherapy. Where relevant, this treatment information was obtained and considered in the treatment planning process as a key radiation protection measure.

In the radiology department, notwithstanding the gaps in compliance outlined under Regulation 4, inspectors saw evidence that referrals were provided for all other medical radiological procedures out side of those identified in the orthopaedic service. Similarly, clinical information was provided to support the requested procedure with the exception of a small number of medical exposures carried out in the theatre service. Relevant information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of information leaflets and posters in all waiting areas of the hospital.

There was evidence to show that justification in advance was recorded by a practitioner in the majority of medical radiological records reviewed which were retained in the hospital's radiology information system (RIS). However, while the process for justifying interventional cardiology procedures in advance was described and understood by staff working in the cardiology service, the record of justification in advance was not evident in the sample of patient medical records reviewed by inspectors during the inspection. Inspectors noted that greater clarity on how justification should be recorded in each modality should be provided in hospital policy for the benefit of staff, and to ensure consistency in meeting the requirements set out under Regulation 8(15).

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Both the the radiology and radiotherapy departments had policies in place for the establishment and review of DRLs. For example, the radiotherapy team had developed a document titled *Guidance on the recording of Dose Reference Levels in Pre-Treatment Planning in the Glandore Centre*, which was last reviewed in March 2025 and outlined the roles and responsibilities for professional groups establishing and annually reviewing DRLs at the centre. Inspectors noted that the undertaking had established local DRLs for CT planning scans which were used by radiation therapists to monitor scan doses and ensure that any high dose scans were identified and investigated. This was identified as an area of good practice in the service.

In the radiology service, inspectors noted that a lot of work was undertaken by staff since the 2020 inspection to review data and establish facility DRLs which was evident in the documentation provided and reviewed by inspectors. Facility DRLs were compared with national DRLs and displayed as a reference point for staff in control rooms in clinical areas. Inspectors were satisfied that reviews were carried out where local DRLs were found to consistently exceed national DRLs. For example, an optimisation review was underway for pelvis X-rays which exceeded national DRLs, and to establish the cause of differences found in radiation doses between two X-ray rooms carrying out the same procedure.

Overall, inspectors found that there was a proactive approach taken by staff at the hospital to ensure the optimisation and radiation protection of service users and good practices were identified in both departments in relation to the establishment and review of facility DRLs.

Judgment: Compliant

Regulation 13: Procedures

Written protocols, in the form of clinical guidelines for specific cancer sites, had been developed in the Glandore Centre at Cork University Hospital as required by Regulation 13(1), and were readily available to practitioners in the clinical areas. A sample of these guidelines were reviewed, and inspectors noted that, among other key information, they contained referral guidelines for referrers for radiotherapy medical imaging. In the radiology department, inspectors also found that protocols for standard medical radiological procedures were available for each modality and referral guidelines were also evident on desktop computers in the clinical area.

In the radiotherapy department, inspectors were informed that a discharge letter was generated after each patient completed their radiotherapy treatment, and from the sample reviewed, inspectors noted that this letter included information on the treatment dose received by the patient. Information relating to patient exposure

was included in the majority of reports from medical exposures viewed in the radiology department, however, gaps were identified in relation to interventional cardiology medical exposures where action was required to comply fully with Regulation 13(2).

Inspectors reviewed a range of clinical audits completed in the radiology and the radiotherapy departments. In the radiotherapy service, audits were carried out on CT scanning borders, the optimisation of patient position imaging and the electronic record for a specific cohort of patients. Inspectors were informed that a number of these audit topics had been identified through incident learning and as a result of quality improvement plan changes. This was identified as an area of good practice in the service. Inspectors also saw evidence that action plans had been developed and implemented as a result of clinical audit outcomes, and that re-audits were planned to monitor the level of improvement as a result of the action plans. Inspectors also saw evidence that action plans had been developed and implemented as a result of clinical audit outcomes, and that re-audits were planned to monitor the level of improvement as a result of the action plans in this service. A sample of audits carried out in the radiology department were also reviewed. For example, an audit of potential foetal doses in pelvic X-rays resulted in a re-categorisation of pelvis and hip X-rays as low foetal dose examinations and also identified the need for a follow up dose audit of these procedures as part of an optimisation study.

Inspectors found there were appropriate reporting arrangements in place from the clinical audit sub-committee within each department up to the RSC, which was evident in RSC minutes reviewed. While a clinical audit strategy for the radiology department was available, the scope of this document did not include the radiotherapy department, and it was unclear if this document was approved for use, as it was not version controlled. There was also scope to strengthen the alignment of this strategy with the principles and essential criteria of the national procedures, specifically, the identification of high risk areas prioritised for audit, and ensuring audits are carried out across the full clinical medical exposure pathway, incorporating the elements of structure, process and outcome. Furthermore, the undertaking should consider a centrally co-ordinated approach to hospital wide audits that includes clinical audit for medical radiological procedures, as this should further improve the quality of radiological services provided.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at the Glandore Centre was provided in advance of this inspection. Inspectors were satisfied that medical radiological equipment in use in the radiotherapy service was kept under strict surveillance as required by Regulation 14(1), this included the calibration equipment used to test treatment planning and delivery equipment.

Inspectors were informed of the daily, monthly and annual testing completed on the CT planning and treatment equipment, and a review of a sample of records for equipment in the radiotherapy department demonstrated that the QA programme was being implemented in accordance with the responsibilities outlined. Inspectors were also informed that the radiation protection unit in RT was tasked with oversight of the QA programme, which in turn reported to the RSC meeting. Also, additional equipment needs and testing were also discussed at the departmental operations meeting as part of discussions on new treatment developments within the department.

In the radiology department, a selection of commissioning reports were reviewed by inspectors and demonstrated that acceptance testing had been completed by an MPE, as per Regulation 14(3)(a). Regular performance testing and annual QA reports were also reviewed and showed that the majority of equipment had been subject to annual QA within defined time lines, however, with some exceptions which were outside the time line indicated in local policy. Inspectors viewed equipment fault logs in each area visited and viewed reports from service engineers.

Inspectors found that appropriate QA programmes were in place to ensure medical radiological equipment in use was safe for clinical use, however, the gap identified must be addressed to provide greater assurance regarding the strict surveillance of equipment, as required under Regulation 14(1).

Judgment: Substantially Compliant

Regulation 15: Special practices

Inspectors found from discussion with staff and a review of documentation, that there were measures implemented at CUH to ensure that patients receiving high dose medical exposures were appropriately protected. Inspectors noted that there was good collaboration between the various disciplines involved in the planning and delivery of radiotherapy medical exposures at the Glandore Centre. For example, inspectors were informed by staff that a multidisciplinary team had previously met to develop site specific tumour clinical guidelines for use in the referral, treatment planning, and treatment imaging and delivery for radiotherapy to patients in the service. This approach to the radiation protection of patients was viewed as a good example of the effective use of knowledge and expertise of available resources in the service.

Inspectors also noted that the radiotherapy staff team place strong emphasis on optimising medical exposures carried out along the patient pathway. For example, the use of immobilisation equipment, methods to reduce organ motion where necessary, and site specific treatment planning protocols which set dose constraints for tissues close to treatment target areas. Inspectors also noted that surface guided radiotherapy (SGRT) was in use in the department which is used for patient

positioning and continuous monitoring throughout treatment without the delivery of additional ionising radiation.

In the radiology department, inspectors saw that patient doses were routinely monitored by a radiographer during each procedure conducted in the interventional cardiology suite. The presence of a radiographer during interventional cardiology procedures provided additional assurance of the optimisation of each medical radiological procedure performed there. Inspectors viewed the document *Procedure for identification and follow-up of high skin doses arising from Interventional Radiology and Neuroradiology procedures involving X-rays* that outlined the steps to be taken to ensure that service users who had received a high skin dose during a procedure were appropriately followed up. This process was also described by staff to inspectors in the interventional cardiology suite.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From the review of a sample of medical radiological records to which this regulation applies, a pregnancy declaration form was completed by a practitioner in advance of the examination and retained on the radiology information system in the radiology service. While meeting the requirements of this regulation, and as discussed under Regulation 6, greater assurance is needed regarding the referrers role to inquire as to the pregnancy status of relevant service users to ensure compliance with hospital policy.

A review of the *Procedure for Determining Pregnancy Status of Patients Receiving Radiotherapy* showed that radiation oncologists and radiation therapists had been allocated responsibility for inquiring on patients' pregnancy or breastfeeding status, where relevant, in line with the regulations. Inspectors reviewed a sample of records for medical exposures and found that, in line with the departmental procedure, such inquiries took place, where relevant, prior to CT scanning and again on the first day of treatment prior to the medical exposure being completed.

Throughout patient waiting areas in the radiology and radiotherapy departments, inspectors observed numerous multi-lingual notices displayed to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From discussions with staff and documentation reviewed, inspectors were satisfied that there was a system implemented for the recording and analysis of events involving involving accidental or unintended medical exposures in both the radiology and radiotherapy departments at CUH. Inspectors noted that significant events were reported from both departments, as they occurred, and as per regulatory requirements and HIQA guidelines. Inspectors saw from RSC minutes viewed that incidents which had occurred in both departments were discussed as a standing agenda item at this forum, thereby, providing assurance that the undertaking has oversight of reported radiation incidents in this service.

Inspectors were informed that an action plan based on the previous inspection findings had been developed for incident management in the Glandore Centre and a number of quality improvement projects had been instigated as a result of incident or near miss investigations. For example, the process of how patient's electronic treatment records are completed after the final treatment has been delivered, was reviewed and amended to minimise the risk of an incident occurring. Also, an incident reporting pathway review group was established, whose membership included key representatives from the radiotherapy department and the hospital's quality office. This group was tasked with reviewing how incidents and potential incidents are reported, analysed and actioned. Inspectors were also informed that although an action time line had been set by the undertaking, it had not been met due to insufficient staffing resources. Therefore, the undertaking should allocate adequate resources to this incident pathway review groups to ensure that all near misses that occur in the department are reported and appropriately managed.

Inspectors noted that similar to the previous inspection, low numbers of near misses were reported in the radiotherapy and radiology departments, relative to the number of procedures completed annually. This issue was identified by staff as an area of improvement and measures were introduced to improve the levels of reporting. The effectiveness of these measures would be determined in time as they were only introduced before this inspection.

Overall, inspectors were satisfied that a system was implemented for the record keeping and analysis of events involving accidental or unintended medical exposures, however, to achieve full compliance with this regulation, improvements are required to ensure that all potential incidents and near misses are recorded so that early risk management actions can be implemented and the risk of potential harm to the patient minimised.

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	Not Compliant
Regulation 5: Practitioners	Substantially Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially 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 Cork University Hospital OSV-0007353

Inspection ID: MON-0044112

Date of inspection: 03/07/2025

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 4: Referrers	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 4: Referrers:</p> <p>Specific:</p> <ul style="list-style-type: none"> – All referrals are now provided by a recognised referrer, as per the regulations. – Medical radiological procedures in CUH are now only carried out by a practitioner based on a referral from a recognised referrer. – Medical radiological procedures in CUH are now only carried out by a practitioner based on a prospective referral from a recognised referrer. The practice of retrospective referrals have ceases and is no longer accepted. – The scope for nurse referrers to refer is discussed at the Local Implementation Group meetings (LIG). Post approval all ANP and NP details are dated, documented and held in a central data base available to the group. The individual scope of the referrer is now clearly defined and monitored within the speciality they work in. Any changes or extensions in practice are discussed and approved or not approved at the LIG and the database is updated. – The list of recognised ANP and NP referrers is available for practitioners in CUH. – All outpatient orthopaedic referral orders are now raised by an orthopaedic doctor. This is done electronically via the ICM and RIS system. Clinical details are provided by the referring doctor and the doctor's medical number is recorded on a mandatory field. – Theatre requests are raised by the Orthopaedic team on duty for the orthopaedic scheduled list, emergency cases and/or late additions – Paper requests are no longer accepted as a means of referring a patient for any radiological examination/investigation for any patient on site. <p>Measurable:</p> <ul style="list-style-type: none"> – All orders raised on the RIS from any speciality are trackable and traceable. These orders have a unique accession number for that order, this is linked directly to the associated imaging. RIS orders can be used for audit purposes and to assess the origin of the order. Radiology have full oversight on all orders from all origins. <p>Achievable:</p>	

– All specialities are now fully compliant for all referrals from recognised referrers to be compliant with regulation 4.

Realistic:

– The orthopaedic pathway was targeted to ensure that the process and practice for all referrals from this cohort was now conducted correctly so that only recognised referrers are now accepted by radiology for diagnostic and Interventional procedures through the ICM and RIS system. Only recognised referrers have approved access.

Timebound:

– The undertaking set out a specific date and time frame to ensure that corrective action and the necessary steps were taken by the orthopaedic teams in CUH to become compliant for all referrals for Radiology. This was communicated post a multidisciplinary discussion for the service, actions agreed upon and a time frame set for implementation. The process was co-ordinated by the Business Manager, Peri-Operative Directorate in conjunction with Radiology.

– A Hospital wide e-mail was circulated with relevant details for all recognised referrers in CUH to comply with the regulations.

– We believe we are now compliant with Regulation 4

Regulation 5: Practitioners	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 5: Practitioners:

Assurance that all aspects of the clinical responsibility for the clinical evaluation of the outcome of a procedure involving ionising radiation will be allocated to a practitioner as per Regulation 10(1).

S – The policy concerned will be updated to include who is responsible for clinical evaluation of the procedure.

M – Once this policy is implemented, it will be audited to check for compliance.

A – This policy update will involve all stakeholders and will be approved at the RPU.

R – This policy update will ensure compliance with Regulation 10.

T – The update of the policy ensuring compliance should be completed by 31 Dec 2025.

Regulation 6: Undertaking	Not Compliant
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Outline how you are going to come into compliance with Regulation 6: Undertaking:

In relation to the following points:

- All referrals are provided by a recognised referrer, as per the regulations.
- Medical radiological procedures are only carried out by a practitioner based on a referral from a recognised referrer.
- The scope for nurse referrers to refer should be clearly defined and monitored within the speciality they work in.
- Please see response to Regulation 4: Referrers

- All aspects of clinical responsibility, particularly, the clinical evaluation of the outcome of a medical exposure must only be taken by an individual entitled to as a practitioner.
- Please see Response to Regulation 5: Practitioners

- An overarching clinical audit strategy for medical radiological procedures carried out at the hospital is developed in accordance with the national procedures.
S – The RSC to oversee the development of an overarching clinical audit strategy for medical radiological procedures in accordance with national PPPG's.
M – Once agreed, the audit strategy will be implemented and monitored by the RSC.
A – The audit strategy will be developed with all relevant stakeholders and approved by the RSC.
R – The audit strategy will be developed with realistic and meaningful goals.
T – Timeline for approval of a clinical audit strategy is Q1 2026.

- The allocation of responsibilities for the oversight, management and approval pathway for applications of new types of practice for submission to HIQA is formalised and reflected in local documentation, and a review of all current practices should be completed to provide assurance of compliance with Regulation 7 requirements.
S – The allocation of responsibilities for the oversight, management and approval pathway for applications of new types of practice for submission to HIQA will be formalised through the RSC and reflected in local documentation.
M – A review will be performed of current practices to ensure compliance with Regulation 7 requirements.
A – No application of new types of practice will be approved without formal submission to HIQA and allocation of responsibilities for oversight and management formalised in each case.
R – Local documentation will be reviewed to ensure realistic goals and timelines,
T – This work will be completed by Q1 2026.

- Greater assurance that as per hospital policy, referrers allocated with the responsibility for making the pregnancy enquiry and providing the relevant information to the practitioner comply with hospital policy
S – Through education, engagement with the clinical directors and the RSC, CUH will ensure referring practitioners are cognisant of hospital policy by the end of October 2025.
M – Compliance will be monitored in real time by the receiving healthcare professionals, and this will be added to the audit programme for retrospective assessment of compliance.
A – Compliance will be monitored and discussed as a routine matter at the RPU.
R – If compliance is found to be unsatisfactory by the RPU the processes will be reviewed

and adjusted to ensure compliance is achieved.

T – This work will be completed by Q4 2025.

– The CUH governance organogram has been reviewed, revised and approved by the Executive Management Team. Clarification of the CUH governance organogram has been received by the RSC and the RSC terms of reference are being updated. This will be complete by the end of 2025.

– The organisational structures in CUH have been reviewed with a view to strengthening governance, management and communication pathways. A number of changes are needed and full implementation of the changes is expected by December 2025.

– This includes communication with the Authority which will remain through email or phone contact to the CEO office - Timeline: Immediate

Regulation 10: Responsibilities

Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:

– Clinical responsibility for the clinical evaluation of the outcome of a procedure involving ionising radiation will be a practitioner as per Regulation 10(1).

– Please see Response to Regulation 5: Practitioners

– In relation to Regulation 10(3)(b): an undertaking shall ensure that the justification process of individual medical exposures involves the referrer.

– Please see response to Regulation 4: Referrers

– Additionally the following measures will be undertaken

S – We will review existing policies procedures and guidelines to ensure that they stipulate that

– all referrals for radiation exposure contain the justification for the radiation exposure,
– where additional information is required to justify the radiation exposure this will need to be sought from and provided by the referrer.

– where radiation exposure is not justifiable this will be communicated with the referrer by the practitioner and the referral request will be declined by the practitioner

M – If these measures are not contained within existing PPGs the PPGs will be amended. Compliance with Regulation 10(3)(b) will form part of the audit schedule referred to in the response to Regulation 6.

A – Compliance with Regulation 10(3)(b) will form part of the audit schedule referred to in the response to Regulation 6.

R – Should audit of compliance with regulation 10(3)(b) be found to be unsatisfactory, root causes will be examined and a plan to bring compliance back to a satisfactory level will be put in place

T – The timeline for completion of review and assurance that PPGs align with Regulation 10(3)(b) will be completed by December 2025

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:</p> <ul style="list-style-type: none"> – Application for renewal of the staff member MPE professional certification was submitted and an updated MPE certificate (new expiry date 27/8/27) received. – Assurance that MPE Responsibilities as outlined by Regulation 20 will be met by: <ul style="list-style-type: none"> S – increasing radiology physics staff numbers from 11 WTE to 14 WTE. Best practice guidelines indicate that 14 WTE are needed to provide adequate cover. M – the radiology physics staff compliment is 11 WTE. Interviews have occurred and a panel of successful candidates has been formed to fill the 3 vacant posts A – the recruitment process to fill vacant posts will be completed once funding and approved position numbers are obtained through Regional Human Resources and the vacant positions filled R – If the vacant positions are not filled through the current recruitment campaign, the posts will be readvertised until they are filled T – Vacant posts are expected to be filled by the end of 2025. – Assurance that the MPE Responsibility for quality assurance is compliant will be achieved by, <ul style="list-style-type: none"> S – Sufficient resourcing of radiology physics. M – The physics QA service is reviewed fortnightly at departmental QA meetings. Analysis of QA performance is facilitated by the department’s equipment database and good QA record keeping. A – The goal of an on-schedule QA performance is achievable with a properly staffed radiology physics department. R – This goal has only been achieved when the demands on the department were at their least. Proper staffing of the department will ensure consistently good QA performance. T – Two of the three units identified at the inspection have passed their routine QA test. The third unit is awaiting repair; it will be tested once this has been successfully achieved. 	

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:</p> <p>Please see the response to Regulation 20 as regards the scope for improvement of MPE involvement and contribution in the Radiology Department.</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <ul style="list-style-type: none"> – Please see response to Regulation 4: Referrers – Please see Response to Regulation 5: Practitioners – Please see Response to Regulation 6: Undertaking – Please see Response to Regulation 10: Responsibilities <p>S – The Undertaking will engage with Cardiology to develop a policy in relation to justification of all procedures involving ionising radiation in the Cath Lab to ensure justification in advance.</p> <ul style="list-style-type: none"> – See Response to Regulation 4 – Referrer <p>M – Once this policy is approved and implemented, it will be audited to check for compliance.</p> <p>A – This policy will be approved by the Cardiology Department and the Radiation Safety Committee (RSC)</p> <p>R – The development of this policy will ensure compliance with Regulation 8.</p> <p>T – The policy will be approved at the January 2026 RSC meeting.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Radiology/Radiation Therapy</p>	

S – The Radiology Department and Radiation Therapy Unit will work towards developing a policy document which supports a Clinical Audit Strategy of medical radiological procedures. This will be based on the HIQA Guidelines 'National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation'.

M – This will be discussed at the Radiology Audit Group. This will be presented to the Radiation Protection Unit and Radiation Safety Committee for discussion and approval.

A – Post implementation of the strategy the process will be reviewed regularly

R – Radiology and Radiation Therapy unit to have an all-encompassing approach to clinical audit for medical radiological procedures across both disciplines and report to the CUH Hospital Audit Committee.

T – This will be implemented by 31st January 2026.

There is scope for ensuring that information relating to the patient exposure in interventional cardiology forms part of the patient's clinical report by:

S – Instructing the vendor of the Cardiovascular Information System (CVIS) to enable the facility to transfer patient dose data from CVIS to the patient's clinical report

M – The patient's dose data will be visible on the patient clinical report.

A – The vendor has confirmed that the next version update of CVIS will facilitate the transfer of dose data to the clinical report.

R – The patient dose data is manually entered into CVIS at the end of procedure and so will be available for transfer to the clinical report. Anecdotal reports indicate this feature is already in use in other hospitals.

T - The vendor has been instructed to install the version update ASAP

Regulation 14: Equipment	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 14: Equipment:

Please see the response to Regulation 20 as regards the scope for ensuring that all MPE Responsibilities, in particular, Quality Assurance are met.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

Radiology:

S – The RPU is currently developing a policy for the reporting of incidents, including radiation incidents in the department. This will include the reporting and management of potential incidents and near misses so that early risk management actions can be implemented and the risk of potential harm to the patient minimised. Once this policy is approved it will be implemented immediately and policy information sessions will be provided to radiology staff.

M – Following implementation of the policy the reporting of potential incidents and near misses will be monitored to ensure the policy is having the desired effect of improved reporting. Additional measures will be taken if reporting does not improve to an acceptable level.

A – This policy will be approved at both the RPU and the RSC.

R – The development of this policy will ensure compliance with Regulation 17.

T – This policy will be approved by the end of September 2025

Radiotherapy:

S – The Radiotherapy Incident Management Working Group supported by line management are reviewing how potential incidents are reported, analysed, actioned and communicated throughout the department. This report will outline new pathways and reporting structures and

M – Upon completion the Radiotherapy Incident Management Working Group Chair will deliver a report of their review to the RSC. On foot of this report, new documentation and a document management system will be approved and available to all staff. New pathways and reporting structures will be defined. Education sessions will be provided to all radiation oncology staff to ensure awareness of the above. Following implementation of the new documentation, pathway and reporting structure, the number of incidents and near misses will be monitored to ensure the changes have the desired effect on reporting.

A – The review and design of the new reporting documentation, pathways and structure will ensure improved reporting is achieved

R – Monitoring of reporting of incidents and near misses will ensure the new documentation, pathways and structure are working to improve reporting so that early risk management actions can be implemented and the risk of potential harm to patients is minimised

T – The review will be completed by the 31st Dec 2025 with staff education sessions completed by Q1 2026.

There is a procedure in place in relation to the reporting of incidents in the Radiotherapy Department.

Both the Radiology RPU and the Radiotherapy Department report their incidents to the RSC.

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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Red	21/07/2025
Regulation 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a practitioner unless	Not Compliant	Red	21/07/2025

	the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),			
Regulation 4(1)(c)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),	Not Compliant	Red	21/07/2025
Regulation 4(1)(d)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or	Not Compliant	Red	21/07/2025
Regulation 4(1)(e)	A person shall not refer an individual for medical	Not Compliant	Red	21/07/2025

	<p>radiological procedures to a practitioner unless the person referring ("the referrer") is a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner, or</p>			
Regulation 4(1)(f)	<p>A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Physiotherapists Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), only if such person meets the standards and requirements set down from time to</p>	Not Compliant	Red	21/07/2025

	time by the Physiotherapists Registration Board in relation to the referral for medical ionising radiation by physiotherapists.			
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	21/07/2025
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Substantially Compliant	Yellow	31/12/2025
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Substantially Compliant	Yellow	31/12/2025
Regulation 5(c)	A person shall not take clinical responsibility for	Substantially Compliant	Yellow	31/12/2025

	<p>an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).</p>			
Regulation 6(3)	<p>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.</p>	Not Compliant	Orange	31/12/2025
Regulation 8(10)(a)	<p>A referrer shall not refer an individual to a practitioner for a medical radiological</p>	Substantially Compliant	Yellow	31/01/2026

	procedure unless the referral is in writing,			
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	Substantially Compliant	Yellow	31/01/2026
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).	Substantially Compliant	Yellow	31/01/2026
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Substantially Compliant	Yellow	31/01/2026
Regulation 8(12)	The referrer and the practitioner	Substantially Compliant	Yellow	31/01/2026

	shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposure.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	31/01/2026
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	31/12/2025
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Orange	31/12/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	30/09/2025

Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	31/01/2026
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	31/12/2026
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented 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,	Substantially Compliant	Yellow	31/10/2025
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:	Substantially Compliant	Yellow	31/12/2026

	<p>(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;</p> <p>(ii) the definition and performance of quality assurance of the medical radiological equipment;</p> <p>(iii) acceptance testing of medical radiological equipment;</p> <p>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and</p>			
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	other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	31/12/2026