

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:	Unannounced
Date of inspection:	09 April 2026
Medical Radiological Installation Service ID:	OSV-0007353
Fieldwork ID:	MON-0049621

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 9 April 2026	09:00hrs to 16:00hrs	Kay Sugrue	Lead
Thursday 9 April 2026	09:00hrs to 16:00hrs	Margaret Keaveney	Support
Thursday 9 April 2026	09:00hrs to 16:00hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors carried out an unannounced inspection at the Cork University Hospital (CUH) on 9 April 2026. This inspection was focused on following up on the corrective actions outlined in the compliance plan submitted by the undertaking, the Health Service Executive (HSE), to address both urgent risks and non-compliances identified by inspectors during the previous inspection in July 2025. Inspectors found that measures taken to mitigate urgent risks identified in the 2025 inspection had addressed the gaps identified at that time and within the time frame specified in the urgent compliance plan response. Inspectors observed that a document tracking the progress for the implementation of other planned corrective actions from the previous inspection was in place. However, many of the actions outlined in this tracker were documented as 'in progress' which meant that they had not been completed in line with the dates to come into compliance documented in the 2025 compliance plan. Consequently, with the exception of Regulations 4 and 5, many of the overall compliance levels identified against Regulations 6, 8, 10, 13, 14, 17, 20 and 21 either remained unchanged or in some cases such as Regulation 13, had disimproved.

On the day of the inspection, inspectors visited both the diagnostic radiology and radiotherapy departments. In the radiology department, inspectors visited fluoroscopy and interventional cardiology areas and records relating to medical radiological procedures carried out in these services and across a range of other modalities were reviewed. In the radiotherapy department, documents and records applicable to high dose rate (HDR) and low dose rate (LDR) brachytherapy exposures were reviewed. Inspectors also met with the management team and several staff, allocated responsibilities for the radiation protection in both departments, through the course of this inspection.

Inspectors reviewed the governance, leadership and management arrangements in place and found that the overall governance structure remained unchanged since the previous inspection. Staff informed inspectors that support from senior management had greatly improved and proved instrumental in changing referral practices that now resulted in compliance with Regulation 4. While noting these and other improvements discussed throughout this report, inspectors found that several issues remain unresolved since the last inspection with some additional findings also identified. It is therefore imperative that oversight of regulatory compliance is further strengthened to improve overall compliance with the regulations.

Regulation 4: Referrers

Inspectors were informed that the corrective actions taken to come into compliance detailed in the compliance plan following the 2025 inspection were implemented and the effectiveness of these were monitored to ensure compliance with the regulations. Communication from the hospital chief executive officer (CEO), who was also the designated manager for medical radiological practices, to referrers, directing that referral practices were to change immediately in the relevant services, to comply with regulatory requirements, had the intended outcome. Inspectors found that only electronic referrals were now accepted at the hospital.

Nurse referrer scope of practice had also been defined for each referrer which was relevant to the specialist area in which they worked in. An approved list of nurse referrers with the associated scope of practice was available in each clinical area for practitioners to view. Inspectors observed that the clinical detail included in referrals had also improved.

In the radiotherapy department, inspectors saw that referrals for brachytherapy exposures were only accepted from appropriately registered medical practitioners, specifically, radiation oncologists.

Judgment: Compliant

Regulation 5: Practitioners

In the radiotherapy department, radiation oncologists and radiation therapists acted as practitioners for brachytherapy exposures.

Inspectors were satisfied following a review of reports from completed medical exposures in the fluoroscopy service that the clinical evaluation of the outcome for these types of procedures was completed by a practitioner recognised under this regulation. Inspectors noted the report and outcome of these procedures was carried out in consultation with other professionals within that speciality. In addition, staff informed inspectors that the hospital policy had been updated to reflect the implemented changes. Final approval was pending and expected to be given at the next radiation protection unit (RPU) meeting. Overall, actions taken in the radiology department since the previous inspection had achieved compliance with this regulation.

Judgment: Compliant

Regulation 6: Undertaking

From discussions with staff and hospital management, inspectors were satisfied that action had been taken to improve the communication and radiology governance

arrangements since the last inspection. Staff spoke positively about these changes and informed inspectors that the new CEO's intervention was instrumental in the implementation of the change to referral practices, mainly in the orthopaedic service, which was required to comply with the regulations. As a result, all medical exposures were now only carried out based on referrals provided by a recognised referrer. While these improvements are welcome, more action is needed to ensure that individual credentials for referrers to log in to the electronic referral system are not shared or inadvertently used by other referrers to refer within the hospital.

Inspectors found that the radiology governance structure remained unchanged since the previous inspection, with day-to-day operations managed by the RPU which reported into the radiation safety committee (RSC). Inspectors reviewed RSC minutes from meetings which occurred in September and November 2025 and January 2026, after the July inspection. Despite the improvements in communication and support provided by hospital management which was articulated by staff to the inspection team, the lack of senior hospital management representation was evident from the attendances listed at these meetings. This meant that there was a lack of a senior decision maker's presence at these meetings. This issue was communicated to the clinical effectiveness committee by the chair of the RSC who received a commitment that there would be senior management representation going forward. Inspectors found that the RSC terms of reference once again remained in draft and noted that this issue had been identified in previous inspections dating back to 2020.

Inspectors viewed a live tracker of corrective actions to be taken to comply with regulations and were informed by staff that it was being monitored by senior management. Inspectors were informed that actions taken were prioritised towards addressing those areas associated with the higher risk non-compliances which was considered a good approach. The tracker showed that some actions assigned to address non-compliant regulations identified from the previous inspection, had been completed while several more were in progress and yet to be closed out. Examples of gaps that had been addressed included the referral issues already discussed under Regulation 4 and the clinical evaluation of the outcome of a sub-set of medical exposures in the fluoroscopy service which were now completed by a practitioner. However, a further gap was identified in relation to Regulation 10(1) during this inspection which again impacted regulatory compliance requiring further action by the undertaking. Many of the incomplete improvements related to documentation updates required because of changes to processes needed to comply with regulations, which had commenced but were not completed. Inspectors found that although discussions had taken place on developing an overarching clinical audit strategy, little progress had been made and therefore remained an outstanding gap in regulatory compliance.

In relation to the allocation of responsibilities for all aspects of medical exposure, the following gaps, some of which have been outstanding since the previous inspection, were identified and included:

- The process and responsibility for approving submissions of applications for generic justification to HIQA was in draft and waiting on a review and approval by the RSC.

- The referral and justification process for interventional cardiology procedures was unclear as was staff awareness in relation to regulatory requirements. Despite efforts made to date to revise the process and circulate the updated policy to relevant staff, approval of this policy had not progressed therefore the situation remained unchanged.
- In the radiotherapy department, the responsibility for the justification of low dose rate (LDR) brachytherapy exposures was not clearly allocated to referrers and practitioners by the undertaking and was not documented, therefore this needs to be addressed to provide greater clarity to staff on the process.
- Documentation updates remained an ongoing issue with several documents still in draft format waiting for final approval.

For all records reviewed, a referrer as per Regulation 4 was identifiable. However, greater assurance was required by the undertaking to ensure that unique login credentials assigned to referrers are restricted to individually assigned users.

Overall, while noting that improvements have been made in the interim between the 2025 and 2026 inspections, it was clear that the timelines for coming into compliance provided by the undertaking in the compliance plan of the 2025 inspection had not been met in relation to several regulations. Inspectors found that more needs to be done to improve regulatory compliance from gaps identified in this and the previous inspection and efforts to strengthen the governance, oversight and management should continue to ensure the radiation protection of service users undergoing medical exposures at the hospital.

Judgment: Not Compliant

Regulation 10: Responsibilities

On the day of inspection, inspectors found that clinical responsibility for medical exposures was completed by radiation oncologists and radiation therapists in the radiotherapy department. From discussions with staff and a review of a sample of patient records, inspectors were also satisfied that both referrers and practitioners were involved in the justification of individual medical exposures in the service. Similarly, inspectors found evidence that practitioners and medical physics experts (MPEs) were appropriately involved in the optimisation of all aspects of all medical exposures carried out in the radiotherapy department.

Like the 2025 inspection, MPE involvement in the optimisation of medical exposures was evident from discussions and documentation reviewed.

Improvements in referral practices discussed under Regulation 4 meant that referrers and practitioners were appropriately involved in the justification of medical exposures as required under this regulation.

Inspectors found that actions taken in diagnostic imaging since July 2025 had addressed the non-compliances identified at the time of the inspection. This was verified from the review of records from a sample of medical exposures carried out in a sub-set of fluoroscopy procedures in diagnostic imaging which demonstrated that a practitioner, as per the regulations had completed the clinical evaluation of the examination. This was also the case for records viewed from examinations carried out in other modalities. However, a further gap in compliance was identified in relation to Regulation 10(1) during this inspection. Inspectors found, from a sample of X-ray records carried out on foot of referrals from the orthopaedic fracture clinic, that the clinical evaluation of the outcome by a practitioner was not evident in records provided. Staff informed the inspection team that there was a pre-existing agreement in place since 2015 in relation to this arrangement. Inspectors noted that this arrangement pre-dated the commencement of the regulations and there was insufficient evidence to demonstrate compliance with Regulation 10(1) for this sub-set of medical exposures. Therefore, the undertaking must further review the existing processes to ensure compliance with the regulations.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Compliance levels with this regulation have remained compliant since 2025. Inspectors were satisfied that continuity of MPE contribution and input was assured through the arrangements in place. Inspectors were informed that recruitment for additional medical physics resources had resulted in the chief physicist's role being filled with an imminent start date which was expected to bolster MPE resources. While noting the efforts made to increase medical physics staffing levels, inspectors were informed that the available levels of resources had fluctuated down in September 2025 due to several reasons before rising again to more sustainable levels at the time of this inspection. Inspectors noted that these levels were below the business case projected resource requirements documented in the compliance plan. Discussions with the CEO and senior management indicated that funding from the HSE for additional medical physics resources was currently not available due to other more pressing competing demands. Despite these constraints, the hospital should continue to work towards sustaining current levels and building on the available resources to maintain continuity arrangements into the future. This is an important consideration given the planned service expansion projects articulated by staff to the inspection team which involve additional radiology services.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors spoke with MPE staff in the diagnostic radiology and radiotherapy departments regarding MPE responsibilities and, similar to the 2025 inspection, were satisfied that MPEs took responsibility for dosimetry, contributed to the review and establishment of DRLs, carried out acceptance testing of new equipment and undertook the quality assurance (QA) testing of all medical radiological equipment.

Following the last inspection, staff at the hospital prioritised completing overdue annual QA testing identified during the inspection within the time scales specified in the compliance plan. However, the RSC minutes from 19 January 2026 stated that while the radiotherapy department annual QA testing was up-to-date, four units were overdue physics QA in diagnostics. It was noted that medical physics resources in diagnostic imaging had dropped between September and December 2025 which more than likely contributed to this status. Inspectors viewed the 2026 programme for annual QA of equipment by an MPE and once again noted that one unit of equipment was overdue QA since January 2026. Access to the unit in question was cited as a contributing factor to this gap as well as physics resourcing. Staff informed inspectors that equipment associated with higher radiological risk was prioritised for QA.

Inspectors found that meeting the annual QA timelines outlined in the hospital's QA programme remained an issue during this inspection, thereby, once again, impacting on regulatory compliance.

Judgment: Substantially Compliant

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

As per Regulation 20, involvement and contribution of MPEs remains an issue at CUH. Staff were optimistic that recent staffing increases should address the gaps identified and ensure improved MPE involvement proportionate to the radiological risk required under this regulation.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the impact of the measures taken to improve compliance with Regulations 8, 13, 14 and 17 since the last inspection. Inspectors found that compliance against some sub-regulations under Regulation 8 had improved as a result of the corrective actions taken by staff while also noting that more needs to be done if full compliance with this regulation is to be achieved. For example, a draft

policy to outline the processes for justifying medical exposures in the interventional cardiology service had been developed and circulated to staff in this service to review but had not progressed beyond this point. This meant that the process for recording justification in advance remained an issue in the cardiology service since the last inspection. Consequently, further action must be taken to implement the necessary changes to improve compliance and increase staff awareness regarding all aspects of regulatory requirements set out under this regulation. In the radiotherapy department, improvements were also required to ensure that the record of justification for low dose rate brachytherapy procedures is clearly evident to demonstrate compliance with Regulation 8(15).

Inspectors found that measures implemented since the 2025 inspection successfully resulted in the inclusion of information relating to the patient exposure in all internal reports generated following procedures carried out for interventional cardiology procedures. These reports were available to hospital-based referrers, which accounted for most referrals in this department. However, from discussions with staff and a review of patient records, it was not clear to inspectors on the day who the referrer was for referrals originating from outside of the hospital. In addition, inspectors noted from the sample viewed that information relating to patient exposure was not evident in reports issued to these external referrers. Therefore, clarification on this issue would help determine the actions needed to come into compliance. During the review of medical radiological reports, the absence of reports for follow-up X-rays based on fracture clinic referrals meant there was a lack of evidence to demonstrate compliance with Regulation 13(2). The undertaking must address this gap to ensure alignment with regulatory requirements.

Outstanding annual QA by an MPE for medical radiological equipment identified during the previous inspection had been prioritised and achieved. However, a similar issue was identified during this inspection in which one unit was overdue QA. The reason given for this related in part to the fluctuating medical physics resources experienced since September 2025 and access to the equipment. Inspectors were informed that staffing levels had since stabilised, which was aided through a recent recruitment campaign and should help ensure that annual QA timelines are met in the future.

In relation to Regulation 17, staff had addressed issues identified in the radiology department since the last inspection and had seen an increase in reporting of near misses within the department in recent months following the range of measures implemented. Inspectors noted the increase in reporting to be a positive outcome. Staff had also worked to improve compliance in the radiotherapy department and had also noted an uplift in reporting levels following the actions taken that were outlined in the 2025 compliance plan. However, an updated policy due to be approved by the end of October 2025 that outlined the new reporting structures and pathways for all incidents, near misses and non-conformances involving medical exposures, remained in draft format with approval for issue delayed until May 2026. Further improvements were also identified to ensure corrective actions and learning from notifiable radiotherapy incidents are fully implemented and monitored for

adherence by staff. This is an important measure to minimise the likelihood of incidents recurring for patients undergoing medical exposures in this department.

Inspectors noted there was good practice in the planning and delivery of brachytherapy procedures to optimise treatment delivery while limiting exposure to normal surrounding tissue which demonstrated compliance with Regulation 15.

Inspectors found that overall, staff had worked to improve compliance with the regulations since the last inspection with a plan to fully address the gaps in compliance identified. Actions taken to date demonstrated that staff at the hospital were committed to achieving compliance with the regulations, many of which related to documentation of processes and relevant updates. Inspectors were satisfied that the radiation protection of service users was central to the radiation practices applied for medical exposures conducted at CUH.

Regulation 8: Justification of medical exposures

Inspectors reviewed the processes in place, including the corrective actions implemented by the undertaking since the previous inspection, to improve compliance with this regulation. Actions taken to comply with Regulations 4, 5 and 10(3)(b) had successfully addressed non-compliances previously identified against sub-regulations 8(10), 8(11) and 8(12). However, more work was needed to ensure the record of justification in advance is clearly recorded and understood by staff working in each modality.

Inspectors found that justification in advance was recorded on the radiology information systems for a sample of records viewed from medical exposures carried out in general radiology, orthopaedic procedures involving image intensifiers in theatre and in the interventional fluoroscopy suite in the main radiology department.

Inspectors re-visited the interventional cardiology suite as part of this inspection and spoke with staff involved in the conduct of medical exposures there. From the discussions with staff and with radiology management, inspectors found that little progress had been made, since the last inspection, to clarify the justification of procedures in this area. While the clinical pathway for patients requiring interventional procedures for diagnostics and treatment purposes was clearly explained by staff, regulatory requirements associated with the medical exposures part of these procedures were less understood. From discussions with staff, it remained unclear to the inspection team what the process was for recording justification in advance for each medical exposure conducted there, as required under the regulations. Inspectors were informed by radiology management that as a corrective action after the previous inspection, a draft policy on the justification of all procedures involving ionising radiation in the Cath Lab had been shared with staff working there, for their review and approval. It had been anticipated that the policy would be ready for approval at the RSC in January of this year, however, progress had stalled on approving this draft policy, as no feedback had been received. It is imperative that individuals with responsibility for justifying the medical exposure part

of interventional cardiology procedures and the process for same is clearly defined to help improve staff awareness and ensure compliance with this regulation.

Inspectors were satisfied that practices for referral, planning and delivery of HDR and LDR brachytherapy procedures were safe and consistent, and that prior to completing these procedures, practitioners considered the reasons for the referral and had access to sufficient medical data to make a justification assessment. However, inspectors were not satisfied that the record of justification for LDR brachytherapy exposures was clearly evident and known to all relevant staff. To strengthen the radiation protection of this cohort of service users, the undertaking must ensure that there is a system in place to ensure that there are clear and consistent records for the justification of LDR brachytherapy medical exposures by a practitioner.

While noting that improvements in compliance against three of the sub-regulations have been achieved through corrective actions taken by staff at the hospital, more measures are needed to address the findings outlined above, to comply with this regulation.

Judgment: Substantially Compliant

Regulation 13: Procedures

Similar to the last inspection, inspectors noted that written protocols for standard medical radiological procedures were in place in the areas visited by inspectors and thereby meeting the requirements of Regulation 13(1). As discussed under Regulation 6, there was scope to improve the version control of the protocols in use in the interventional fluoroscopy unit to ensure only approved amendments or revisions can be made to the protocols by the designated staff allocated with the responsibility for the review and update of these documents.

Inspectors reviewed a sample of written protocols for radiotherapy exposures and noted that they were easily accessible by staff. A review of patient records showed that the radiation dose received by patients having HDR brachytherapy was included in a discharge letter, which was generated for each patient after they finished their treatment course. However, inspectors found that while information on the patient exposure during LDR brachytherapy was available, it did not form part of the report on the medical radiological procedure, as required by Regulation 13(2).

Inspectors found that actions had been taken by staff to ensure the information relating to the patient exposure was included in the reports on medical radiological procedures in the Cath Lab. Inspectors verified that this information was included in the auto-generated reports which were stored in the patient's medical record and available to referrers based in CUH. However, ambiguity arose for the reports issued to external referrers who did not receive this auto-generated report as part of the correspondence issued to them. Furthermore, discussions with staff provided

differing points of view as to who the referrer was for these procedures. Inspectors determined that greater clarity is therefore needed on what constitutes the report for all interventional cardiology procedures to improve regulatory compliance. In addition, the lack of reports for follow-up X-rays originating from fracture clinic referrals and previously discussed under Regulation 10, resulted in a lack of evidence of compliance with the requirements of Regulation 13(2) which must be addressed.

In relation to clinical audits of medical radiological procedures and as previously discussed under Regulation 6, an overarching clinical audit strategy was not in place to ensure clinical audit practices aligned fully with the national procedures established by HIQA. Therefore, the undertaking was not compliant with Regulation 13(4).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors found from a review of records and discussions with staff that regular testing of medical radiological equipment in both departments was completed and acceptance testing was carried out. Inspectors noted that overdue annual QA of equipment identified by inspectors during the 2025 inspection had been prioritised for completion. Staff in the radiology department informed inspectors that ongoing challenges in meeting QA time scales had persisted from September to December 2025 which was mainly attributed, by staff, to a drop in medical physics resources during this period. Inspectors noted from the 2026 QA programme that one unit was overdue annual QA which was attributed by staff to resource issues and access to the X-ray room in question. Staff informed inspectors that prioritising high risk equipment for QA was the approach taken when challenges have arisen and it was anticipated that recent increases to medical physics resources should enable QA timelines to be met going forward.

Judgment: Substantially Compliant

Regulation 15: Special practices

During the course of the inspection, inspectors were satisfied that the undertaking had given special attention to appropriate radiation protection practices for patients receiving brachytherapy treatment in the radiotherapy department. Inspectors observed that there was a strong multidisciplinary approach to the planning and delivery of these exposures, and that imaging modalities, such as computed tomography (CT) and ultrasound, were used to optimise treatment delivery by identifying the position of the target area and of the surrounding normal tissue. It

was also noted that specific treatment planning protocols were used to develop individual treatment plans which ensured that the doses to normal tissue are kept as low as possible and that desired treatment doses were delivered.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

In the radiology department, the low levels of reporting near misses had been addressed since July 2025 through the implementation of several measures. These included the development of a new policy, staff education and the introduction of a tip sheet for staff to refer to for the management of near misses and radiation incidents. Staff reported to inspectors that since introducing these measures the levels of reporting had increased with a month-on-month increase noted. Inspectors were therefore satisfied that the gaps in compliance observed previously had been addressed in this department.

Following the previous inspection, the undertaking's management team in the radiotherapy department had committed to achieving full compliance with Regulation 17. During this inspection, inspectors were informed that, in line with this compliance plan, an incident pathway review group had been formed, whose membership included key multidisciplinary personnel. This group had developed a *Policy for Incident Management in Radiation Oncology, Cork University Hospital*, which outlined new reporting structures and pathways for all incidents, near misses and non-conformances involving medical exposures that occur in the radiotherapy department. Inspectors were informed that the formal implementation of this policy was delayed due to issues with getting key personnel in the department approved access to a national incident reporting system. However, inspectors were informed that this issue had recently been resolved and that the new policy and reporting system were due to be implemented in early May 2026. Inspectors were also informed that since the previous inspection, staff training on reporting near misses had resulted in increased reporting within the department and that all reports were analysed and trended by the radiation protection officer.

During this inspection, inspectors followed up on the action plans for a number of incidents notified to HIQA and saw that action was required to ensure that all actions were fully and effectively implemented in the department. For example, for one incident, additional checks had been introduced as part of the pre-treatment process for a particular radiotherapy exposure. However, these checks had not been included in a recent review of the procedure that supported and guided staff delivering these exposures. In addition, for another notifiable incident, inspectors noted that while the incident investigation actions had been implemented, staff were not consistently adhering to them. The undertaking must ensure that, as part of its measures to minimise the likelihood of incidents for patients undergoing medical exposures in the radiotherapy department, there is appropriate monitoring of

incident investigation actions to ensure that they are adhered to by staff and are effective in reducing the risk of a similar incident occurring.
Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Substantially 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 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 15: Special practices	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Cork University Hospital OSV-0007353

Inspection ID: MON-0049621

Date of inspection: 09/04/2026

Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiology: Radiation Safety Committee- Terms of Reference. Approved at RSC 18/05/2026. Uploaded on QPULSE CUH-COMM-8/TOR-CUH-CUH-26. S: Policy for the management of audit in the Radiology/Radiation Therapy Department in Cork University Hospital. M: Audit calendar established to monitor and review progress of audit within the department. A: Clinical audit presentation morning at regular intervals to promote audit and share learning. R: The policy update and approval will ensure compliance. T: This policy with be approved at the Radiation Protection Unit on 23/06/2026 and the Radiation Safety Committee on 21 September 2026. S: Policy and procedure to obtain generic justification from HIQA for any new diagnostic or therapeutic patient therapy in CUH. M: New developments will require the HIQA application form to the RSC for approval. A: The policy update has involved all relevant stakeholders. R: The policy update and approval will ensure compliance. T: This policy with be approved at the Radiation Protection Unit on 23/06/2026 and the Radiation Safety Committee on 21 September 2026. S: Policy and procedure on the justification of examinations in cardiology at Cork University Hospital. M: Compliance can be measured through audit and inspection. A: The policy update has involved all relevant stakeholders. R: The policy update and approval will ensure compliance. T: This policy with be approved at the Radiation Protection Unit on 23/06/2026 and the	

Radiation Safety Committee on 21 September 2026.

Refers Log On:

S: Guidance will be developed incorporating hospital and national guidelines around the safe use of IT Log on and credentials.

M: Ongoing update and review of guidelines.

A: The guidance update will involve all relevant stakeholders.

R: The update and approval will ensure compliance.

T: This guidance will be approved at the Radiation Protection Unit meeting in September and the Radiation Safety Committee on 21 September 2026.

Radiotherapy

S Finalise and implement the Policy for Audits In the Radiology and Radiation Oncology Departments in Cork University Hospital.

M Completion will be demonstrated by an approved audit strategy, approved through the Radiation Oncology Quality Meeting and issued in the quality management system.

A A draft already exists and required expertise and regulatory guidance are available to complete the work.

R Supports statutory compliance, strengthens quality assurance, and ensures oversight of medical radiological exposures.

T This policy will be approved at the Radiation Oncology Quality Meeting on 18/06/2026 and the Radiation Safety Committee on 21 September 2026.

S Update the PPG CUH RTX 2 "Policy on the Management of Prostate Brachytherapy" to include a new section detailing the documentation and communication requirements for justification of medical ionising radiation exposure, ensuring alignment with current legislation.

M Completion is demonstrated by the revised policy containing a clearly defined section on justification documentation and communication, reviewed and approved through the Radiation Oncology Quality Meeting and issued in the quality management system.

A The update will be completed using existing legislative guidance, clinical expertise, and policy governance structures within the organisation.

R Ensures compliance with statutory requirements for medical ionising radiation exposure and strengthens clinical governance and patient safety.

T Final approved policy update completed by 31 July 2026.

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

S: To be compliant with Regulation 10(1) there needs to be clinical evaluation performed of images taken post fracture clinic review. This amounts to over 13,500 reports per

year. M: The appointment of additional resources is required to achieve compliance with this Regulation. A: The completion and submission of a business case for the appointment of these additional resources will allow this workload to be managed appropriately. However as an interim arrangement, CUH will seek immediate approval to provide overtime to existing consultant radiologists to report all of these scans. The consultant radiologists have agreed to this proposal. R: Compliance with this regulation will be dependent on approval of these additional resources. The interim arrangement will be put in place pending financial approval. T: The business case will be completed and submitted to management by 5 October 2026. However, the interim arrangement will be in place by 30 September 2026.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: • Annual QA testing has been completed for the overdue unit of equipment. • Assurance that MPE responsibilities as outlined by Regulation 20 will be met by: - S – Radiology physics under-resourcing has been identified as a risk to service delivery, and a business case will be developed and submitted to address required staffing levels. - M - Submission of formal business case to CUH senior management. Since the inspection, CUH has recruited to the full approved staffing complement. - A - The business case will be prepared using staffing data, workload analysis and identified service/compliance risks. In the interim the fully staffed MPE department will prioritise QA on all relevant equipment. - R - Addressing staffing levels is necessary to support service delivery, reduce risk and achieve compliance obligations. - T – The business case will be completed and submitted to management. 3 WTE to be onboarded by 31 March 2027. The interim arrangement is currently in place.	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: • Please see the response to Regulation 20 as regards the scope for improvement of MPE involvement and contribution in the Radiology Department.	
Regulation 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: Radiology: Justification of examinations in cardiology -Please see response to Regulation 6: Undertaking Radiotherapy Justification of LDR Brachytherapy -Please see response to Regulation 6: Undertaking	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Radiology: S: Improve the version control of the protocols in use in the interventional fluoroscopy unit. M: Protocols in use in all areas of the Radiology Department will be checked to ensure that they are 'read only' so that the protocols are version controlled. CSRs to confirm by email to the RPO that their policies are version controlled. A: The confirmation by the CSRs that the protocols are version controlled. R: All emails from the CSRs to be received by the RPO by 19/06/2026. T: Compliance with this will be mentioned at the Radiation Protection Meeting on the 23/06/2026. S: Detail the process for the provision of Cath Lab auto-generated reports for all patients undergoing procedures in the Cath Lab. M: Once completed and authorised, a hard copy is filed in the CUH notes.	

If available on time of transfer back to all referring centres a hard copy will accompany the patient.

The procedure report is available to all hospitals within the group on ICM & CVIS. The report is available to be printed and filed into the patient's primary hospital Notes.

If transferring back to a referring hospital outside our group, ie Waterford, Clonmel a hard copy will be sent. If not authorised at time of transfer, a copy of the report will be forwarded to the referring hospital as soon as available.

A: This process is included in the policy and procedure on the justification of examinations in cardiology at Cork University Hospital.

R: The policy update and approval will ensure compliance.

T: This policy will be approved at the Radiation Protection Unit on 23/06/2026 and the Radiation Safety Committee on 21 September 2026.

Policy for the management of Audit in the Radiology/Radiation Therapy Department in Cork University Hospital - Please see Response to Regulation 6: Undertaking

Lack of reports for follow-up Fracture Clinic patients- Please see Response to Regulation 10: Responsibilities

Radiotherapy

S Develop and implement a new procedure and work instruction that includes a formal report capturing dose information for LDR Brachytherapy.

M Approved procedure through the Radiation Oncology Quality Meeting and issued in the quality management system.

Dose report template created and in operational use.

Evidence of compliance available for inspection.

A Work will be completed using existing clinical expertise, legislative guidance, and organisational policy development processes.

R Supports statutory compliance with medical ionising radiation regulations, strengthens clinical governance, and ensures transparent documentation of exposure justification and monitoring.

T All components—the procedure, work instruction and exposure report will be fully implemented by 31/07/2026.

Policy for the management of Audit in the Radiology/Radiation Therapy Department in Cork University Hospital - Please see Response to Regulation 6: Undertaking

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

- Annual QA testing has been completed for the overdue unit of equipment.

- Please see the response to Regulation 20 as regards the scope for ensuring that all MPE Responsibilities, in particular, quality assurance is met.

Regulation 17: Accidental and unintended exposures and significant events

Substantially Compliant

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

Radiotherapy

S The revised Policy for Incident Management in Radiation Oncology, Cork University Hospital will be fully implemented.

M• The revised Policy for Incident Management in Radiation Oncology, Cork University Hospital has been formally implemented and communicated to all relevant staff as of the 18th of May 2026.

- 100% of actions arising from the incident review at the Radiation Oncology Incident Meeting will have a named responsible person and a completion due date.
- All documents requiring edits as part of an incident action plan will be submitted to the Radiation Oncology Quality Meeting within 1-month of discussion at the Radiation Incident Meeting.
- Relevant audits will be scheduled and completed within 3 months of updated documents being issued via the QMS and reported to the Radiation Oncology Subcommittee for Audit and Radiation Safety Committee via the RPU.

A Action completion will be tracked through the Radiation Oncology Incident Meeting. Document updates and audits will be tracked through the Radiation Oncology Quality Meeting.

R This goal ensures compliance with Regulation 17, strengthens governance of incident management actions.

T Policy implementation completed in May 2026.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	21/09/2026
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	21/09/2026

	specific objectives of the exposure and the characteristics of the individual involved.			
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.	Not Compliant	Orange	21/09/2026
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	30/09/2026
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	30/09/2026
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	21/09/2026
Regulation 14(1)	An undertaking shall ensure that all medical radiological	Substantially Compliant	Yellow	02/07/2026

	equipment in use by it is kept under strict surveillance regarding radiation protection.			
Regulation 17(1)(a)	An undertaking shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,	Substantially Compliant	Yellow	31/05/2026
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: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical	Substantially Compliant	Yellow	01/07/2026

	radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and 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	Substantially Compliant	Yellow	01/07/2026

	posed by the practice.			
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