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:	25 October 2023
Medical Radiological Installation Service ID:	OSV-0007353
Fieldwork ID:	MON-0039916

About the medical radiological installation:

Cork University Hospital (CUH) is the largest statutory / HSE hospital in Ireland and the only Model 4 (Specialist Academic Teaching) Hospital in the state with all acute surgical and medical specialities integrated on the same campus (adults, paediatrics, maternity and mental health). It is consistently one of the busiest Model 4 hospitals in Ireland. At a national level, CUH is one of two designated Level 1 trauma centres in the country, one of two 24/7 neurosurgical and stroke thrombectomy centres, one of five 24/7 PPCI centres, one of four cardiothoracic surgical centres, one of two comprehensive coagulation & haemophilia centres, a cystic fibrosis centre, and one of eight (NCCP) Cancer Centres, the only one with all tumour pathways, diagnostics, modalities and treatments under one provider.

CUH is the tertiary referral centre for the HSE Southern area, and the supra regional area of Limerick, Clare, Tipperary, Waterford and Kilkenny. CUH therefore acts as a regional centre for secondary and tertiary care for a catchment population of 550,000 served by the HSE Southern area and a supra-regional centre for a total a population of 1.1 million. The CUH Hospital group comprises of CUH, St. Finbarr 's Hospital, Bantry General Hospital and Mallow General Hospital.

The Radiation Oncology Department at CUH delivers an advanced radiotherapy service at its NPRO Radiation Oncology building which opened in November 2019. The department comprises 5 Elekta versa HD Linear Accelerators, 2 GE CT-simulators, an Xstrahl superficial therapy unit and an Elekta Flexitron High Dose Rate (HDR) brachytherapy unit. The department provides radiotherapy services to an area which serves the population of counties Cork, Kerry, Limerick, Waterford and south Tipperary. These services include external beam radiotherapy, superficial therapy treatments, HDR gynaecological treatments and prostate seeds implantation. The department also provides radiotherapeutic treatments to patients using radio-isotopes Iodine-131 and Radium-223.

The Division of Radiology provides comprehensive, high-quality imaging services and image guided procedures on a 24/7 basis. Imaging in the following sub-specialities is

provided by the Radiology Department at CUH: CT, Vascular, Paediatric, Interventional, Screening, Nuclear Medicine, Ultrasound, Breast Imaging, Neuro-radiology, Cath Lab, Chest, Abdominal, Musculoskeletal Imaging and Oncology Imaging. All of our equipment is digital and integrated into our RIS/PACS interface.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 25 October 2023	09:15hrs to 17:35hrs	Margaret Keaveney	Lead
Wednesday 25 October 2023	09:15hrs to 17:35hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

On 25 October 2023, an inspection was conducted at the radiotherapy department of Cork University Hospital (CUH) to assess compliance with the regulations. At the opening meeting of this inspection, inspectors met with the management team of both the radiology and radiotherapy departments. The compliance plan actions from an inspection of the radiology department on 25 August 2020 were discussed. While inspectors were assured that many of these compliance actions had been completed, inspectors found that further improvement in the hospitals overall governance and management arrangements for radiation protection of service users in both the radiotherapy and radiology departments was required. Inspectors also noted that compliance actions and learning from the 2020 inspection had not been applied by the undertaking's management team to the radiotherapy department. For example, improvements in radiation protection governance and management structures and in the document management systems. This is further discussed throughout this report.

Documentation submitted to inspectors prior to the inspection outlined that the undertaking had established a radiation safety committee (RSC), which reported to an Executive Quality and Safety Committee. This committee, in turn, should report to an Executive Management Board (EMB) which was chaired by the Chief Executive Officer (CEO). The CEO was also the designated manager for the facility, and in this role, the designated manager is required to engage in and be responsible for the day-to-day management of services providing medical exposures. However, from the minutes reviewed and discussions with staff and management, inspectors found that the Executive Quality and Safety Committee had not formally reported to the EMB in the previous 12 months, and therefore radiation protection matters discussed at the RSC were not reported to the EMB. There was also insufficient evidence that key radiation protection matters in the radiotherapy department were discussed at the RSC, and therefore that the undertaking's senior management team had adequate oversight of these matters. Improvements were also required in relation to the incident reporting and document management systems within the radiotherapy department, which inspectors found could benefit from additional support from the hospital management team. Overall from the evidence gathered during the inspection, inspectors observed that stronger oversight by the undertaking was required on the day-to-day operations of radiotherapy practices. Also greater assurances were required that allocated roles and responsibilities associated with the governance and oversight of radiation protection matters were being fulfilled by the hospital's senior management team. This is further discussed under Regulation 6 below.

While noting the areas above that required improvement, good practices were observed in relation to the referral process for radiotherapy treatments. Similarly, inspectors were assured that clinical responsibility for medical exposures was only taken by those entitled to act as practitioners as per the regulations.

The management at the Cork University Hospital also had measures in place to ensure the appropriate involvement of medical physics expertise, and inspectors noted that this involvement was proportionate to the level of radiological risk in the radiotherapy department. Inspectors also noted that the medical physics expert (MPE) team took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

While the gaps identified in relation to the allocation of roles and responsibilities at CUH senior management level impacted on regulatory compliance, inspectors were assured that service users attending the radiotherapy department were receiving a safe and quality service, at the time of inspection.

Regulation 4: Referrers

The management team in the radiotherapy department at Cork University Hospital had developed a '*Policy for the Communication, Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital'* which clearly stated that only radiation oncologists employed by the hospital, registrars working within the radiation oncology team and CORU registered radiation therapists were entitled to act as referrers in the radiotherapy department.

Inspectors were informed that radiation therapists were allocated the role of secondary referrers, and could refer patients for CT replanning during treatment if required. Inspectors spoke with a number of radiation therapists who were clear on the responsibilities allocated to them in this role.

Inspectors reviewed a sample of patients' medical records and spoke with staff, and were assured that only referrals from those outlined above were carried out in the department.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, inspectors observed that only those entitled to act as practitioners as per the regulations were found to take clinical responsibility for medical exposures in the radiotherapy department. The '*Policy for the Communication, Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital*' clearly stated that radiation oncologists employed by the hospital, registrars working within the radiation oncology team and CORU registered radiation therapists could act as practitioners in the radiotherapy department.

Also staff who spoke with inspectors demonstrated awareness as to the individual

roles of the practitioner for radiotherapy procedures.

Judgment: Compliant

Regulation 6: Undertaking

The undertaking had allocated roles and responsibilities on radiation protection matters both to personnel within the radiotherapy department and to hospital committees outside of the department. From a review of the terms of reference for the RSC, inspectors observed that this committee was responsible for ensuring that it had oversight of all radiation protection matters under its remit within the hospital radiology and radiotherapy departments. On the day of the inspection, the hospital management team informed inspectors that the chair of the RSC reported twice yearly to the Executive Quality and Safety Committee, which in turn reported quarterly to the Executive Management Board on radiation protection matters. Inspectors were also informed by the management team that these radiation protection structures were under review and that the reporting lines presented in the documentation submitted prior to the inspection had changed.

On the day of the inspection, inspectors saw that within the radiotherapy department the roles and responsibilities on radiation protection had been allocated appropriately as per the regulations. For example, within the department, there were systems and processes in place to ensure that the equipment QA programme was completed as planned, and that good justification and optimisation processes were in place along the patient's radiotherapy pathway. However, inspectors were not assured that the roles and responsibilities on radiotherapy radiation protection matters, allocated by the undertaking to committees and persons outside the radiotherapy department, were being adequately fulfilled. For example;

- From a review of the terms of reference for the RSC, inspectors observed that the RSC was responsible for ensuring that it had oversight of all activity involving radiation exposure in the radiotherapy department . Although the RSC had met four times in the previous 12 months, from a review of RSC meeting minutes, inspectors saw that key matters of radiation protection including, the radiotherapy equipment quality assurance programme and diagnostic reference levels (DRLs) were not discussed at these meetings, and that discussions on radiotherapy incidents involving medical exposures of ionising radiation were limited and did not include the learning or recommendations from the incident investigation reports. Inspectors also noted that new or revised radiotherapy policies and procedures were not approved at the RSC meetings.
- From a review of the minutes of the Executive Quality and Safety Committee, inspectors identified that the reports from the RSC had not been discussed. During the inspection, inspectors also requested the quarterly reports from the Executive Quality and Safety Committee to the Executive Management Board for the previous 12 months, and were informed that none were

available as the Executive Quality and Safety Committee had not reported to the Board in this time.

- During the inspection of August 2020, inspectors had observed that the policies and procedures document management system in the radiology department was an area for improvement in relation to radiation protection. On the day of this inspection, inspectors met briefly with the radiology management team and were assured that management systems for new or revised documents in the radiology department were now in place, with oversight by the Quality, Patient Safety and Risk Department. However, inspectors identified that the undertaking had not applied similar roles, responsibilities and systems to the document management system in the radiotherapy department, and were informed by the hospital management team that the management of radiotherapy documents was at department level only. From a review of radiotherapy policies, procedures and guidelines, inspectors noted that some were available to staff in draft format only, and that others did not have an approver or an approval date. Although inspectors were satisfied that practices in the radiotherapy department were safe and consistent with regard to the referral, justification, and planning and delivery of medical exposures, they could not be assured that staff had access to the most up-to-date, peer reviewed version of policies and procedures to support and guide them in these practices, or that there was adequate multidisciplinary involvement in the development and approval of such documents. For example, inspectors observed that many policies and procedure had been developed by radiation therapists or MPEs, and not reviewed by another discipline.

The significant gaps in the radiation protection governance reporting lines and the limited evidence to show that the senior management team had adequate oversight of radiation protection matters within the radiotherapy department of Cork University Hospital were discussed with the hospital management team on the day of the inspection, and inspectors were provided with information on governance restructuring plans within the hospital.

Notwithstanding the issues discussed above, inspectors found that the radiation protection of service users attending for radiotherapy treatment was not an issue at the time of the inspection. This was mainly due to the commitment of staff working in the department who had ensured that there were effective quality assurance (QA) and quality control (QC) processes throughout the radiotherapy pathway. Following on from this inspection, the undertaking must ensure that reporting lines within the governance structures are strengthened to ensure effective oversight of radiotherapy radiation protection practices.

Judgment: Not Compliant

Regulation 10: Responsibilities

During the course of the inspection, inspectors were informed that only radiation oncologists and radiation therapists were entitled to act as practitioners in the radiotherapy department, and that all medical exposures took place under the clinical responsibility of these practitioners.

From discussions with staff and a review of a sample of patient records, inspectors were satisfied that the optimisation of radiotherapy treatment and associated imaging involved radiation oncologists, radiation therapists and MPEs. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for all individual medical exposures.

The radiotherapy management team had developed a number of policies and procedures such as '*Policy for Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital*' and '*Policy for Referral for Radiotherapy in Cork University Hospital*' to ensure that referrers and practitioners were clearly aware of their roles and responsibilities while planning and delivering a course of radiotherapy treatment. Inspectors also reviewed a '*Policy & Procedure on the Role of Medical Physics Experts outlined in SI 256*' and saw that it clearly defined the responsibilities of MPEs in optimisation processes along the radiotherapy patients pathway.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, inspectors were satisfied that the management team in Cork University Hospital had appropriate resources in place to ensure the continuity of medical physics expertise in the radiotherapy department. Inspectors noted that a team of medical physics experts were permanently employed in the department.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics in the radiotherapy department.

From a review of documents and records, inspectors noted that the MPE team took responsibility for dosimetry and were involved in the analysis of events involving accidental or unintended medical exposures in the service. Inspectors also saw that MPEs had defined and completed monthly and annual quality assurance testing on all medical radiological equipment in the service, and had completed acceptance testing on each new piece of equipment.

The MPE team were also involved in the optimisation of medical exposures, which included contributing to the establishment of dose reference levels for the CT units and of planning templates for particular treatment sites and prescriptions.

Judgment: Compliant

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

From discussions with staff and a review of documentation, inspectors were satisfied that a team of MPEs were closely involved in the radiotherapy service in line with the level of radiological risk within the service, as required by the regulations.

Inspectors were informed that the MPE team had developed a training video on radiation protection, which was available as a training tool to staff in the department.

Judgment: Compliant

Safe Delivery of Medical Exposures

Over the day of the inspection, inspectors were assured that the radiotherapy management team had appropriate systems and processes in place for service users undergoing radiotherapy medical exposures. For example, an appropriate QA programme had been implemented in line with local policy, which included regular performance testing and preventative maintenance by the equipment manufacturers.

Inspectors were assured from speaking with staff and from the review of a sample of referrals in the radiotherapy department that all referrals were in writing, and were accompanied by a reason for the request and sufficient additional data. Inspectors were also satisfied that medical exposure procedures in the radiotherapy departments were justified in advance by a person entitled in the regulations to take clinical responsibility for justification.

Information relating to the risks and benefits associated with the radiotherapy medical exposures was provided at various points along the patient pathway by radiation oncologists and radiation therapists. Inspectors also noted that staff working in the radiotherapy department demonstrated a strong multidisciplinary approach to the optimisation of medical exposure procedures, and found examples of good practices in the department.

Although the document quality management system was identified as an area of improvement, inspectors observed that comprehensive clinical guidelines and

treatment procedures had been developed and implemented for the standard treatment types delivered in the department. While some had been developed by a multidisciplinary team, inspectors reviewed other documents that would benefit from greater multidisciplinary input and review. Inspectors were informed that a recently developed clinical guideline had been peer reviewed by an international peer group, and this was identified as an area of good practice in the department.

Inspectors found that the undertaking had ensured that there was appropriate monitoring of radiation incidents. However, improvement was required to ensure that potential incidents or near misses were adequately reported and monitored. Inspectors also noted that the system of submitting notifiable incidents to HIQA required improvement.

Overall, inspectors identified areas of good practice in this radiotherapy service, in particular around justification, optimisation and the surveillance of equipment. Although there was no evidence that the gaps identified under Regulation 17 presented a patient safety issue, the undertaking's management team should take action to achieve compliance with this regulation.

Regulation 8: Justification of medical exposures

The radiotherapy management team in Cork University Hospital had developed a guidance document for staff titled '*Policy for Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital*' which specified that radiation oncologists, specialist practice registrars, registrars and radiation therapists were responsible for justifying in advance radiation exposures to patients, having considered the risks and benefits to the patient. The justification process was carried out at various points along the patient's radiotherapy treatment pathway, and inspectors spoke with a number of referrers and practitioners and noted that all spoken with were clear on their roles and responsibilities in the process.

Inspectors also reviewed a sample of patients medical records, including their referral for radiotherapy. Each referral viewed had been submitted in writing by a radiation oncologist, using an online booking form and clearly stated the reason for the treatment. The referrals viewed were accompanied by supplementary information, such as previous imaging, and surgical and pathology reports. Inspectors were informed that this information was considered by radiation oncologists during the referral process for radiotherapy medical exposures to ensure that they resulted in sufficient net benefit to patients. Inspectors saw that the radiation oncologist had signed each referral form electronically and included their medical council number, and were informed that this was the record of justification in advance by the referrer.

In Cork University Hospital, radiation oncologists and radiation therapists had also been allocated the role of practitioners, and were responsible for the justification of each medical exposure of ionising radiation along the patient's pathway. On the day

of inspection, records of justification in advance were viewed by inspectors and radiation therapists, who spoke with inspectors, adequately described how they carried out the justification process. For example, at the radiotherapy planning CT, two radiation therapists carried out justification in advance by completing a list of checks and tasks, and then recording the justification by adding their initials and professional registration numbers in an electronic record and verification system. The system also allowed radiation therapists to specify the medical data reviewed during the justification process. This was identified as an area of good practice within the service.

Also, in advance of delivering daily radiotherapy medical exposures, radiation therapists completed a series of checks such as reading updated medical notes and checking the patient's treatment position with verification imaging. Again, these checks were electronically documented on a daily treatment record with the initials of the two radiation therapists who had responsibility for justifying the procedure.

During a tour of the radiotherapy department, inspectors observed that information booklets and posters on the risks and benefits of medical exposures to ionising radiation, associated with radiotherapy planning and treatment, were available to patients. Inspectors were also informed that this information was provided by radiation oncologists to patients during an initial consultation meeting, in advance of any exposure to ionising radiation, and that patients had frequent opportunities to meet with the radiotherapy multidisciplinary team to discuss any queries that they had on the risks and benefits of the medical exposures.

Judgment: Compliant

Regulation 9: Optimisation

During the inspection, inspectors observed that the management team in the radiotherapy department of Cork University Hospital had in place a number of processes and procedures to ensure that all medical exposures to ionising radiation in the radiotherapy department were optimised. There was a multidisciplinary team approach to these optimisation processes, which included radiation oncologists and radiation therapists, as practitioners, and also the medical physics team. Inspectors were informed that some optimisation processes were allocated based on the practitioner's level of training and experience, and that the rights to complete these processes were assigned and controlled electronically. This was identified as an area of safe and good practice within the service.

Prior to the inspection, inspectors reviewed the '*Policy for Justification and Optimisation of Medical Exposures in Radiotherapy Practice at Cork University Hospital*' which clearly outlined the various points along the patients' radiotherapy pathway where optimisation was to be performed and those responsible for same. The radiotherapy management team and staff had developed treatment site-specific guidelines and procedures, for example for prostate cancer, breast cancer and colo-

rectal cancer. Each guideline viewed by inspectors outlined how optimisation was best achieved at CT planning by specifying the optimal patient position and aids to be used, and also the extent of the area to be imaged. Each guideline also outlined the frequency and imaging type to be adhered to when verifying the location of the target area before the delivery of the patient's daily treatment. These guidelines ensured that all radiotherapy medical exposure doses were kept as low as reasonably achievable, while achieving the desired outcome of accurately delivering the planned dose to the target area. The development of these comprehensive guidelines were viewed by inspectors as an area of good practice within the service.

Inspectors also spoke with radiotherapy treatment planning staff who explained the importance of optimising individual treatment plans and how this was achieved by completing a series of pre-planning checks and then applying a site-specific treatment planning protocol to each individual plan. Inspectors were informed that the radiotherapy medical physics team had developed these treatment planning protocols, which ensured that the planned dose was delivered to the target area, while doses to non-target areas were kept as low as possible.

Inspectors were also informed that radiotherapy staff had recorded the dose length product (DLP) for each type of radiotherapy planning CT scan. This information was used to establish the average dose reference level for each scan protocol, which was then compared to international levels. Staff informed inspectors that these levels were readily available to them as part of a CT procedure document, and were referred to when completing CT planning scans. This practice ensured that scan doses were within the acceptable range and that any deviations from the normal range were identified and investigated. The management team had also developed a '*Guidance on the recording of Dose Reference Levels (DRL's) in Pre-Treatment Planning in the Glandore Centre*' to support this initiative and an audit programme for the process. This practice of establishing CT planning diagnostic reference levels was identified as an area of good practice in the radiotherapy department.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written guidelines for the range of radiotherapy treatments completed in the department.

Inspectors were informed that the practice of generating a discharge letter, after patients completed their radiotherapy treatment, had recently commenced in the department. This letter included the planned radiation dose received by the patient. This practice satisfied inspectors that the undertaking was in compliance with Regulation 13(2), in the radiotherapy department at Cork University Hospital, at the time of the inspection.

Inspectors were informed that the quality lead radiation therapist and the radiation

protection officer in the radiotherapy department were responsible for the scheduling and completion of clinical audits. Inspectors were informed that a clinical audit strategy was under development within the department, which would focus and drive the clinical audit programme. Inspectors were also informed that clinical audit results from the department were submitted annually to the Radiation Safety Committee, although this committee did not govern the clinical audit programme in the radiotherapy department or oversee that audit recommendations were completed.

Inspectors reviewed a sample of audits completed, and observed that the audit topics enhanced the radiation protection of service users. For example, audits on a number of CT planning scans were performed to ensure that the optimal patient anatomy was included in the scan.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were satisfied that the radiotherapy management team in Cork University Hospital had established a QA programme for all medical radiological equipment in use in the service. As outlined in the '*Policy & Procedure on the Role of Medical Physics Experts outlined in SI 256*' document, the MPE team were responsible for developing quality assurance (QA) programmes, which comprised of weekly, monthly and annual testing for the CT and treatment equipment.

A review of records showed that the programme was fully completed as scheduled, which satisfied inspectors that the equipment was kept under strict surveillance. Inspectors were informed that radiation therapists performed the daily QA programme, while MPEs carried out the monthly and annual QA testing. On the day of the inspection, inspectors also reviewed documentation that demonstrated that acceptance and commissioning testing had been completed for radiotherapy CT planning and treatment delivery equipment.

The inspectors also spoke with a number of radiotherapy staff on how they reported any concerns on the equipment's functionality. Staff spoke of recording, in writing, any issues that arose and of a reporting pathway to the MPE team.

An up-to-date inventory of radiotherapy equipment was provided to inspectors in advance of the inspection.

Judgment: Compliant

Regulation 15: Special practices

Throughout the inspection, inspectors observed that the management team in the radiotherapy department had a number of appropriate measures in place to ensure that patients receiving high dose medical exposures received appropriate radiation protection. From discussions with staff and a review of documentation, inspectors saw that optimisation of medical exposures was prioritised along the patient's pathway. For example, patient immobilisation was carefully considered at CT planning and continued during treatment delivery. Some patients were also provided with specific preparation to reduce organ motion during the radiotherapy medical exposures. Inspectors were informed that the purpose of such preparation was to minimise verification imaging and doses to normal tissue. Inspectors were also informed that, for specific patients, body surface moulds were generated electronically. This system of electronically generating the moulds improved their fit on patients, which subsequently added to the optimisation of the medical exposures.

Inspectors were also informed that specific planning protocols were used for each treatment site to ensure that the doses to normal tissue is kept as low as possible while delivering the desired treatment dose to the target area. Inspectors were also informed that each treatment plan created was discussed at a treatment planning quality assurance (TPQA) meeting, where they were peer reviewed by a radiotherapy multidisciplinary team. This system of peer reviewing treatment plans was identified as an area of good practice within the service.

Inspectors were also informed that an imaging system was in place on the treatment units that effectively monitored the patient's position and breathing patterns. This system had resulted in a reduction in the number of repeat images taken and subsequently a reduction in radiation dose.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed that notices were displayed in patient waiting areas throughout the radiotherapy department to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation.

The radiotherapy management team had also developed a '*Procedure for determining pregnancy status of patients receiving radiotherapy in Cork University Hospital*' which provided guidance and support to the radiation oncology and radiation therapist teams on assessing and confirming the pregnancy status of patients undergoing the radiotherapy treatment pathway in the service. From a review of the procedure and discussions with staff, inspectors were informed that patients were educated on the risks associated with potential foetal irradiation during medical exposure along the radiotherapy pathway. Inspectors were also informed that patients received education on the risks of medical exposure during pregnancy, and that practitioners enquired on and recorded the pregnancy status of relevant patients both prior to the planning CT being performed and the first

radiotherapy treatment. Inspectors also reviewed a number of patient records which verified that the enquiry process had been completed prior to the planning CT scan and prior to the first day of treatment by the radiation therapists. The process of enquiring on and recording pregnancy status on the first day of treatment was identified as an area of good practice in this radiotherapy service.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

On the day of the inspection, inspectors were informed that a Radiotherapy Incident Sub-committee had been established by the undertaking and that this committee reviewed and investigated all reported potential and actual incidents involving medical exposures that occurred within the radiotherapy department. All incidents were recorded on an electronic incident management system, which automatically notified the RPO and the radiotherapy management team. Inspectors were also informed of the arrangements in place to notify other key personnel and to instigate an incident investigation process,when required. From a review of the '*Procedure for Radiation Incidents and Near Misses*' and a review of incident records, inspectors were assured that the radiotherapy management team had implemented measures to minimise the likelihood of incidents occurring for patients undergoing medical exposures in the radiotherapy department. Staff spoken with were also able to describe the process for reporting incidents and this was in line with the local policy. Inspectors were also satisfied that the radiotherapy management team had a programme in place to study the risk of incidents, with incident trending for recent years submitted to inspectors prior to the inspection.

However, inspectors were not satisfied that there was an appropriate system in place for recording and analysing potential incidents involving medical exposures. Inspectors spoke with staff across the radiotherapy multidisciplinary team, and found that they were not consistent in their definition of a potential incident or non-conformance to a process in the department, and therefore were not consistent on if and when such potential incidents were to be reported. It is important that all potential incidents are recorded and analysed so that early risk management actions can be implemented and the risk of potential harm to the patient minimised.

Although, inspectors saw that the undertaking had arrangements in place to ensure that HIQA was notified of significant events, inspectors had noted that a significant number of incidents were not submitted within the timelines defined by HIQA and therefore were not consistently meeting their regulatory requirements. During discussions with the management team, it was established that delays in reporting to HIQA were often as a result of key personnel not being promptly available.

Inspectors also highlighted to the management team that in order to provide adequate assurances to HIQA that appropriate corrective measures were in place to minimise the risk of incidents recurring, greater detail was required in the

investigation reports submitted to HIQA.

Although no immediate risks were identified in relation to the gaps outlined above, the undertaking must address these gaps in order to come into compliance with this regulation.

Judgment: Not Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant

Compliance Plan for Cork University Hospital OSV-0007353

Inspection ID: MON-0039916

Date of inspection: 25/10/2023

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

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

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

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Outline how you are going to come into compliance with Regulation 6: Undertaking: CUH Radiation Safety Committee (RSC) The RSC meeting agenda has been revised to include the following standing agenda points: • Radiotherapy Equipment QA programme • Diagnostic Reference Levels (DRLs) • Incidents (i) Learning (ii) Recommendations from Investigation reports • Document Control – PPPG revision & approval The RSC terms of reference are to be revised to include the above CUH Clinical Effectiveness Committee Under the agreed governance restructuring that is currently ongoing in CUH the RSC no longer reports to the Executive Quality & Safety committee now reports to the Clinical Effectiveness Committee. The chair of the RSC is a member of the Clinical Effectiveness Committee. The Clinical Effectiveness Committee receives the minutes of all RSC meetings and is informed of any matters for escalation or further action. The Clinical Effectiveness Committee escalates relevant matters to the EMB The terms of reference for CUH's Clinical Effectiveness Committee are agreed and approved (Dec'23) CUHG Executive Management Board (EMB) A reporting schedule is now in place regarding reports to be received by the EMB. The Clinical Effectiveness Committee reports monthly to the EMB Document Control & Management	

Responsibility and systems relating to the management of documents in the radiotherapy department to be reviewed to ensure they are consistent with those practices in place in the Radiology department and hospital policy which is overseen by the hospital's QPS department.

Regulation 17: Accidental and unintended exposures and significant events	Not Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
1. CUH Procedure for Radiation Incidents and Near Misses to be revised to ensure:
(i) clear definitions on potential incident or non-conformance;
(ii) completion of investigation reports relating to reportable events;
(iii) systems to be followed to ensure correct analysis of incidents involving medical exposures.

The definitions and systems will be in line with (i) HIQA Guidance for undertakings carrying out medical exposures to ionising radiation on the statutory requirement to notify significant accidental or unintended exposure events to HIQA (September 2019) and (ii) HSE Incident Management Framework (2020).

Training on any changes to the current procedure to be provided and supported by CUH's Quality & Patient Safety Department

2. Local Radiation Safety KPI's to be developed to ensure incident reporting timelines as defined by HIQA are consistently being met.

These KPI's are to be monitored by CUH's Radiation Safety Committee, with deviations from the KPI's escalated to the Clinical Effectiveness Committee and/or Executive Management Board as necessary.

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	31/03/2024
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	Substantially Compliant	Yellow	31/03/2024

	events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and	Not Compliant	Orange	31/03/2024
Regulation 17(1)(f)	An undertaking shall ensure that the results of the investigation into any significant event notified under subparagraph (e) and the corrective measures to avoid such events, are reported to the Authority within the time period specified for such events by the Authority in guidelines issued by it for that purpose.	Substantially Compliant	Yellow	31/03/2024