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:	Mid Western Radiation Oncology Centre
Undertaking Name:	Mater Private Hospital
Address of Ionising Radiation Installation:	University Hospital Limerick, Limerick
Type of inspection:	Announced
Date of inspection:	10 October 2024
Medical Radiological Installation Service ID:	OSV-0007397
Fieldwork ID:	MON-0040997

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

The Mid-Western Radiation Oncology Centre provides External Beam radiotherapy treatments as part of the multidisciplinary approach to Oncology at University Hospital Limerick. Patients have an initial treatment planning scan, followed by a course of external beam radiotherapy – duration and number of fractions depend on the clinical site and staging of disease.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

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

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 10 October 2024	09:15hrs to 15:15hrs	Emma O'Brien	Lead
Thursday 10 October 2024	09:15hrs to 15:15hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

An inspection of the radiotherapy department at Mid Western Radiation Oncology Centre was completed on 10 October 2024 to follow up on the compliance plan actions from the previous inspection on 23 May 2022 and to also assess the undertaking's ongoing compliance with the regulations.

On the day of the inspection it was evident that the undertaking, the Mater Private Hospital, had implemented measures to address gaps identified during the previous inspection and improve compliance with Regulations 6, 8, 13, 17, 20 and 21. However, during this inspection, inspectors identified gaps in compliance with Regulation 9 and further gaps under Regulation 6.

Inspectors observed that since the previous inspection in May 2022, the undertaking had implemented a number of corrective actions to improve the allocation and definition of the roles and responsibilities of individuals for the radiation protection of patients. From a review of documents and from speaking with staff on the day of the inspection inspectors were satisfied that there were appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day-to-day operations in the facility up to the undertaking. While inspectors were satisfied that roles and responsibilities were defined and allocated by the undertaking, improvements are required to ensure that all radiation safety policies, procedures and protocols are reviewed and updated to ensure that staff have access to the most up-to-date version of a document to assist them in carrying out their roles and responsibilities.

Inspectors were satisfied that appropriate persons, as per the regulations, were involved in referring for radiotherapy procedures completed at the service. Inspectors were also satisfied that only those entitled to act as practitioner, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

From the records viewed and discussions with staff, inspectors were satisfied that the undertaking had ensured contingency arrangements for the continuity of medical physics expert (MPE) expertise in the facility. Inspectors saw strong evidence of MPE involvement in all areas of MPE responsibilities as per the regulations and were therefore satisfied that the level of MPE involvement was proportionate to the level of radiological risk posed by the service.

Overall, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at the Mid Western Radiation Oncology Centre.

Regulation 4: Referrers

Inspectors were assured that the medical exposures carried out in the radiotherapy department of the Mid Western Radiation Oncology Centre were referred only by individuals entitled to refer as per the regulations, namely by appropriately registered medical practitioners and by radiation therapists for adapted and modified referrals.

Judgment: Compliant

Regulation 5: Practitioners

On the day of the inspection, inspectors found that radiation oncologists and radiation therapists acted as practitioners and took clinical responsibility for individual medical exposures carried out in the radiotherapy department of the Mid Western Radiation Oncology Centre, which satisfied the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors observed that the undertaking had effective governance and management arrangements in place to provide appropriate oversight of radiation protection measures in the radiotherapy department at Mid Western Radiation Oncology Centre. Documentation reviewed by the inspectors prior to and during the inspection demonstrated that there were clear lines of communication within the clinical governance and management structures at Mid Western Radiation Oncology Centre. These documented arrangements aligned with those described by staff to the inspectors. Locally within the department staff informed inspectors that there were weekly incident meetings and radiation protection unit (RPU) meetings. Any issues arising from these local meetings were escalated to the radiation safety committee (RSC) via the radiation therapy services manager (RTSM) or the MPE. The RSC provided oversight for radiation protection in the service and met twice a year to discuss items such as radiation safety incidents, clinical audit, training and the radiological equipment quality assurance (QA) programme. The RSC reported to the Quality Using Effective Safe Treatment (QUEST) Committee which met every two months and was chaired by the group director of quality and patient experience. Inspectors viewed minutes from a recent QUEST committee meeting which provided evidence that radiation incidents and trends from the Mid Western Radiation Oncology Centre were discussed at this forum. The QUEST committee reported to the Quality Board which in turn reported directly into the Mater Private Hospital

Board. A radiation audit committee (RAC) was also in place and this cross-site forum was responsible for the oversight of clinical audit practices in the radiotherapy departments and for the review of incidents, near miss occurrences and incident trends within the departments. The RAC met twice a year and reported to the QUEST committee also.

Since the previous inspection in May 2022 the undertaking had implemented a number of improvements to define roles and responsibilities in the radiation protection of service users in the department. These improvements included the development of a number of documents including the *Process for referral and justification of medical radiological procedures in radiotherapy* which clearly outlined the referrer and practitioner roles and responsibilities of radiation oncologists and radiation therapists in the department. In addition to this document, inspectors also viewed the *Policy on recognition of defined roles and associated responsibilties of individuals under ionising radiation regulations (SI256 of 2018)* which clearly documented the responsibilities of the MPE in the service. Inspectors also noted the involvement of the MPE and staff in the radiotherapy department in completing annual quizzes and training relating to the radiation safety procedures to ensure staff have ongoing awareness regarding radiation protection. This initiative was seen as an example of good practice within the department.

While inspectors were satisfied that there were appropriate radiation safety platforms and lines of communication in place for the safe delivery of medical exposures in the Mid Western Radiation Oncology Centre, improvements in the allocation of responsibility are required in order to ensure that the procedures and protocols available to staff in the department are reviewed and, when required, updated by the appropriate personnel. For example, in one area it was observed by inspectors that additional information that had been handwritten onto a printed copy of a protocol had not been included on the most up-to-date electronic version of this document. In order to ensure that staff are aware of and understand local protocols and policies and are supported in carrying out their individual roles the undertaking must ensure that all documents are regularly reviewed and updated if required.

Judgment: Substantially 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 treatments 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.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors noted that the undertaking had engaged a team of MPEs, which provided assurances that there were arrangements in place to ensure access to and continuity of medical physicist expertise in the radiotherapy department as required by Regulation 19(9). Inspectors were also informed that another member of the physics staff, employed in the service, was in training to become an MPE which positively supported ongoing MPE contingency arrangements and the radiation protection of service users in the service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied, following discussions with staff and a review of documentation, that the corrective actions implemented since the previous inspection, including the development of documentation as discussed under Regulation 6, were effective in clearly defining the roles and responsibilities of the MPE in the radiotherapy service. From the evidence viewed on the day of the inspection the inspectors were assured that there was appropriate MPE involvement in and contribution to medical exposure to ionising radiation. Inspectors were satisfied that an MPE was involved in all aspects of medical exposures as per the regulations. This included overall responsibility for the QA programme for medical radiological equipment and its implementation. In addition, inspectors noted their involvement in dosimetry and the analysis of accidental and unintended exposures. A review of RSC meeting minutes showed that there was MPE representation on this committee, and on other departmental committees tasked with the radiation protection of service users.

Judgment: Compliant

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

On the day of inspection, inspectors found that MPE involvement in medical radiological procedures was in line with the level of radiological risk at Mid Western Radiation Oncology Centre.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the computed tomography (CT) unit, the radiotherapy treatment planning department and one of two treatment units, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the Mid Western Radiation Oncology Centre. While Regulations 8, 13, 14, 15, 16 and 17 were compliant, inspectors noted that there was further work required to bring Regulation 9 into full compliance.

Inspectors found a number of improvements had been made since the previous inspection to achieve compliance with Regulation 8, including the development of the *Process for referral and justification of medical radiological procedures in radiotherapy* document and staff education and training on the multi-stage process of justification in the department.

Inspectors observed that the undertaking had considered alternative techniques to reduce the use of ionising radiation and this was seen as an example of good practice in the radiation protection of service users attending this facility**.**

Inspectors were satisfied that written protocols were available for the range of radiotherapy medical exposures completed in the department and that information relating to patient treatment dose was included on the discharge letter that was completed when a patient finished a course of radiotherapy treatment. Inspectors were also satisfied that the equipment in this facility was kept under strict surveillance, with an appropriate QA programme in place.

Inspectors noted that work had commenced locally in the radiotherapy department on the development of a clinical audit strategy as part of a wider organisational improvement initiative that is due for implementation by January 2025. Inspectors were also satisfied that there was a good culture and system in place for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures as required by Regulation 17, and that pregnancy enquiries were made and documented by a practitioner demonstrating compliance with Regulation 16.

From speaking with staff and a review of practice inspectors were satisfied that a number of measures were in place in the department to ensure that radiation doses to patients were optimised, however, inspectors were not assured that the system implemented by the undertaking to assess and evaluate patient doses encompassed all stages of the radiotherapy pathway, and this is further discussed under

Regulation 9. Despite this gap in compliance inspectors were satisfied that there were appropriate systems and processes in place to ensure the safe delivery of medical radiological exposures to service users at Mid Western Radiation Oncology Centre.

Regulation 8: Justification of medical exposures

Since the previous inspection in May 2022, the management team in the Mid Western Radiation Oncology Centre had developed a document titled *Process for referral and justification of medical radiological procedures in radiotherapy* which clearly defined the roles and responsibilities of referrers and practitioners in the multi-stage process of justification along the radiotherapy pathway. From discussion with staff, inspectors were assured that staff were aware of their responsibilities on recording the justification decision and that the day-to-day practice of justification aligned with the process outlined in this document. Inspectors were informed that by electronically signing a treatment request form, the radiation oncologist justifies the patient's radiotherapy CT planning scan in advance of the scan. Similarly, by reviewing and approving the final treatment plan, the radiation oncologist justifies in advance the medical exposures that are carried out along the radiotherapy treatment course. Inspectors also observed that radiation therapists are responsible for the justification of daily medical exposures of radiotherapy treatment and indicate these justification decisions by electronically completing quality checklists in patient records.

On the day of the inspection, inspectors reviewed a sample of medical records, including referrals 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 were also informed that during the initial consultation with the radiation oncologist enquiries were made to determine if a patient had completed previous radiotherapy treatment. Where relevant, this treatment information was obtained and considered in the treatment planning process as a key radiation protection measure.

While assessing the requirements of Regulation 8(2) inspectors were informed of an ongoing trial in the department and saw evidence that this trial had been approved by a recognised ethics committee as outlined in S.I. No. 29 of 2023.

Judgment: Compliant

Regulation 9: Optimisation

From discussions with staff and a review of documents inspectors were satisfied that the undertaking had implemented a number of measures to ensure that all radiotherapy treatments were individually planned and that their delivery was appropriately checked to ensure doses to treatment areas were delivered as prescribed and doses to surrounding normal areas were kept as low as reasonably achievable.

Inspectors spoke with staff in the radiotherapy planning department who explained how all treatment plans were individually planned and dose limitations applied to keep doses to surrounding normal areas as low as achievable. Staff explained to inspectors that all treatment plans were reviewed and electronically approved by a radiation oncologist. Inspectors were also informed that prior to treatment commencing QA checks were completed on radiotherapy plans to provide additional assurances that doses to the treatment area would be delivered as prescribed. From a review of records on the day of the inspection the inspectors were satisfied that the undertaking had implemented a system to assess and evaluate patient doses from daily treatment exposures on the treatment units. However, staff informed inspectors that there was no system in place to assess and evaluate patient doses from CT planning procedures. The undertaking should ensure that the system in place to assess and evaluate patient doses encompasses every stage of the radiotherapy pathway in order to achieve full compliance with Regulation 9(4).

Inspectors also reviewed numerous policies and procedures which outlined how optimisation was best achieved at treatment planning and delivery. The staff and management in the radiotherapy department had also developed a number of protocols on the imaging type and frequency of imaging to be followed for each radiotherapy treatment site. This was to ensure the accurate delivery of the dose to the treatment area.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of the inspection, inspectors reviewed a number of written protocols for the range of radiotherapy medical exposures completed in the department. These protocols were specific to the treatment sites commonly treated in the service. While meeting the requirements of this regulation the undertaking must ensure that all written protocols are regularly reviewed and updated, if required, to ensure that staff have access to the most up-to-date information, as discussed under Regulation 6.

Inspectors were also informed that national and international referral guidelines were in use in the service. Additionally, inspectors observed that a discharge letter

was generated after each patient completed their radiotherapy treatment, and this included information on the treatment dose received by the patient.

On the day of the inspection the management team informed inspectors of an ongoing programme of work regarding clinical audit that had commenced following a recent inspection of another Mater Private Hospital site. Inspectors viewed evidence, including the *Radiotherapy Clinical Audit Strategy,* which demonstrated that management and staff at the Mid Western Radiation Oncology Centre had started to contribute to this organisational improvement initiative. Inspectors acknowledged that the due date for the implementation of this piece of work was January 2025, as previously provided to HIQA.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at the Mid Western Radiation Oncology Centre was provided to HIQA in advance of this inspection. Inspectors were satisfied that the undertaking had ensured that appropriate measures were in place to ensure that all medical radiological equipment in this radiotherapy department was kept under strict surveillance regarding radiation protection. The MPE team were assigned responsibility for developing and implementing the QA programme, which comprised of weekly, monthly and annual testing for the equipment as outlined in the *Procedure for Quality Control Checks of Linear Accelerators* document. Inspectors found that radiation therapists and MPE's were involved in carrying out on-going performance testing. Records of this testing were reviewed by inspectors on the day of inspection which demonstrated that all QA testing was up-to-date, and that acceptance and commissioning testing had been completed for equipment in use in the department. Additionally, inspectors were also informed by the management team that proactive planning was underway to replace one piece of equipment that is due for replacement in 2025.

Judgment: Compliant

Regulation 15: Special practices

Inspectors observed that the undertaking had mechanisms in place in the Mid Western Radiation Oncology Centre to ensure special attention was given to optimising radiotherapy treatment plans. This included the careful selection of immobilisation equipment and using methods and technology to reduce organ motion where necessary. Site specific protocols were designed and implemented for all treatment procedures and carefully selected parameters for treatment delivery

were used when planning treatments to ensure the doses to normal tissue are kept as low as possible.

Inspectors also noted the recent implementation of surface guided radiotherapy (SGRT) for patients undergoing treatment for breast cancer in the department. Inspectors were informed that this was an evidence based imaging technique which can be used daily for patient positioning and continuous monitoring throughout treatment without the need for additional ionising radiation. The undertaking's consideration of alternative non-ionising radiation methods to support the delivery of radiotherapy was seen as an example of good practice in the radiation protection of service users.

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 radiation protection for the unborn child* which provided guidance and support to the radiation oncology and radiation therapist teams on assessing and confirming the pregnancy status of patients undergoing radiotherapy treatment. 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, and that practitioners enquired on and recorded the pregnancy status of relevant patients both during the initial consultation and prior to the planning CT scan being performed. While meeting the requirements of this regulation this process could be further strengthened by including an additional pregnancy check before patients start radiotherapy treatment.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied that the Mid Western Radiation Oncology Centre had a system in place to record and analyse incidents involving, or potentially involving, an accidental or unintended exposure to ionising radiation. This included an electronic incident reporting system and a weekly departmental incident meeting to discuss all reported incidents and near misses. Inspectors viewed the *Procedure for reporting radiation errors/incidents* document, which outlined the process for the management of accidental and unintended exposures and significant events, and the *Procedure in*

the event of a level 1 radiotherapy incident document which included the requirement to notify HIQA of any reportable incidents. Staff who spoke with inspectors were able to describe the process of reporting an incident or near miss involving a medical exposure.

From a review of incident records on the day of the inspection inspectors saw evidence of an improvement in the approach to incident investigations since the previous inspection in May 2022, through the engagement of all members of the multidisciplinary team within the department. This improvement provided inspectors with assurance that the investigation process was now commensurate with the level of radiological risk posed by this service.

Inspectors were satisfied that there was a good culture of incident and near miss reporting in the department and that all incidents were individually assessed to determine if they meet the threshold for reporting to HIQA. Inspectors also viewed evidence that the undertaking had implemented methods to identify trends in incidents and that these trends were reviewed regularly and discussed at the appropriate forums. However, as an area for improvement, the undertaking should consider, upon review of the incident trend data, if patterns in similar types of incidents that occur should be reported to HIQA, and also if the implemented corrective actions are effective in reducing the likelihood of similar incidents in the future.

Overall, inspectors were satisfied that the undertaking had implemented effective systems and processes in the Mid Western Radiation Oncology Centre for the management of accidental and unintended exposures and significant events.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Substantially 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	Compliant

Compliance Plan for Mid Western Radiation Oncology Centre OSV-0007397

Inspection ID: MON-0040997

Date of inspection: 10/10/2024

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: 1. Document POL-GEN-070 POLICY ON GOVERNANCE STRUCTURE AND RESPONSIBILITIES and Document POL-GEN-021 POLICY ON MANAGEMENT OF DOCUMENT DEVELOPMENT IMPLEMENTATION AND CONTROL detail document control process and the responsibilities assigned to document owners. 2. Good Documentation Practice training will be provided to appropriate personnel. Training to be completed by end of Q1 2025, action owner General Manager	
Regulation 9: Optimisation	Substantially Compliant
Outline how you are going to come into compliance with Regulation 9: Optimisation: Data for 2024 is being compiled on the typical CT scan doses for standard treatment sites by MPE staff. This data will be used to obtain a "typically expected" dose value for each site. When this data becomes available, RTs will compare the scan dose for newly acquired scans with the expected value. Target completion date: End Q1, 2025	

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/03/2025
Regulation 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent	Substantially Compliant	Yellow	31/03/2025

	production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.			