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

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| 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: | 23 May 2022 |
| Medical Radiological Installation Service ID: | OSV-0007397 |
| Fieldwork ID: | MON-0035039 |

## About the medical radiological installation:

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 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 |
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| Monday 23 May 2022 | 09:30hrs to 16:10hrs | Maeve McGarry | Lead |
| Monday 23 May 2022 | 09:30hrs to 16:10hrs | Kay Sugrue | Support |

## Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations was conducted at the Mid Western Radiation Oncology Centre, on the 23 May 2022. Inspectors reviewed documentation provided to HIQA in advance of the inspection, and on the day of the inspection inspectors visited the radiotherapy department and spoke with staff working in this area. Following on from the inspection, further documentation was provided to HIQA by the undertaking including some recently developed policies. This follow up documentation demonstrated the undertaking's positive response to address aspects of the regulations where clarity was needed to fully meet regulatory compliance.

Inspectors reviewed documentation outlining the governance structures in place for the radiation protection of service users and spoke with several staff members. Inspectors were satisfied that reporting lines in place from the Mid Western Radiation Oncology Centre up to the undertaking and the Board of Directors of the hospital group facilitated appropriate oversight of medical radiological procedures at this installation. However, findings from this inspection indicate that the local governance at the Limerick facility could be improved upon, and would benefit from further support by the wider hospital group.

The Mater Private Group Chief Operating Officer (COO) was the designated person responsible for radiation protection for the facility and was a member of the Radiation Safety Committee (RSC). The RSC was the main forum for radiation protection at undertaking level. The RSC reported to the Board of Directors through the Quality Using Effective and Safe Treatments (QUEST) Committee. The Mid Western Radiation Oncology Centre is one of two radiotherapy services under the remit of this undertaking. A Radiation Audit Committee was set up by the undertaking and this committee focuses on trending and sharing learning from potential and actual incidents. From minutes reviewed, inspectors found that this committee was attended by radiation oncologists, medical physics experts (MPEs) and radiation therapists from both of this undertaking's radiotherapy facilities.

From the documents and records reviewed and discussions with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were assured that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. The undertaking had also ensured the continuity of medical physics expertise in this radiotherapy department.

However, inspectors found that overall, local governance including the allocation of responsibility for roles defined under the regulations including MPE and practitioners should be improved at the centre. Responsibilities of individual roles as per the regulations were not clearly articulated by staff on the day of inspection and did not fully align with documentation provided to inspectors in advance of the inspection.

For example, from discussions with staff there was ambiguity around the role of radiation oncologists as practitioners, while their responsibilities as outlined to inspectors included practitioner tasks. In addition, the role of an MPE as distinct from a general physicist was not clearly expressed by staff. Recently developed policy documents provided to inspectors following on from this inspection aimed to clarify the shared practitioner responsibilities between radiation oncologists and radiation therapists. Also, documentation in development at the time of the inspection aimed to clarify the role of the MPE. The undertaking should ensure that these policies are embedded in practice and are understood by staff. In future revisions of policy, the undertaking should also include any delegation of practical aspects to non-practitioners to ensure full clarity on the allocation of responsibilities for medical exposures as per the regulations.

Inspectors found that gaps in documentation content and lack of clarity in relation to the allocation of responsibilities demonstrated by staff, while impacting regulatory compliance, did not pose a safety concern for this service. The undertaking should implement the recently developed policies and policies in draft to ensure that there is a clear allocation of responsibility which is aligned with daily practices, understood by staff and ensures adherence with the regulations.

## Regulation 4: Referrers

All referrals reviewed by inspectors were from referrers as defined in Regulation 4. Staff who spoke with inspectors could describe who was entitled to refer individuals for medical radiological procedures. Inspectors were informed that the radiation oncologist was the primary referrer for radiotherapy procedures. The circumstances under which radiation therapists acted as referrer were clearly documented in policy and were articulated by staff on the day of the inspection.

Judgment: Compliant

## Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures. The clarity regarding the roles and responsibilities of practitioners are discussed under Regulation 8.

Judgment: Compliant

## Regulation 6: Undertaking

The governance structure in place for the radiation protection of service users at the centre was outlined to inspectors by management during the inspection and through the documentation provided. The Group Chief Operating Officer (COO) was the designated manager for the facility and was a member of the RSC. The COO communicated upward to the organisation's board via group governance structures. Inspectors were provided with an example of how the oversight arrangements worked in practice from RSC to the board in relation to the replacement of ageing medical radiological equipment at the facility in Limerick.

However, inspectors found that local governance including the allocation of responsibilities at the Limerick centre requires review by the undertaking. While inspectors found that practitioners and MPEs were involved in the radiotherapy process, the responsibilities as per the regulations were not clearly articulated by staff on the day of inspection. For example, documentation provided in advance of the inspection recognised the radiation oncologists as referrers only. However, the role of the radiation oncologists, as outlined to inspectors on the day of inspection, was found to also include practitioner responsibilities aligned to the regulations. Following on from the inspection recently developed policy documents, provided to HIQA, provided greater clarity around the shared practitioner responsibilities between radiation oncologists and radiation therapists. The undertaking should ensure that this policy is embedded in practice and that a clear allocation of practitioner responsibilities at this facility are understood by staff.

Documentation was in development at the time of inspection to describe the allocation of MPE responsibilities as defined in Regulation 20. However, on the day of inspection staff could not clearly articulate the MPE role as distinct from the general physicist support role. The undertaking should ensure there is close involvement of MPEs which is in line with the regulations, is clearly outlined in policy, understood by staff and implemented in practice.

A document control system for policies, procedures, protocols and guidelines (PPPGs) was in place at the centre and all PPPGs reviewed were within specified review dates. However, inspectors identified that the PPPGs available to support the radiotherapy service were limited and there was a lack of evidence of multidisciplinary involvement in PPPG development from the documents provided in advance of the inspection. For example, the *'Radiotherapy Limerick Departmental Imaging Policy'* and '*Procedure for Computerised Tomography (CT) Simulation of a Patient with Breast Cancer'* were developed by radiation therapists and not reviewed by another discipline. Furthermore, guidelines used to inform clinical decision making were not available for review on the day of inspection. For example, for prostate cancer radiotherapy the evidence basis, patient selection criteria and prescription dose rationale was clearly articulated by a radiation oncologist, but this was not supported by documentation available on the day of inspection. Following on from the inspection, a sample of treatment planning protocols were provided to HIQA which included reference to the evidence basis used for clinical decision making. The undertaking should continue to progress the development of such policies to provide assurance around the consistent and safe delivery of medical exposures.

Furthermore, the undertaking should ensure that the allocation of responsibilities is strengthened around the management of accidental and unintended exposures. The undertaking should ensure that the investigations carried out following on from an accidental or unintended exposure are sufficient to inform the quality assurance programme of the service, and are commensurate with the radiological risk posed.

A number of deficiencies in the allocation of responsibilities for radiation protection of service users at the centre were identified on this inspection. While the individual findings did not pose a risk to the service, the composite of deficiencies in the allocation of responsibilities should be addressed by the undertaking to ensure compliance with the regulations.

Judgment: Not Compliant

## Regulation 10: Responsibilities

From discussions with staff and from reviewing a sample of procedures inspectors were satisfied that the optimisation of radiotherapy treatment and associated imaging involved the radiation oncologists, radiation therapists and the MPEs. Furthermore, all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations.

As discussed under Regulations 6 and 8, the delineation of practitioner roles, including responsibilities for justification were not clearly articulated by staff at the time of inspection. However, documentation submitted after the inspection provided greater clarity on the delineation of practitioner roles. The undertaking should ensure that the recently updated documentation aligns with the day-to-day responsibilities described to inspectors and any delegation of practical aspects of medical exposures is outlined and is in line with the requirements of Regulation 10(4).

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

Inspectors were informed that there were three MPEs based at the facility and that contingency arrangements were in place to ensure continuity of medical physics expertise, with cover available from another hospital within the Mater Private Group should the need arise.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Inspectors discussed MPE responsibilities with staff including MPEs on the day of inspection and reviewed records evidencing the involvement of the MPEs in the radiotherapy process. An MPE produced an annual summary of equipment quality assurance (QA) and inspectors were informed that this MPE had overall responsibility for QA. In addition, one MPE outlined their involvement in technical specifications for equipment and the analysis of accidental and unintended exposures.

However, on the day of inspection, medical physics staff could not clearly distinguish the responsibilities of the MPE as per this regulation from general physicist responsibilities. Inspectors were informed that all physicists working at the centre were involved in patient dosimetry including performing treatment planning, quality control checks of treatment plans and performing patient specific QA. Specific responsibility of the MPE, as distinct from a general physicist, in terms of the evaluation of the dose delivered to the patient was not evident in practice, therefore inspectors were not assured of the MPEs involvement in dosimetry. Similarly, oversight of an MPE was not articulated and therefore inspectors were not assured that an MPEs involvement in this service was in line with the requirements of Regulation 20(2).

A draft policy was reviewed by inspectors on the day of inspection which included an outline of the responsibilities of MPEs at the facility. This policy, and relevant documentation, should be further developed by the undertaking to ensure clarity around the roles of MPEs in line with the requirements of this regulation are implemented in practice and are known by staff.

Judgment: Substantially Compliant

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

From discussions with staff on the day of inspection, inspectors were satisfied that physics staff were closely involved in the radiotherapy service. However, as per Regulation 20, to ensure full alignment with the requirements of this regulation, draft documentation should be progressed by the undertaking to clearly outline how MPEs are closely involved in the radiotherapy service, commensurate with the radiological risk posed and that this close involvement of MPEs is understood by staff.

Judgment: Substantially Compliant

## Safe Delivery of Medical Exposures

Inspectors were assured from evidence gathered that the Mid Western Radiation Oncology Centre had appropriate systems and processes in place for service users undergoing radiotherapy medical exposures. This included evidence that an appropriate QA programme was implemented and maintained in line with local policy, which included regular performance testing and quarterly preventative maintenance by the equipment manufacturers.

Inspectors found that the undertaking had identified the need to replace ageing medical radiological equipment and had a replacement programme in place. Staff informed inspectors that down-time due to equipment faults was carefully monitored but had the potential to impact on service delivery. Minutes of meetings reviewed by inspectors outlined that the service was experiencing growing demand. Therefore, planned equipment replacements should be progressed by the undertaking to ensure the continued safe delivery of medical exposures and continuity of the service.

Information relating to the risks and benefits associated with the radiotherapy medical exposures were provided at various points along the patient pathway by radiation oncologists and radiation therapists. Furthermore, inspectors were satisfied from evidence gathered that there was a strong emphasis placed on the optimisation of radiotherapy procedures ensuring the safe delivery of treatment to service users. This was evidenced in a number of patient treatment pathways reviewed by inspectors and from discussions with staff.

Inspectors found that the process of justification within the radiotherapy pathway articulated by staff to inspectors did not fully align with documented processes and it was unclear to inspectors where justification was recorded. This meant that while the undertaking met some aspects inspected under Regulation 8, compliance with Regulations 8 (8) and 8 (15) was impacted.

Other areas of improvement identified by inspectors were in relation to the need to progress the development of clinical protocols to support radiotherapy practice. The local policies and protocols submitted by the undertaking in advance of the inspection were relatively limited, particularly in relation to clinical protocols. Furthermore, from the documentation provided in advance of the inspection and from discussions with staff, inspectors determined that the development of PPPGs would benefit from greater multidisciplinary input. Following on from this inspection, a sample of treatment planning protocols were provided to inspectors. On review of these policies, inspectors noted that many gaps in documentation identified by inspectors during the inspection had been incorporated and included in these documents. However, there was a notable lack of awareness by staff of these policies on the day of inspection.

Inspectors found that the undertaking had ensured that there was appropriate

monitoring of radiation incidents. However, more assurance was required to ensure that the level of investigation being carried out following a significant event is representative of the radiological risk posed by this service.

Overall, inspectors found that there were several areas of good practice identified in this radiotherapy service. The gaps identified did not represent patient safety issues but should be addressed to provide the undertaking greater assurance around compliance with the regulations.

## Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Inspectors were satisfied that previous medical records were sought relevant to the planned exposure. For example, staff outlined to inspectors how a particular patient's treatment plan took into consideration the dose received by this service user from a previous course of radiotherapy.

Information relating to the risks and benefits associated with radiotherapy medical exposures were available to service users via site specific information booklets and leaflets. Inspectors viewed a number of booklets including a booklet specifically for prostate cancer patients. Inspectors were informed that this information was provided by the radiation oncologist at the time of consent and that further information was provided at the time of the pre-treatment computed tomography (CT) scans by radiation therapists. The information provided at CT included the potential risks of treatment and possible side effects to expect from treatment.

On the day of inspection, inspectors spoke with radiation therapists and a radiation oncologist about the justification of radiotherapy medical exposures. Inspectors found that justification involved appropriate individuals as defined in Regulation 5. Furthermore, the role of the radiation therapists in justification was outlined in documentation provided in advance of the inspection. However, on the day of inspection staff did not clearly articulate the justification process for radiotherapy medical exposures. A radiation oncologist informed inspectors that the radiation oncologists, had an inherent role in justification, and that this took place at a number of different points in the patient pathway. This included when the patient was evaluated prior to commencing treatment and again when the treatment plan and prescription were approved. However, documentation provided in advance of the inspection did not outline the role of radiation oncologists in the justification process. Furthermore, staff could not clearly demonstrate where the record of justification was recorded.

A *'Process for referral and justification of medical radiological procedures in radiotherapy'* document was provided to HIQA following on from the inspection. This policy outlined the justification process at the facility, however, this process did not fully align with the process communicated to inspectors on the day of the inspection. The undertaking should ensure that documentation is updated to reflect the day-to-

day practices at the facility and that the process and record of justification as incorporated into the radiotherapy pathway are understood by staff. In addition, the undertaking should ensure that the records evidencing compliance with this regulation are clearly identifiable for review to ensure compliance with Regulation 8(15).

Judgment: Substantially Compliant

## Regulation 9: Optimisation

Inspectors reviewed records including those of a sample of patients with breast, prostate and head and neck cancer. Inspectors were assured that radiotherapy treatments were optimised by individually planning all exposures to the target area, while reducing the dose to nearby organs as much as possible and ensuring the dose is delivered consistently.

Examples were reviewed for various treatment intents including palliative cases. For a palliative treatment reviewed, inspectors were informed that the treatment was optimised using mulitleaf collimators, wedges and a patient specific beam arrangement which accounted for previous treatment delivered. Inspectors spoke with staff involved in treatment planning and reviewed complex treatment plans. Inspectors were informed how the plan was developed and optimised with respect to the target dose and constraints applied for organs at risk. Dose verification was outlined through image-guided radiation therapy (IGRT) practices, patient specific QA (PSQA) for all intensity-modulated radiation therapy plans and how an independent planning system check was carried out for all conformal plans.

Furthermore, inspectors were informed how the consistency of treatment delivery was assessed through the QA processes in place, including checks carried out regularly on treatment records and images.

Judgment: Compliant

## Regulation 13: Procedures

Written protocols were in place for processes undertaken by radiation therapists such as image guidance procedures. However, policies provided in advance of the inspection indicated that there was a gap in the PPPGs available to support clinical rationale and dose delivery for radiotherapy treatments. The radiation oncologist verbally outlined to inspectors the clinical indications applied for radiotherapy in patients with various types of prostate cancers. Inspectors were informed that up-to-date national guidelines were used to guide clinical decision making. However,

this was not supported by the documentation available on the day of inspection.

The process for including information about patient exposure on the patient's report by the radiation oncologist was explained to inspectors. The radiation oncologists wrote a letter to the other physicians involved in the care of the patient summarising the radiotherapy treatment given including dose and fractionation.

From documentation viewed and discussions with staff, inspectors were satisfied that the undertaking had processes in place to ensure regular quality control checks and continuous monitoring were conducted throughout radiotherapy treatment for patients. Quality improvement projects undertaken in 2020 and 2021 were also outlined to inspectors. Given the complexities associated with radiotherapy delivery and the relative radiological risk, inspectors found that the overarching approach to clinical audit within the service could be improved. There was potential to expand the range of clinical audit undertaken to provide further assurance around adherence to local policy and to determine areas for quality improvement.

Judgment: Substantially Compliant

## Regulation 14: Equipment

From documentation viewed and discussions with staff, inspectors were satisfied that medical radiological equipment was kept under strict surveillance. Evidence was provided that a QA programme was implemented and maintained. Inspectors also saw evidence that dose assessment and verification programmes were implemented, such as patient specific QA for complex radiotherapy treatment plans.

The frequency of QA and regular performance testing were outlined in a document viewed by inspectors and this aligned with the process described by staff to inspectors. Inspectors reviewed QA reports from 2021 and 2022 for both linear accelerators (treatment units) and quarterly preventative maintenance manufacturer reports. Annual QA for CT by an MPE was also reviewed.

An up-to-date inventory was provided in advance of the inspection. The inventory indicated that the nominal replacement dates for the linear accelerators were 17 years and 15 years after installation respectively. While all medical radiological equipment was regularly assessed and approved for clinical use, issues with ageing equipment and down-time were ongoing and were closely monitored at local and group level. Inspectors were informed that the ageing equipment was also recorded on the hospital risk register.

Management informed inspectors that a programme to replace medical radiological equipment was in place and that the selection process was underway for one of the linear accelerators to be replaced. A timeline for the installation of the new linear accelerator not defined but was estimated to be approximately seven months from selection to installation and commissioning in documentation viewed by inspectors. Inspectors were informed that the demand on the service was growing with a

potential need to expand the service. The progression of medical radiological equipment replacement should be prioritised by the undertaking to ensure the continued safe delivery of medical exposures.

Judgment: Compliant

## Regulation 15: Special practices

Inspectors found that appropriate medical radiological equipment, practical techniques and ancillary equipment were used for radiotherapy treatment at the facility. Inspectors found that optimisation of radiotherapy procedures included the selection of equipment. While ageing equipment was identified as an issue by the undertaking, newer ancillary equipment including motion management systems which can monitor patient's breathing during treatment had been purchased and installed. This ensured that this technology was available on both treatment machines. Further ancillary equipment used at the facility included immobilisation devices such as head and neck masks and a breast board used for breast and thoracic treatments.

The verification of dose included imaging used to guide treatment delivery. Inspectors were provided with an example of a situation where a query about the consistent delivery of treatment was identified by imaging carried out before treatment was delivered. The imaging showed a variation in the patient's contour compared to the planned treatment and inspectors were informed how this query was addressed by the multidisciplinary team to ensure optimised treatment was delivered to the patient. This is an example of how special attention was given at the facility to ensure the verification of dose being received by the patient was accurate.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

From the documents reviewed and speaking with staff, inspectors were informed of the process for inquiring about and recording pregnancy status. Inspectors viewed a sample of written records documenting pregnancy inquiries made by staff.

Measures were taken to increase the awareness of people to whom this regulation applies. Inspectors observed posters on display in the waiting area, in a variety of languages, alerting patients to inform staff of their pregnancy status.

Judgment: Compliant

## Regulation 17: Accidental and unintended exposures and significant events

The measures taken by the undertaking to minimise the risk of accidental or unintended exposures to service users were demonstrated through the hospital's procedures, surveillance of equipment and quality assurance programmes. A Radiation Audit Committee focused on the review of incident and accident reports. This forum facilitated shared learning across the radiotherapy services within the Mater Private Hospital Group. Trending of incidents was evident and incidents were communicated up to the undertaking via the group's quality department.

Notifications submitted to HIQA since commencement of the regulations demonstrated the undertaking's compliance with reporting significant events within the requested timelines. Inspectors reviewed documentation, notifications received to-date and had discussions with staff on the day of inspection. Inspectors were informed that the investigations following on from the occurrence of a reportable incident to HIQA consisted of a review by radiation therapists only. Inspectors determined that these investigations would benefit from greater multidisciplinary input and in some cases could be more comprehensive and include a study of the risk, particularly in the context of the potential risk in this setting. The events reported to HIQA were of a significant level to meet the reporting threshold, and took place in a radiotherapy setting which is an area of high potential risk when compared to other radiological services. The undertaking should ensure that the investigation process is commensurate with the level of radiological risk posed by this service and is sufficient to inform the quality assurance programme of the service.

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 and 2019. The regulations considered on this inspection were:

| Regulation Title | Judgment |
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| **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 | 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 9: Optimisation | Compliant |
| Regulation 13: Procedures | Substantially 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 | Substantially Compliant |

# Compliance Plan for Mid Western Radiation Oncology Centre OSV-0007397

## Inspection ID: MON-0035039

## Date of inspection: 23/05/2022

**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: "RTH-LMK-114 : Roles and Responsibilities of Practitioners, Referrers and Medical Physicist Experts" has been amended to clearly define roles and responsibilities and is with MDT for review prior to issuing. Training on new policy to be completed with all members of the Physics, radiation therapist and radiation oncology teams. Training form to be completed as evidence of understanding and training. The document control process (outlined in policy POL-GEN-021) requires multidisciplinary approach to the production & review of documentation. Existing documentation for the centre will be audited and re-submitted for multidisciplinary review where applicable. Guidelines to inform clinical decision-making will be produced for the main clinical treatment sites with input from all members of MDT. Investigations for incidents & unintended exposures will record input from and review from multidisciplinary team on the local investigation report. | |
| 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:<br>Policy RTH-LMK-114 "Roles and Responsibilities of Practitioners, Referrers and the Medical Physics Experts" is with MDT for review. This policy provides detail on the roles of the MPE and their involvement in dosimetry, patient specific- and treatment plan QA checks, optimisation of protection, definition and performance of QA, acceptance testing of equipment, preparation of technical specifications for medical radiological equipment and installation design, surveillance of the facility, analysis of events related to actual or potential unintended medical exposures. The roles of MPE and general Physicist are | |

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| clearly outlined and distinguished as to responsibilities. Training to be completed on policy for all physics team, Radiation oncologists, Radiation Therapists and management team. |

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| Regulation 21: Involvement of medical physics experts in medical radiological practices | Substantially Compliant |

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| Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:<br>Policy RTH-LMK-114 "Roles and Responsibilities of Practitioners, Referrers and the Medical Physics Experts" is with MDT for review. This policy provides details of the close involvement of the MPE in the radiotherapy service as required by section 21(2)(a) of the legislation. Training to be completed on policy for all physics team, Radiation oncologists, Radiation Therapists and management team. Training form will be completed to acknowledge understanding and completion of training. |

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| Regulation 8: Justification of medical exposures | Substantially Compliant |

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| Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:<br>RTH-LMK-111 Process for referral and justification of medical radiological procedures in radiotherapy has been revised to recognise the multi-stage process of justification in centre's radiotherapy setting. This revision includes alignment to day-to-day practice in the centre. The document is currently under review by relevant multidisciplinary team and will be submitted for document control by Mater Private Quality Department prior to release. Training to be completed on the released policy to Radiation Oncologists, Medical Physics and Radiation Therapists. Training form will be completed to acknowledge understanding and completion of training. |

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| Regulation 13: Procedures | Substantially Compliant |

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| Outline how you are going to come into compliance with Regulation 13: Procedures: |

Treatment site-specific documentation will be produced and released in adherence to POL-GEN-021 (Document Control Process) including relevant multidisciplinary review. Documentation will reference applicable National guidelines and will be reviewed as required with any updates in released guidelines. Training to be completed on the released documents to Radiation Oncologists, Medical Physics and Radiation Therapists. Training form will be completed to acknowledge understanding and completion of training.

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| 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:
Local investigation process will be completed with input and review from multidisciplinary team. All contributors to the investigation will be recorded on the Local investigation form and subsequent report. The undertaking has a risk rating system in place. This system will be utilised to generate risk ratings specific to the incident under investigation. The relevant team members will be involved in designating the risk rating depending on the incident type. Where remedial actions have been taken after occurrence, but prior to submission of the report, details of the actions will be included in the investigation report and include date of completion. The existing practice of identifying actions and timeframes for completion of associated actions which are pending or in-progress will continue to be used. Mater Private Quality department are included in all investigations and will ensure a full comprehensive investigation is completed prior to closure. The hospital runs a weekly incident meeting which is attended by a representative of the Limerick Radiation Therapy department. A Multidisciplinary team local incident meeting will also be commenced end Q3 2022 and subsequently continued on a quarterly basis. Training on the updated process for incident investigation will be completed with Radiation Therapists, Medical Physics experts, Radiation oncologists and nursing team. Training forms to be completed to acknowledge understanding and completion.

## 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 |
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| 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 | 22/08/2022 |
| 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 | 30/08/2022 |

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| | 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. | Substantially Compliant | Yellow | 30/08/2022 |
| Regulation 13(1) | An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients. | Not Compliant | Orange | 30/10/2022 |
| Regulation 17(1)(b) | An undertaking shall ensure that for radiotherapeutic practices, the quality assurance programme includes a study of the risk of accidental or unintended exposures, | Not Compliant | Orange | 22/08/2022 |
| Regulation 17(1)(c) | An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for | Substantially Compliant | Yellow | 22/08/2022 |

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| | the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice, | | | |
| Regulation 20(1) | An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive. | Substantially Compliant | Yellow | 22/08/2022 |
| Regulation 20(2)(a) | An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals | Not Compliant | Orange | 22/08/2022 |

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| | subject to medical exposure, | | | |
| 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:<br>(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;<br>(ii) the definition and performance of quality assurance of the medical radiological equipment;<br>(iii) acceptance testing of medical radiological equipment;<br>(iv) the preparation of technical specifications for medical radiological equipment and installation design;<br>(v) the surveillance of the medical radiological installations;<br>(vi) the analysis of events involving, | Substantially Compliant | Yellow | 22/08/2022 |

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| | 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 posed by the practice. | Substantially Compliant | Yellow | 22/08/2022 |
| Regulation 21(2)(a) | In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved, | Substantially Compliant | Yellow | 22/08/2022 |