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: | St Luke's Radiation Oncology Network at St James Hospital |
| Undertaking Name: | Health Service Executive |
| Address of Ionising Radiation Installation: | Saint James's Hospital, James Street,<br>Dublin 8 |
| Type of inspection: | Announced |
| Date of inspection: | 20 April 2022 |
| Medical Radiological Installation Service ID: | OSV-0007880 |
| Fieldwork ID: | MON-0032796 |

## About the medical radiological installation:

It is over 65 years since St Luke's began caring for cancer patients in Ireland and over a decade since the network of St. Luke's Radiation Oncology Network (SLRON) was established. SLRON expanded its service in 2010 and opened two new radiation centres on the campus of Beaumont Hospital and St James's Hospital. These two centres along with St Luke's Hospital in Rathgar operate as a single network with a single executive management team directly reporting to Dublin Midland's Hospital Group CEO.

High specification linear accelerators (the main equipment used to treat cancer patients with external beam radiotherapy) are available across the SLRON and provide public radiotherapy cancer services for Dublin along with a range of specialist radiotherapy services nationally. Approximately 55% of radiotherapy patients in Ireland are treated in Dublin and 75% of these are treated in SLRON, with 5,000 new cases treated per year (80,000 radiation treatments) on 14 linear accelerators making SLRON one of the largest radiation centres in Europe. Patients also benefit from access to clinical trials for multiple tumour types. Four of the linear accelerators in this network are located in the centre at St. James's Hospital.

## 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 20 April 2022 | 09:30hrs to 16:30hrs | Agnella Craig | Lead |
| Wednesday 20 April 2022 | 09:30hrs to 16:30hrs | Lee O'Hora | Support |

## Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership and management arrangements in place at St Luke's Radiation Oncology Network at St James Hospital, one of three facilities which make up the St. Luke's Radiation Oncology Network (SLRON) in Dublin. Documentation reviewed in advance of the inspection identified that a Radiation Safety Committee (RSC) had been established to ensure the structures and processes in place to manage the radiotherapy service provided in this facility. This committee was chaired by a consultant radiation oncologist and reported to the Quality, Patient Safety and Risk Management Committee and to the network director. The network director was the designated manager who reported to the Health Service Executive (HSE), the undertaking for this facility.

In advance of discussions at the RSC, radiation safety issues were firstly discussed locally at an Incident Learning Committee (ILC) which operated in each of the three facilities. These local ILCs reported up to the Network Radiotherapy Incident Learning Committee (NRILC) and this was seen as an example of good practice which facilitated learning to be shared across the facilities in this network.

From the documents and records reviewed, 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 taken by personnel entitled to act as practitioners as per the regulations. However, the recently updated documentation outlining the specific details of practitioners would benefit from a further review to ensure full clarity on the situations when radiation therapists act as practitioners.

Inspectors were informed of the process in place to ensure involvement and continuity of medical physics expertise. From the evidence gathered as part of this inspection, inspectors were assured that the level of involvement of the medical physics expert (MPE) was proportionate to the level of risk in this installation. However, to ensure full compliance with the regulations, documentation should be updated to clearly outline the allocation of responsibilities to the MPEs as distinct from other physics personnel.

Notwithstanding the documentation updates required, inspectors were assured of the governance arrangements in place in this facility.

## Regulation 4: Referrers

Inspectors found that referrals for medical radiological procedures were received from persons as defined in Regulation 4. The referral process in place for medical

radiological procedures was clearly outlined in documentation reviewed in advance of this inspection. These documents detailed the personnel who can refer patients for different types of radiotherapy procedures. Referrals were received in either electronic or paper-based formats. From the records reviewed on the day of inspection, inspectors were assured that only consultant radiation oncologists and radiation oncology registrars referred patients for external beam radiotherapy.

Judgment: Compliant

## Regulation 5: Practitioners

The documentation reviewed in advance of this inspection detailed who was entitled to act as practitioner for medical exposures in this facility. The documentation included details about how the practitioner responsibilities along the patient pathway can be shared among different personnel while overall clinical responsibility for patients is held by one practitioner.

On the day of inspection, a sample of records and other documentation was reviewed and inspectors were assured that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

## Regulation 6: Undertaking

From reviewing the documentation in advance of this inspection, inspectors were informed of the governance structures in place for the radiation protection of service users within this facility. The network director was the designated manager and the organisation chart showed how the network director communicated up to the HSE as the undertaking of this facility. A chart detailing the radiation safety organisation structure was also provided and inspectors noted that a local ILC reported to the NRILC, which in turn reported to the RSC. The designated manager was a member of the RSC which reported to the Quality, Patient Safety and Risk Management Committee and to the Network Executive Management team.

From speaking with staff and reviewing the documents, inspectors were informed of the allocation of responsibilities in this facility. This included information on the situations where a radiation therapist (RT) can act as a practitioner, and the situations where the RT is delegated the practical aspects. Although documentation had recently been updated to reflect these situations, staff who spoke with inspectors on the day of inspection had differing interpretations of this. Therefore, the documentation would benefit from a further review to ensure no ambiguity in relation to the situations where an RT acts as practitioner for example, when taking

responsibility for reviewing the medical exposures.

In addition, detail about the allocation of responsibilities to the MPEs was not clearly outlined in the documentation provided in advance of this inspection. Inspectors were informed by staff that this is currently being addressed as the document titled *'Radiation Safety Procedures'* is undergoing a revision and will include details about the allocation of responsibilities specific to MPEs. However, a draft document titled *'The role of the MPE in treatment planning'* was provided to inspectors on the day of the inspection. Although in draft format, this document detailed how the responsibilities of the MPE in the treatment planning department will be allocated.

Notwithstanding the documentation updates required to provide full clarity on the allocation of responsibilities, from the information gathered as part of this inspection, inspectors were satisfied that the structures and systems in place facilitated the undertaking to have oversight of this facility.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

From the documentation reviewed and discussions with staff, inspectors were assured that all medical exposures took place under the clinical responsibility of a practitioner. Radiation oncologists were deemed practitioners with details of the situations where RTs acted as practitioners also outlined in documentation reviewed in advance of inspection. As described earlier under Regulation 6, the documentation would benefit from updating to ensure full clarity for all personnel on their specific roles and responsibilities.

Inspectors were also assured that the optimisation process included the practitioner and the medical physics expert and that the justification process included both the referrer and the practitioner, as required by the regulations.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

From the information described on the day of inspection, inspectors were assured that the mechanisms in place provided continuity of medical physics expertise at this facility.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

From documents reviewed prior to, and on the day of inspection, and from speaking with staff, it was evident that the MPEs took responsibility as detailed in the regulations. However, as detailed in Regulation 6, relevant documentation should be updated to ensure the responsibilities of the MPE as distinct from a physicist or a radiation protection adviser are clearly outlined.

From the evidence reviewed, the observations on the day of inspection and the information provided by staff, inspectors were satisfied that MPEs were involved in dosimetry, optimisation, and in quality assurance (QA). In addition, evidence was provided of the MPEs role in analysing events involving or potentially involving ionising radiation.

Judgment: Compliant

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

Mechanisms were in place to ensure that the MPEs involvement in medical radiological procedures was in line with the level of radiological risk in this facility.

Judgment: Compliant

## Safe Delivery of Medical Exposures

On this inspection of the St Luke's Radiation Oncology Network at St James Hospital, inspectors found evidence that the facility had appropriate systems and processes in place to ensure that safe and effective medical exposures are provided to service users. This included evidence of appropriate processes to ensure the optimisation of radiotherapy procedures and processes for reporting accidental and unintended exposures. Evidence that exposures were justified in advance and a record kept of justification was also seen, along with records that an enquiry of pregnancy status had been made where relevant, by the appropriate personnel.

Written protocols for different types of procedures were available, however, these protocols should be updated as a matter of priority as many were past their review date. Although clinical audits had been conducted in this facility, staff identified that this was an area requiring more focus in the future.

Documentation on the QA programme in place and records of the maintenance of equipment used to perform medical radiological procedures were also provided and

provided assurance of the safe delivery of ionising radiation in this installation. However, records outlining the actions taken to address issues identified during performance testing and QA were not available and should be addressed to ensure full compliance with Regulation 14.

## Regulation 8: Justification of medical exposures

The recently updated document titled *'Optimisation and Justification Procedure for Ionising Radiation'* reviewed in advance of this inspection contained a graphic *'Radiotherapy Optimisation and Justification Pathway at SLRON'*. This graphic outlined the personnel who had responsibility for justification at all stages of the patient's pathway through the radiotherapy department, from initial referral to the end of treatment. Staff who spoke with inspectors on the day of inspection identified the steps that are taken if insufficient information was provided to justify a medical exposure.

Information given to patients about the benefits and risks associated with medical exposures was described to inspectors and the consent form signed by patients was available in all records reviewed on the day of inspection.

In line with Regulation 8, all referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Judgment: Compliant

## Regulation 9: Optimisation

The recently updated document titled *'Optimisation and Justification Procedure for Ionising Radiation'* reviewed in advance of this inspection outlined the personnel who had responsibility for optimisation at different stages of the patient's pathway. This document detailed the types of actions to be considered such as requesting additional procedures or additional modifications, constraints or changes to the treatment prescription to facilitate further optimisation of the patients' treatment plans.

Staff who spoke with inspectors on the day of inspection also explained the steps they take in order to ensure the dose from medical exposures in both the pre-treatment planning scans and during treatment is optimised. These steps included the use of specific software to guide the level of dose given in the CT scanner and individually planning all treatment plans and applying specific recognised constraints to keep doses to non-target volumes as low as achievable. The processes used to ensure medical exposures are verified before proceeding with treatment was

outlined in documentation reviewed by inspectors with details of the type and frequency of imaging used to guide and verify treatment outlined in site specific policies, for example, one policy was applicable for patients with lung cancer and a separate policy was available for patients with cervical cancer patients.

Policies reviewed by inspectors also outlined the routine quality control checks performed throughout the patient pathway by radiation therapists and physics team members. Inspectors reviewed patient records which demonstrated that multiple checks took place and that additional patient specific quality assurance (PSQA) was used to verify dose delivery for complex cases in advance of the first treatment.

Judgment: Compliant

## Regulation 13: Procedures

From the documents provided in advance of inspection, inspectors noted a significant number of written policies, procedures, protocols and guidelines were available for staff. However, from the sample of clinical guidelines reviewed, inspectors noted that many documents had passed their identified review date. Inspectors were informed of the plan to update these and of the human resources that were now available to act on this. In order to come in to compliance with Regulation 13 (1), this plan should be prioritised.

Inspectors were also informed that summary reports are produced once patients finish their treatment and information relating to the dose of radiation received by patients is included in these.

A list of clinical audits was provided to inspectors, but staff informed inspectors that routine clinical audit is an area requiring further attention in this facility. However, details of an evaluation of a quality improvement initiative was provided to inspectors and this identified that changes to the processes for completing regular checks of patients charts had been a positive initiative. Conducting an audit to evaluate quality improvement projects was viewed as an example of good practice showing how audit can be used effectively.

Judgment: Substantially Compliant

## Regulation 14: Equipment

Inspectors were provided with documentation detailing the approach taken to QA and performance testing and documents reviewed on the day of inspection showed that the QA programme was up to-date. Staff explained how any equipment issues are addressed and or escalated, however, records showing the type of, and the

timing of, follow up actions taken when issues were identified were not available. Inspectors discussed with staff the importance of recording how and when issues are managed, and staff recognised that record-keeping in these situations is an area for improvement.

Inspectors noted that although the equipment was passed its nominal replacement date it was deemed fit to continue in clinical use. Inspectors were informed that a business plan for replacing equipment in the radiotherapy department had been developed and submitted to the undertaking and the equipment is listed on the HSE's equipment replacement list.

Although inspectors were satisfied that the equipment had passed the quality assurance testing and that the undertaking had appropriate processes in place to ensure ongoing oversight, records of the actions taken when issues are identified is necessary in order to be fully compliant with Regulation 14 (11).

Judgment: Substantially Compliant

## Regulation 15: Special practices

St Luke's Radiation Oncology Network at St James Hospital had mechanisms in place to ensure special attention was given to optimising high dose medical exposures. This included the careful selection of immobilisation equipment and using methods and technology to reduce organ motion where necessary, for example, motion due to respiration. Specific protocols were designed and implemented for higher risk treatment procedures and carefully selected parameters were used when planning treatments to ensure the doses to normal tissue is kept as low as possible, for example, for paediatric patients or for patients undergoing complex radiation treatment.

Inspectors were also informed of an initiative in place to identify which patients benefit from having an additional PSQA check completed in advance of their first treatment. This was viewed as an example of good practice which prevented delays if a PSQA was not necessary.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

In line with the regulations, both radiation oncologists and radiation therapists, acting as practitioners, took responsibility for inquiring about and recording pregnancy status. From samples of records reviewed on the day of inspection, inspectors saw evidence that pregnancy status was checked at the initial referral

stage, before the pre-treatment planning scan and before the first radiation treatment.

On the day of inspection, notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were available in public places such as waiting areas.

Judgment: Compliant

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

From reviewing documents in advance of this inspection, inspectors were aware of the measures implemented by the undertaking to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at a number of committee meetings including locally, at the local ILC, and across the network at the NRILC. Incidents were also discussed at the RSC meetings.

The *'Network Radiation Incident Learning Committee Annual Report 2020'* was provided in advance of this inspection and the draft report for 2021 was also made available to inspectors. These reports identified that the number of radiation safety incidents reported in 2021 had reduced, when compared with figures from 2020. This decrease was attributed to the cyber-attach in May 2021 which prevented access to the incident reporting system. Staff identified the alternative reporting arrangements put in place during this time, but asserted that some under-reporting of minor issues may have occurred.

Staff also provided information on a quality improvement initiative that had been implemented to reduce issues relating to routine checks of patients' charts. This initiative used the functionality available in the information system to create an alert when a chart check was due. This resulted in eliminating the issue of patients completing treatment without having their chart undergo regular and routine checks.

From the evidence gathered during this inspection, inspectors were assured of the measures taken within this facility to minimise the probability of accidental or unintended exposures. Oversight from senior management within this hospital was evident and all reportable significant events were reported to HIQA in a timely manner.

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 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 | 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 | Compliant |
| Regulation 13: Procedures | Substantially Compliant |
| Regulation 14: Equipment | Substantially Compliant |
| Regulation 15: Special practices | Compliant |
| Regulation 16: Special protection during pregnancy and breastfeeding | Compliant |
| Regulation 17: Accidental and unintended exposures and significant events | Compliant |

# Compliance Plan for St Luke's Radiation Oncology Network at St James Hospital OSV-0007880

## Inspection ID: MON-0032796

## Date of inspection: 20/04/2022

**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 | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 6: Undertaking: Procedure RS P 011 (justification and optimisation) has been amended to reflect that Radiation Therapists are acting in practitioner roles (with the associated responsibilities) for the delivery of daily radiation treatments. This document will be peer reviewed and approved by the Radiation Safety Committee at the next meeting. The document will be live and staff briefed by the end of 2022.<br><br>RS P 01 Radiation Safety Procedures will be updated to include reference to the responsibilities of Medical Physics Experts (MPE). This updated document will be peer reviewed, live and staff briefed by the end of 2022<br><br>The draft document with the working title of the Role of MPE in Treatment Planning will be peer reviewed, live and staff briefed by the end of 2022 | |
| Regulation 13: Procedures | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 13: Procedures: Similar to inspection MON-0031744's report from SLRON Rathgar, this report noted that a number of clinical guidelines were past their revision dates. The Quality Assurance in Radiotherapy (QART) Committee are aware of this and the documents have been circulated to lead authors for revision. SLRON aim to have these updated and peer reviewed by the end of 2022.<br><br>A Clinical Specialist Radiation Therapist with a special interest in QART audit has been appointed in March 2022. Her role includes developing a QART audit schedule that will include radiation safety audits by the end of 2022. | |

| | |
|---|---|
| Regulation 14: Equipment | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 14: Equipment:
The report identified a need for the improvement of the recording of actions required following repairs and QC tests performed on radiotherapy equipment. The current use of log books that occurs in the St. Luke's Hospital Rathgar is to be extended to the St. James and Beaumont centres. Individual QA log books for each linear accelerator will be accessible through the Oncology Information System. A summary of work performed on the equipment will be logged identifying closing off of previous issues and any remaining work required after repairs and routine QC tests. The staff member performing the work will sign off on the entries. These log books will be referenced during the monthly QA review to provide the chain of events and those responsible for actions required. The Quality Assurance Programme Guidelines for Radiotherapy Equipment document will be updated to reflect the new practice. SLRON aims to have this process operational by end of 2022.

## 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 | 31/12/2022 |
| Regulation 13(1) | An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for | Substantially Compliant | Yellow | 31/12/2022 |

| | | | | |
|---|---|---|---|---|
| | each type of equipment for relevant categories of patients. | | | |
| Regulation 14(11) | An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request. | Not Compliant | Orange | 31/12/2022 |