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 Beaumont Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Beaumont Hospital, Hospital Road, Beaumont, Dublin 9
Type of inspection:	Announced
Date of inspection:	11 July 2023
Medical Radiological Installation Service ID:	OSV-0007879
Fieldwork ID:	MON-0040435

About the medical radiological installation:

St Luke's began caring for cancer patients in Ireland over 65 years ago. The St. Luke's Radiation Oncology Network (SLRON) was established over a decade ago and expanded its service in 2010 when it 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 Chief Executive Officer (CEO).

SLRON has 14 high specification linear accelerators (the main equipment used to treat cancer patients with external beam radiotherapy) with 4 located at the Beaumont Centre. SLRON provides 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) making SLRON one of the largest radiation centres in Europe. Patients also benefit from access to clinical trials for multiple tumour types.

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
Tuesday 11 July 2023	09:30hrs to 17:10hrs	Kirsten O'Brien	Lead
Tuesday 11 July 2023	09:30hrs to 17:10hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

An inspection of St Luke's Radiation Oncology Network (SLRON) at Beaumont Hospital was carried out on the 11 July 2023 to assess compliance with the regulations. Inspectors spoke with staff and visited a CT unit and one of the external beam radiotherapy treatment units on the day of inspection.

SLRON at Beaumont Hospital is one of three facilities that make up the SLRON. These three facilities share an overarching governance and management structure for the radiation protection of service users. On the day of inspection, appropriate governance and management arrangements were in place to provide oversight of medical exposures to ionising radiation in SLRON at Beaumont Hospital.

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 only taken by personnel entitled to act as practitioners as per the regulations. However, documentation outlining the specific details of practitioners should be reviewed to ensure that it aligns with day-to-day practice. In particular, SLRON should provide further clarify in the documentation about the allocation of practitioner roles at the facility for justification at all points along the patient's pathway.

From the evidence gathered as part of this inspection, inspectors were assured that the level of involvement of medical physics expertise was proportionate to the level of risk at SLRON at Beaumont Hospital. Inspectors found that MPEs (medical physics experts) took responsibility for the dosimetry of patients undergoing medical exposures at the facility, and contributed to optimisation, quality assurance (QA) of medical radiological equipment, the analysis of events involving, or potentially involving medical exposures and training of practitioners and other staff where relevant.

Notwithstanding the areas for improvement identified on the day of inspection to come into full compliance with the regulations, inspectors were satisfied that governance and oversight arrangements were in place to ensure the safe delivery of medical exposures at this facility.

Regulation 4: Referrers

On the day of inspection, inspectors were satisfied that medical exposures were only carried out when referred by an individual entitled to refer as per the regulations. From the documentation reviewed as part of the inspection, and from speaking with staff and reviewing a sample of patient records, inspectors found that only

consultant radiation oncologists and senior non-consultant hospital doctors (NCHDs), who were either specialist registrars (NCHDs that are part of a training programme in radiation oncology) or registrars working in the SLRON, referred patients for radiotherapy exposures at SLRON at Beaumont Hospital.

Judgment: Compliant

Regulation 5: Practitioners

From evidence reviewed over the course of the inspection, inspectors found that clinical responsibility for individual medical exposures carried out at SLRON at Beaumont Hospital was only taken by individuals entitled to act as practitioners as defined in Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Over the course of the inspection, a sample of records and documentation was reviewed by inspectors who also spoke with staff and management working at SLRON at Beaumont Hospital. Inspectors were assured that appropriate governance and management arrangements were in place, and the allocation of responsibility for the management and oversight of the delivery of medical exposures was clearly outlined in the diagram illustrating the overarching organisational structures and committees (organogram). However, while what was described to inspectors by management aligned with the organogram, the terms of reference of the Radiation Safety Committee (RSC) should be reviewed to ensure clarity and remove ambiguity relating to the RSC reporting structures and membership.

On the day of inspection, the network director was the designated manager for all facilities that formed the SLRON. The RSC reported to the Quality, Patient Safety and Risk Management (QPSRM) Committee who in turn reported to the designated manager and the Network Executive Management team. Additionally, a local Incident Learning Committee (ILC) was in place in SLRON at Beaumont Hospital and this local ILC reported to the Network Radiotherapy Incident Learning (NRIL) Committee. Inspectors were informed that the local ILCs at the other SLRON facilities also reported to the NRIL. The NRIL Committee then reported to the RSC. The RSC also had a specific linked reporting relationship with the Quality and Risk Team (QART).

Inspectors reviewed documentation in advance of this inspection, including *RS P 11 Optimisation and Justification procedure for Ionising Radiation Medical Exposures* and *RS P 12 Procedure for Practitioners of Ionising Radiation Medical Exposures*

which detailed who was entitled to act as practitioner for medical exposures and who was delegated the practical aspects in this facility. This documentation also included details about how the practitioner responsibilities along the patient pathway were allocated to different personnel. Management communicated to inspectors on the day of inspection that only specific individuals were allocated a practitioner role and could take clinical responsibility for different aspects of medical exposures along each patient's pathway. However, from a review of patient records and speaking with staff, inspectors found evidence that individuals, although entitled to act as a practitioner under Regulation 5 but not allocated practitioner responsibilities at SLRON, had taken clinical responsibility for justifying the CT planning scan in advance. Inspectors were however satisfied from the evidence found on the day of inspection that all treatment exposures were justified by an individual allocated practitioner responsibility at SLRON.

Following this inspection the process and documentation for justification in advance should be reviewed to ensure the clear allocation of responsibility for the radiation protection of service users undergoing medical exposures. Additionally, clearly documenting practitioner roles would reduce any ambiguity about the responsibilities of different individuals with regards to the various aspects of clinical responsibility they can undertake.

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 an individual entitled to act as a practitioner as defined in Regulation 5. Radiation oncologists and specialist registrars were deemed practitioners with radiation therapists also allocated responsibility as practitioners at specific points along the patient pathway.

However, while an individual entitled to act as a referrer and a practitioner, as defined by the regulations, was found to be involved in individual justification of medical exposures, inspectors noted that in some instances, the individual acting as the practitioner was not allocated responsibility at SLRON to take clinical responsibility particularly with regards to the CT planning component of a patient's pathway. However, inspectors were assured that justification in advance was considered by other individuals allocated practitioner responsibility before any medical exposure took place. Management at SLRON at Beaumont Hospital must review their processes and documented allocations of responsibility to ensure that day-to-day practice is aligned with documentation outlining roles and responsibilities. As described earlier under Regulation 6, this would help to ensure full clarity for all personnel on their specific roles and responsibilities.

Inspectors also reviewed documentation and spoke with staff and found that the

practitioner and an MPE were involved in the optimisation process as required by the regulations.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors reviewed documentation and records and spoke with staff and management and found that arrangements were in place to ensure the continuity of medical physics expertise at SLRON at Beaumont Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors found that MPEs were involved in dosimetry, optimisation, and in quality assurance (QA) at the facility. Inspectors also found that MPEs contributed to the analysis of events involving, or potentially involving, accidental or unintended medical exposures. Other responsibilities held by MPEs were also communicated to inspectors, and included for example, the MPEs role in training and in the selection of equipment.

Judgment: Compliant

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

On the day of inspection, inspectors found that MPEs involvement in medical radiological procedures was in line with the level of radiological risk at SLRON at Beaumont Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection, inspectors found evidence that SLRON at Beaumont Hospital had appropriate systems in place to ensure the safe delivery of medical exposures to service users. This included evidence of appropriate processes to

ensure the optimisation of radiotherapy procedures and medical radiological equipment was kept under strict surveillance. Inspectors also found that an enquiry of pregnancy status had been made where relevant, by the appropriate personnel.

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. Inspectors also found evidence of a shared learning and multidisciplinary approach to reporting and analysing accidental and unintended exposures was in place across the SLRON facilities and this was identified as an area of good practice.

While inspectors found that all medical exposures were justified in advance by an individual entitled to act as a practitioner as defined in Regulation 5, in some instances an individual who had not been allocated practitioner responsibility locally at SLRON was found to justify CT planning scans in advance. As discussed in Regulation 6, documentation and processes for justification in advance should be reviewed and updated to ensure the clear allocation of clinical responsibility along the patient's pathway.

Overall and notwithstanding the area for improvement to come into full compliance with the regulations, inspectors found that SLRON at Beaumont Hospital had a good level of compliance with the regulations to ensure the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

Inspectors reviewed documentation, a sample of patient records and spoke with staff about the processes in place at SLRON at Beaumont Hospital for the justification of medical exposures. All referrals were in writing using an electronic treatment referral form. The roles and responsibilities of individuals in the justification of each exposure to ionising radiation along the patient's pathway was contained in *RS P 11 Optimisation and Justification procedure for Ionising Radiation Medical Exposures*. Inspectors spoke with staff who explained the process of providing information to patients about the benefits and risks associated with medical exposures. On the day of inspection inspectors also reviewed a sample of consent forms completed by patients.

However, from a review of patient records inspectors found one example where clinical responsibility for the justification in advance for a patient's planning CT was taken by an individual who, although entitled to act as a practitioner as defined in Regulation 5, was not allocated practitioner responsibility for this task locally at SLRON at Beaumont Hospital. Additionally, inspectors spoke with staff working at a CT planning unit about their processes in advance of conducting a CT planning scan. From this discussion inspectors were assured that those conducting the CT scan, who were allocated practitioner responsibility, also assessed the request to ensure it was justified before proceeding, although these checks were not recorded as part of the patient records. Inspectors were however satisfied that a person allocated

practitioner responsibility did justify treatment exposures in advance. Clarity on who has been allocated clinical responsibility and the point or different points in the pathway where justification for a CT planning scan occurs is required, including who documents this justification in advance.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff and management about how medical exposures at SLRON at Beaumont Hospital were optimised. In particular, inspectors found that a document titled *RS P 11 Optimisation and Justification procedure for Ionising Radiation Medical Exposures* outlined who was responsible and involved in optimisation at the different stages of a patient's pathway. This document detailed the types of actions to be considered such as requesting additional procedures or additional modifications**,** or applying constraints or changes to the treatment prescription to facilitate further optimisation of the patients' treatment plans.

On the day of inspection, inspectors were informed about the steps taken to ensure the dose from medical exposures at the pre-treatment planning stage and during treatment were optimised. Staff detailed the specific software used in the CT scanner to optimise the dose during the pre-treatment scanning stage and how protocols were developed and reviewed to set scan limits appropriately. Inspectors were also informed that all treatment plans were individually planned and specific internationally recognised constraints were applied to keep doses to non-target areas as low as achievable.

Staff communicated to inspectors how treatments were individually planned and optimised. Patient Specific Quality Assurance (PSQA) had also been developed and implemented to provide additional assurances that doses to non-target areas were kept as low as achievable and that doses to the planned area was as prescribed.

Judgment: Compliant

Regulation 14: Equipment

An inventory of all medical radiological equipment at the SLRON at Beaumont Hospital was provided to HIQA in advance of this inspection. Inspectors reviewed documentation and spoke with staff about the involvement of the multidisciplinary team in carrying out the QA programme at the facility. Inspectors also reviewed records of QA with members of the physics and clinical engineering team, including

the mechanisms for recording equipment downtime and handover procedures.

Overall, inspectors were satisfied that staff and management at the facility had ensured that a QA programme had been implemented to ensure that all medical radiological equipment was kept under strict surveillance.

Judgment: Compliant

Regulation 15: Special practices

SLRON at Beaumont Hospital had mechanisms in place to ensure special attention was given to optimising all high dose medical exposures for radiotherapy. In addition, inspectors spoke with staff who described measures in place such as the use of specialised equipment to enhance precision and accuracy when delivering very high dose radiation to very small target areas. Inspectors were also informed about initiatives being developed to further enhance patient set-up and comfort when treating small areas requiring immobilisation devices.

Staff communicated to inspectors the measures used to confirm bladder dimensions before commencing treatment for some patient groups, such as those undergoing prostate cancer treatment. For example, ultrasound was used in advance of some treatments to ensure optimum treatment delivery. Using non-ionising imaging techniques, where appropriate, was viewed by inspectors as an example of good practice.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From speaking with staff and reviewing documentation and records, inspectors found that both radiation oncologists and radiation therapists, acting as practitioners, took responsibility for inquiring about and recording pregnancy status. Pregnancy status was checked at the initial patient referral stage and before the CT planning scan and a record of this inquiry was documented and recorded in the patient's electronic file. Prior to the patient's first radiation treatment, pregnancy status was reviewed by a radiation therapist to ensure that there had not been any changes since the last inquiry.

Inspectors observed that posters were available in public places such as waiting areas for the CT planning scan and treatment units. These posters were used to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

On the day of inspection, inspectors reviewed documentation and records and spoke with staff about the systems in place for recording and analysing events involving, or potentially involving, accidental and unintended exposures. Staff and management described to inspectors the electronic reporting pathway used for reporting incidents which included an automated notification to the radiation therapy services manager.

Inspectors were assured that SLRON had effective processes in place to ensure that management at SLRON at Beaumont Hospital had oversight of accidental and unintended exposures. Each facility had a local ILC which reported to a NRIL committee which encompassed all three sites in the SLRON. The ILC met fortnightly and included the radiation therapy services manager, an MPE and a consultant radiation oncologist.

Inspectors also reviewed the *Network Radiation Incident Learning Committee Annual Report 2022* which included examples of how accidental or unintended exposures and potential accidental or unintended exposures (near misses) were analysed and learning incorporated across all SLRON facilities. This multidisciplinary and shared learning approach was noted as an example of good practice which contributed to minimising the likelihood of incidents for patients undergoing medical exposures in this facility.

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	Substantially 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	Substantially Compliant
Regulation 9: Optimisation	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 St Luke's Radiation Oncology Network at Beaumont Hospital OSV-0007879

Inspection ID: MON-0040435

Date of inspection: 11/07/2023

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The Radiation Safety Committee (RSC) terms of reference will be reviewed and approved by the RSC to ensure it is aligned with overarching Network organograms by the end of 2023. The RSC will review who are practitioners (with the associated responsibilities) for the delivery of radiotherapy and ensure both procedures RS P 011 (justification and optimisation) and RS P 012 (practitioners) are updated accordingly. 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 2023.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: The RSC will review who are practitioners (with the associated responsibilities) for the delivery of radiotherapy (CT and treatment) and ensure that RS P 012 (practitioners) is updated accordingly. 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 2023.	
Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: The RSC will review who are practitioners (with the associated responsibilities) for the delivery of radiotherapy (CT and treatment) and ensure both procedures RS P 011 (justification and optimisation) and RS P 012 (practitioners) are updated accordingly. 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 2023.	

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	31/12/2023
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	31/12/2023

	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	31/12/2023
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	31/12/2023