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: | St Luke's Radiation Oncology Network, St Luke's Hospital |
| Undertaking Name: | Health Service Executive |
| Address of Ionising Radiation Installation: | Highfield Road, Rathgar, Dublin 6 |
| Type of inspection: | Announced |
| Date of inspection: | 29 April 2025 |
| Medical Radiological Installation Service ID: | OSV-0007377 |
| Fieldwork ID: | MON-0041000 |

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

It is over 65 years since St. Luke's first opened its doors to care 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 2010 and opened two radiation centres on the campus of Beaumont and St. James's Hospital. These two centres along with St. Luke's Hospital, Rathgar, operate as a single network with a single executive management team directly reporting to the HSE Dublin and Midlands regional executive officer.

We have high specification linear accelerators available to us in SLRON. Six Clinac iX Linear Accelerators with integrated 3D IGRT capability, 120-leaf high resolution multi leaf collimators and rapidarc, two trilogy multipurpose linear accelerators with stereotactic radiosurgery capability in the Beaumont centre and two truebeam varian machines in Rathgar. SLRON currently provides public radiotherapy cancer services for Dublin along with a range of specialist national radiotherapy services. Approximately 55% of Irish radiotherapy patients are treated in Dublin and 75% of these are treated in SLRON. We treat 5,000 new cases per year (80,000 linac radiation fractions) on 14 linear accelerators making SLRON one of the largest radiation centres in Europe. Patients also benefit from access to clinical trials across multiple tumour types. In addition to external beam radiotherapy St. Luke's Hospital provides brachytherapy, radiology and both therapeutic and diagnostic nuclear medicine.

## How we inspect

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

As part of our inspection, where possible, we:

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

## About the inspection report

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

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

**1. Governance and management arrangements for medical exposures:**

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

**2. Safe delivery of medical exposures:**

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

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

**This inspection was carried out during the following times:**

| Date | Times of Inspection | Inspector | Role |
|---|---|---|---|
| Tuesday 29 April 2025 | 09:15hrs to 15:45hrs | Emma O'Brien | Lead |
| Tuesday 29 April 2025 | 09:15hrs to 15:45hrs | Margaret Keaveney | Support |

## Governance and management arrangements for medical exposures

An inspection of the radiotherapy and radiology departments at St Luke's Radiation Oncology Network (SLRON), St Luke's Hospital was completed on the 29 April 2025 to follow up on the compliance plan actions from the previous inspection in October 2021 and to also assess the undertaking's ongoing compliance with the regulations. As part of this inspection, inspectors reviewed documentation, spoke with staff and management teams, and visited the clinical areas in the radiotherapy and radiology departments.

Since the previous inspection of October 2021, inspectors saw that a number of radiation safety documents had been updated to reflect day-to-day practice in the facility. However, during this inspection of April 2025, inspectors noted the undertaking is required to take further action to ensure that all allocated radiation protection roles and responsibilities are appropriately outlined in relevant documentation. This is further discussed under Regulation 6 within this report. In addition, similar to the previous inspection, inspectors found that a number of clinical guidelines and radiation safety policies and procedures for both the radiology and radiotherapy departments had not been reviewed by their review date.

From a review of documents and from speaking with staff on the day of the inspection, inspectors were satisfied that there were appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day-to-day operations in the facility up to the undertaking.

Inspectors were satisfied that appropriate persons, as per the regulations, were involved in referring for medical exposures completed in both the radiotherapy and radiology services. Inspectors were also satisfied that only those entitled to act as practitioner, as defined in Regulation 5, were taking clinical responsibility for medical exposures. While inspectors were satisfied that, in practice, roles and responsibilities relating to radiation protection had been allocated within the radiotherapy and radiology services, some gaps were identified in documentation regarding this allocation of responsibility that should be addressed by the undertaking. This is further discussed under Regulation 6 within this report.

From documentation reviewed and discussions with staff, inspectors found that there was a process in place to review and approve new practices that require generic justification by HIQA in SLRON, St Luke's Hospital. Inspectors noted that there was a proactive approach taken by the SLRON in communicating with HIQA on queries relating to new practices in radiotherapy which was identified as an area of good practice in the service. Inspectors also noted that an application for generic justification of a new radiotherapy practice had previously been made by the SLRON in November 2023 which was generically justified by HIQA.

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

Overall, despite the areas noted for improvement to meet regulatory compliance, inspectors were satisfied that the undertaking had implemented and maintained effective governance and management arrangements for the radiation protection of service users at SLRON, St Luke's Hospital.

## Regulation 4: Referrers

Inspectors found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at SLRON, St Luke's Hospital. In the radiotherapy department, referrals were only accepted from appropriately registered medical practitioners, and from radiation therapists for image guided radiation therapy (IGRT) exposures. While in the radiology department, referrals were only accepted from appropriately registered medical practitioners, and from radiographers for adapted referrals.

Judgment: Compliant

## Regulation 5: Practitioners

Following the review of radiation safety procedure documentation and a sample of referrals for medical radiological procedures, and from speaking with staff and management, the inspectors were satisfied that the undertaking had systems in place to ensure that only appropriate individuals as per Regulation 5 acted as practitioners in both the radiology and radiotherapy departments at SLRON, St Luke's Hospital.

Judgment: Compliant

## Regulation 6: Undertaking

Inspectors spoke with staff and management working in the radiotherapy and radiology services at SLRON, St Luke's Hospital, and reviewed documentation and other records to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures.

Documentation reviewed by the inspectors prior to and during the inspection demonstrated that there were clear lines of communication within the clinical governance and management structures in the hospital. These documented arrangements aligned with those described by staff to the inspectors.

On the day of inspection, the network director was the designated manager for all medical radiological facilities that form the SLRON. A chart detailing the radiation safety management structure was provided in advance of the inspection and inspectors noted that a local radiotherapy incident learning committee (ILC) was in place in SLRON, St Luke's Hospital and that this local ILC reported to the network radiotherapy incident learning committee (NRILC). Inspectors were informed that the local radiotherapy ILCs at the other SLRON facilities also reported to the NRILC. Inspectors were also informed by staff that incidents that occurred in the radiology department were discussed separately at the radiology management group which reported to the NRILC. The NRILC subsequently reported to the radiation safety committee (RSC). The RSC provided oversight for radiation protection in the service and met a minimum of three times per year to discuss items such as radiation safety incidents, radiation protection training, equipment quality assurance (QA) and generic justification of new practices. The RSC reported to the quality, patient safety and risk management (QPSRM) committee which, in turn, reported to the designated manager and the network executive management team.

Inspectors were satisfied that the undertaking had established governance and management arrangements to provide oversight of the radiation protection measures in place in both the radiotherapy and radiology services at SLRON, St Luke's Hospital. However, despite these arrangements, inspectors noted that action was required to ensure that all allocated roles and responsibilities on radiation protection are clearly documented in the relevant radiation safety policies and procedures. For example;

- During discussions with staff and management regarding the fluoroscopy service in theatre, inspectors were informed that, in addition to the anaesthetist, a radiographer was present for all fluoroscopy exposures. Inspectors also noted that radiographers had been allocated the role of practitioner in this service in the *Procedure for Practitioners of Ionising Radiation Medical Exposures* document. However, their specific responsibilities regarding the radiation protection of service users during fluoroscopy procedures were not clearly allocated in documentation viewed by the inspectors.
- The document titled *Referral Procedure for Ionising Radiation Medical Exposure* allocated responsibility for referrals for general X-ray procedures to medical professionals and to advanced nurse practitioners. On the day of the inspection inspectors saw evidence of referrals from medical professionals in line with this allocation, however, inspectors were informed that in practice referrals were not received from advanced nurse practitioners.
- Inspectors were informed by staff that there were specific circumstances when radiographers in general X-ray could adapt referrals, for example, if the left side was requested incorrectly for an image required on the right side on the primary referral from the medical practitioner. However, this allocation of

responsibility to radiographers was not outlined in any of the radiation safety documentation viewed by inspectors.
- Action was required to ensure that the roles and responsibilities of staff in the justification of therapeutic nuclear medicine procedures were clearly allocated in radiation safety policies and procedures, so that appropriate staff are guided and supported in this role.

The undertaking should ensure that roles and responsibilities of staff are clearly allocated and that radiation safety documentation aligns with day-to-day practice in all modalities to assist staff in carrying out their roles.

During the previous inspection in October 2021 inspectors found that a number of clinical guidelines were passed their review date. Inspectors acknowledged that the undertaking had made good improvements since that inspection in reviewing and updating radiation safety documentation, however, further improvements are required to ensure that all documents are reviewed and updated by their review date. From a review of minutes from a recent QPSRM meeting inspectors saw evidence that the issue with documents not being reviewed and updated on time had been escalated appropriately, and were satisfied that the executive management team was taking action to address this gap.

Notwithstanding the gaps in compliance with Regulation 6, identified on the day of inspection, inspectors were satisfied that service users were receiving a safe service at SLRON, St Luke's Hospital.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

Inspectors noted that all medical exposures performed in both the radiology and radiotherapy departments took place under the clinical responsibility of a practitioner, as defined in the regulations.

Inspectors were assured following a review of radiation safety documentation and from discussions with staff that the presence of radiographers was retained in areas where medical exposures were conducted outside of the radiology department, for example, for fluoroscopy procedures performed in theatre. In the absence of training requirements prescribed by a training body approved by the Medical Council, as per Regulation 22, this was viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation.

Practitioners and MPEs were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to the inspectors by staff and management. All evidence supplied satisfied the inspectors that SLRON, St Luke's Hospital had the necessary arrangements in place to ensure continuity of MPE expertise in both the radiotherapy and radiology departments.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of the MPEs engaged by the undertaking to provide specialist advice, as appropriate, on matters relating to radiation physics which met the requirements of Regulation 20(1). Evidence viewed in documentation, and discussions with the undertaking's management team and the medical physicists, demonstrated that the MPEs fulfilled a range of responsibilities as per Regulation 20(2) relevant to the service. For example, inspectors noted that the MPEs contributed to the optimisation of the radiation protection of patients and were responsible for dosimetry and advising on the dose calculations for radiation incidents in both departments. They were also involved in the quality assurance and acceptance testing of medical radiological equipment, and in the selection of new equipment, for example, the new general X-ray equipment in the radiology department. A review of RSC meeting minutes showed that there was MPE representation on this committee, and on other departmental committees tasked with the radiation protection of service users.

Judgment: Compliant

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

Inspectors were satisfied that the level of MPE involvement was commensurate with the radiological risk posed by the medical radiological practices, in both the radiology and radiotherapy departments, at SLRON, St Luke's Hospital.

Judgment: Compliant

## Safe Delivery of Medical Exposures

During the course of the inspection, inspectors observed that the undertaking had implemented many effective processes and procedures in both the radiology and the radiotherapy departments to ensure the radiation protection of patients and the safe delivery of medical exposures.

From speaking with staff and a review of practice, inspectors were satisfied that a number of measures were in place in the hospital to ensure that radiation doses to patients were optimised, including the implementation of appropriate equipment QA programmes and the use of site-specific protocols when conducting medical exposures. While inspectors were satisfied that DRLs had been established for all common diagnostic examinations further improvements are required to ensure that local DRLs are reviewed in line with local policy and that, where relevant, national DRLs are available to staff. This is further discussed under Regulation 11.

During the previous inspection in October 2021 inspectors found that pregnancy enquires were being completed by staff members that were not recognised as practitioners in the service. During this recent inspection inspectors were satisfied that the undertaking had implemented effective actions, as detailed in the previous compliance plan, in response to this finding and inspectors saw numerous examples of pregnancy enquiries being made and recorded by practitioners in patient records viewed in both the radiotherapy and radiology departments on the day of the inspection.

From speaking with staff and a review of a sample of referrals in both the radiotherapy and radiology services, inspectors were assured that all referrals for medical exposures were in writing, contained the reason for the request and were accompanied by sufficient medical data. From this review, inspectors were also satisfied that procedures were justified in advance, by a person entitled to take clinical responsibility for justification. Inspectors were also satisfied that there was a good culture and system in place for the record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures as required by Regulation 17.

Inspectors were satisfied that written protocols were available for all standard radiological procedures and that referral guidelines were available to staff. However, inspectors noted that action was required by the undertaking to achieve full compliance with Regulation 13(4), as the clinical audit programme in place in the hospital on the day of the inspection was not fully aligned with HIQA's national procedures. This is further discussed under Regulation 13 below.

Overall, despite some gaps in compliance, inspectors were satisfied that the undertaking had good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users at SLRON, St Luke's Hospital.

## Regulation 8: Justification of medical exposures

On the day of the inspection, inspectors reviewed a sample of referrals in both the radiology and radiotherapy departments and saw that they were available in writing and stated the reason for the request. From a review of this sample, inspectors were also assured that sufficient medical data, including diagnostic imaging and histology reports, were available to enable the practitioner to adequately consider if the referral was justified.

In the radiotherapy department inspectors were informed that, during the initial consultation with the radiation oncologist, enquiries were made to determine if a patient had completed previous radiotherapy. Where relevant, this treatment information was obtained and considered in the treatment planning process as a key radiation protection measure. Inspectors were also informed that new patient consent forms were being implemented in the radiotherapy department. Inspectors were informed that these new forms were site specific and the aim of their implementation was to ensure that patients are fully informed when consenting to a course of radiotherapy. This initiative was identified by inspectors as an area of good radiation protection within the service.

Prior to the inspection, inspectors reviewed the *Optimisation and Justification procedure for Ionising Radiation Medical Exposures* document which outlined the roles and responsibilities of staff involved in the justification process along the different stages of the radiotherapy pathway. Inspectors were informed that the radiation oncologist justifies the patient's radiotherapy CT planning scan by electronically signing a treatment request form. At the CT planning stage radiation therapists carry out pre-scanning checks to ensure that the exposure is justified. By reviewing and electronically approving the final treatment plan, the radiation oncologist justifies in advance the treatment course, including the treatment prescription and patient position verification imaging. In advance of delivering daily radiotherapy medical exposures, radiation therapists complete a series of checks such as reading updated medical notes and checking the patient's treatment position with verification imaging. Again, these checks are electronically documented on a daily treatment record with the initials of the two radiation therapists who have responsibility for justifying the procedure.

In the radiology department inspectors found evidence that all medical radiological procedures were justified in advance by an individual entitled to act as a practitioner. As part of the inspection a sample of patient records were reviewed and inspectors found that a record of this justification was available for review. Inspectors were also assured that SLRON, St Luke's Hospital had measures in place to provide patients attending the radiology department with adequate information about the risks and benefits, relevant to the level of radiological risk involved in the procedure, through the use of posters and information leaflets in the waiting areas.

While meeting the requirements of this regulation the undertaking should ensure that policies and procedures are updated to include the justification process for each

modality to provide clarity for all staff involved in the justification process, as discussed under Regulation 6.

Judgment: Compliant

## Regulation 9: Optimisation

From discussions with staff and a review of documents, inspectors were satisfied that the undertaking had implemented a number of measures to ensure that all doses due to medical exposures are kept as low as reasonably achievable in both the radiotherapy and radiology services in SLRON, St Luke's Hospital. Inspectors found that there was good multidisciplinary team involvement in optimisation in both departments which included relevant practitioners and MPEs.

In the radiotherapy department, staff in the CT planning unit described how they optimised each CT exposure through the use of immobilisation equipment, and specific scanning protocols for each treatment site. As an additional optimisation measure, the undertaking could consider the development of DRLs for CT planning scans in the radiotherapy department.

Inspectors spoke with staff in the radiotherapy planning department who explained that all treatments were individually planned to deliver the prescription dose to the treatment area and to keep doses to surrounding normal tissues as low as possible. Staff explained to inspectors that prior to treatment commencing QA checks were completed on all radiotherapy plans to provide additional assurances that doses to the treatment area would be delivered as prescribed. The processes used to ensure medical exposures are verified before proceeding with treatment were outlined in documentation reviewed by inspectors, with details of the type and frequency of imaging used to guide and verify treatment for each treatment site outlined in site specific imaging policies.

In the nuclear medicine department inspectors viewed a bespoke leaflet that provided patients undergoing radionuclide treatment with information on the risks of ionising radiation and appropriate written instructions on restricting doses to persons in contact with the patient as far as reasonably achievable, meeting the requirements of Regulation 9(7) and 9(8).

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

As part of this inspection inspectors viewed the document titled *Procedure for review of diagnostic reference levels in the Diagnostic Imaging and Nuclear Medicine Departments*. This local policy detailed individuals with responsibility for establishing diagnostic reference levels (DRLs) at the hospital, the procedure for reviewing facility DRLs annually and the process to follow when a DRL level consistently exceeded or was significantly lower than national DRLs.

Inspectors found that DRLs for common medical radiological procedures conducted in the radiology department were established and used at SLRON, St Luke's Hospital, and staff described to inspectors how facility DRLs were applied in practice. However, inspectors identified that some local facility DRLs were not reviewed on an annual basis, as set out in the local policy. This was noted in the nuclear medicine department, where the DRLs on display and available to staff had been established in June 2022. While inspectors saw that a review of the DRL data for this modality had recently been completed and was due to be approved at an upcoming RSC meeting, there was no evidence that DRLs for nuclear medicine had been reviewed between June 2022 and April 2025. Inspectors also noted that national DRLs for nuclear medicine procedures, which were published by HIQA in November 2023, were not readily available and used by staff in the clinical area.

In advance of the inspection, inspectors were provided with recently reviewed general X-ray DRLs for the two most frequently performed X-ray procedures in the radiology department, and noted that both were below national DRLs. On the day of the inspection, inspectors were informed that at times other X-ray procedures were performed in the department, but due to the low number of these procedures local DRL data could not be established. Inspectors noted that national DRLs for these infrequently performed procedures were not readily available to staff in the general X-ray area. The undertaking should ensure that practitioners have access to national DRLs in order to facilitate patient dose optimisation.

In order to meet compliance with Regulation 11 the hospital should ensure that all DRLs are reviewed regularly having regard for national DRLs where available and the undertaking should ensure that staff have access to the most up to date local and national DRLs for all procedures to assist them in optimising medical exposures.

Judgment: Substantially Compliant

## Regulation 13: Procedures

On the day of the inspection, inspectors reviewed a number of written protocols for the range of medical exposures completed in the radiotherapy and radiology departments as required by Regulation 13(1). These protocols were specific to the treatment sites commonly treated in the service. While meeting the requirements of Regulation 13(1) the undertaking must ensure that all written protocols are regularly

reviewed and updated, if required, to ensure that staff have access to the most up-to-date information, as discussed under Regulation 6.

In the radiotherapy department, inspectors were informed that when a patient completed a course of radiotherapy treatment a letter was dictated by the radiation oncologist which included information on the treatment dose received by the patient. In the radiology department inspectors reviewed a sample of reports for general X-ray, CT, nuclear medicine and fluoroscopy procedures and found that information relating to the patient exposure formed part of the report for each modality, meeting the requirements of Regulation 13(2).

Inspectors were satisfied that referral guidelines for medical imaging were available to referrers in both departments, as required under Regulation 13(3).

Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's *National Procedures for Clinical Audit of Radiological Procedures involving medical exposure to ionising radiation*, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). On the day of the inspection, inspectors saw evidence that clinical audits were being completed in both the radiotherapy and radiology departments, however, the approach to clinical audit in SLRON, St Luke's Hospital did not align with the national procedures. Inspectors were informed that the position of clinical audit clinical specialist had recently been filled following a protracted period of time, which had affected the hospital's ability to align their approach to clinical audit with the national procedures. Inspectors saw evidence that clinical audit documentation, aligned with the national procedures, had been drafted and were informed by staff that the implementation of a revised clinical audit programme was imminent.

In order to come fully into compliance with Regulation 13, SLRON, St Luke's Hospital must ensure that a clinical audit strategy for medical radiological procedures is implemented in line with the requirements of the national procedures published by HIQA.

Judgment: Substantially Compliant

## Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at SLRON, St Luke's Hospital was provided to HIQA in advance of this inspection. Inspectors noted that some of the equipment in clinical use was past the nominal replacement date. However, inspectors were assured that, while issues with ageing equipment and down-time were ongoing, all equipment was subject to regular performance checks and QA testing, and was deemed to be performing within tolerance and fit for clinical use. Inspectors were also provided with evidence that the ageing equipment

was recorded on the hospital's risk register and were informed of equipment replacement plans.

Inspectors were satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1). A number of documents including the *Quality Assurance Programme Guidelines for Radiotherapy Equipment* and the *Procedure for Quality Assurance of General X-ray and Fluoroscopy* outlined the equipment QA programme in place in both the radiotherapy and radiology departments. These documents provided information on the checks involved and the frequency of testing for each piece of equipment and also assigned responsibility to staff for completing these checks. Inspectors viewed a sample of QA records for equipment in the radiotherapy and radiology departments and were satisfied that the QA programmes outlined in documentation were implemented. From discussions with staff and a review of documentation inspectors were assured that there was appropriate oversight of all completed testing.

Judgment: Compliant

## Regulation 15: Special practices

On the day of the inspection, inspectors observed that there was good cooperation and collaboration between the various disciplines involved in the planning and delivery of radiotherapy medical exposures at SLRON, St Luke's Hospital.

Inspectors were informed by staff that site specific tumour groups had been established across the SLRON. Membership of these working groups included radiation oncologists, radiation therapists, members of the physics teams and other relevant disciplines. The purpose of these groups included the review and update of radiotherapy imaging techniques and protocols, the review of any new clinical trials and radiotherapy dose prescriptions relevant to the tumour site, and also the standardisation of treatment planning parameters. Inspectors viewed these specialist working groups as a good example of the effective use of knowledge and expertise of available resources to ensure the radiation protection of service users undergoing radiotherapy.

Inspectors observed that the undertaking had mechanisms in place to ensure special attention was given to optimising radiotherapy treatment plans. This included the careful selection of immobilisation equipment and using methods and technology to reduce organ motion where necessary. Additionally, site specific protocols were designed and implemented for the various stages of the patient's radiotherapy pathway.

Inspectors were also informed of a contouring software system in the treatment planning department, which automatically outlined the structures located close to the treatment target to avoid or limit the dose to these structures. This system was

used to optimise contouring of these structures, and improve radiation protection in treatment planning.

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

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, inspectors observed multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation displayed in public areas of the radiotherapy and radiology departments.

In the radiotherapy department radiation oncologists and radiation therapists had been allocated responsibility for carrying out the inquiry of patients' pregnancy or breastfeeding status, where relevant, in line with the regulations. Inspectors reviewed a sample of records for medical exposures and found that an inquiry regarding the pregnancy status of the patient took place, where relevant, prior to CT scanning and again on the first day of treatment prior to the medical exposure being completed. All enquires were recorded in writing in the patients electronic healthcare chart.

From a sample of records reviewed in the radiology department, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users, where applicable, and recorded the answer to this inquiry in writing.

Judgment: Compliant

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

Inspectors spoke with a number of staff who clearly described the incident reporting processes in the radiotherapy and radiology departments which aligned with the processes outlined in radiation safety documentation. Inspectors noted that both the radiotherapy and radiology departments at SLRON, St Luke’s Hospital had systems in place for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, which were appropriate in

meeting the requirements of Regulation 17(1)(c). Additionally, inspectors were satisfied that there were arrangements in place to notify HIQA of any incidents that meet the threshold of a significant event.

Across the SLRON each radiotherapy department had a local radiation incident learning group which was responsible for the review and management of all reported incidents and near misses. The local radiotherapy incident learning group at SLRON, St Luke's Hospital met monthly and attendees included the radiotherapy services manager, radiation oncologists and members of the physics team. In the radiology department incidents were discussed at the radiology management group meetings which met every two to three months. Membership of this group included the director of radiation services, the director of physics, the MPE and the radiology services manager. Both of these forums reported into the NRILC on a monthly basis. Inspectors also saw evidence that incidents were discussed at the RSC and QPSRM meetings, thereby providing assurance that there is comprehensive oversight of radiation incidents in this facility.

On the day of the inspection inspectors were informed of quality improvement projects that were implemented as a result of the analysis of incident and near miss reporting, in order to minimise the likelihood of incidents re-occuring. For example, in CT planning a number of verbal checks had been implemented to remind staff to check that key radiation protection measures were in place before they completed a medical exposure.

Inspectors also reviewed the *NRILC Annual Report for 2024* which included examples of how accidental or unintended exposures and potential accidental or unintended exposures 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 both in this facility and other facilities within the network.

Judgment: Compliant

## Appendix 1 – Summary table of regulations considered in this report

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

| Regulation Title | Judgment |
|---|---|
| **Governance and management arrangements for medical exposures** | |
| Regulation 4: Referrers | Compliant |
| Regulation 5: Practitioners | Compliant |
| Regulation 6: Undertaking | Substantially Compliant |
| Regulation 10: Responsibilities | Compliant |
| Regulation 19: Recognition of medical physics experts | Compliant |
| Regulation 20: Responsibilities of medical physics experts | Compliant |
| Regulation 21: Involvement of medical physics experts in medical radiological practices | Compliant |
| **Safe Delivery of Medical Exposures** | |
| Regulation 8: Justification of medical exposures | Compliant |
| Regulation 9: Optimisation | Compliant |
| Regulation 11: Diagnostic reference levels | Substantially 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 | Compliant |

# Compliance Plan for St Luke's Radiation Oncology Network, St Luke's Hospital OSV-0007377

## Inspection ID: MON-0041000

## Date of inspection: 29/04/2025

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

This document is divided into two sections:

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

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

A finding of:

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

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

## Section 1

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

**Compliance plan undertaking response:**

| **Regulation Heading** | **Judgment** |
|---|---|
| Regulation 6: Undertaking | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 6: Undertaking:<br>SLRON will review the document 'Procedure for Practitioners of Ionising Radiation Medical Exposures Document' and make amendments as required in relation to the roles and responsibilities during Fluoroscopy procedures.<br>In the interim RS P 01 Radiation Safety Procedures, section 6.26 covers use of the C-Arm in theatre – it includes safety instructions for staff, and optimisation strategies for patient imaging. Additionally SLRON Document DID WI 27 Theatre Fluoroscopy using the C-Arm can be referenced for theatre cases.<br><br>The Radiation Safety Committee will review the role of the Nurse Practitioner within SLRON and adjust 'Referral Procedure for Ionising Radiation Medical Exposures' accordingly. This will be considered in the next meeting due end of September 2025<br><br>SLRON will review all relevant radiation safety documentation to account for Radiographers adapting referrals, and will amend accordingly. These amendments will be considered in the next meeting due end of September 2025<br><br>The roles and responsibilities of staff in the justification of Therapeutic Nuclear Medicine procedures will be added in tabular format to the document RS P 011 'Optimisation and Justification of Ionising Radiation Medical Exposures'. A new table is being drafted which will be reviewed in the September Radiation Safety Committee meeting with a view to the document being re-issued by the end of October 2025.<br>In the interim the current practice will continue whereby justification is by the approval of a radionuclide therapy prescription document by a Consultant Radiation Oncologist and this is valid for 6 months. The availability of this prescription is documented on the triple ID on the day of administration by the person administering the therapy and both documents are scanned to NIMIS as part of the patient record. The Radionuclide therapy prescription is also scanned to the patient record of the administration with the actual activity administered. There is routine audit of Nuclear medicine documentation to ensure compliance. | |

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| Regulation 11: Diagnostic reference levels | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Documents DID F 17 Diagnostic Reference Levels for Diagnostic CT will be updated, as will Document NM F 35 Diagnostic Reference Levels for diagnostic tests carried out in the Nuclear Medicine Department. Where local DRLs do not exist, national DRL's will be made available to staff. These amendments will be considered in the next meeting due end of September 2025

NM F 35 Diagnostic Reference Levels for Nuclear Medicine DRLs has already been updated to include both local and national DRLs (where available), and will work though the standard document approval steps. In the interim, a draft document will be displayed for reference. A similar draft for CT is in progress.

All NM and DID staff have been notified of the location of the HIQA 2023 DRL report. This is always available to staff to consult as an interim measure.

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| Regulation 13: Procedures | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 13: Procedures:
SLRON's Radiation Safety Committee will implement a Radiation Services clinical audit strategy in line with HIQA, National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation.
Draft documents are in place which will be reviewed and approved over the next 2 Radiation Safety Committee meetings.
Audit activity will continue to take place across radiation services in the interim.

## 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 | 31/10/2025 |
| Regulation 11(5) | An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional | Substantially Compliant | Yellow | 31/10/2025 |

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| | radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available. | | | |
| Regulation 13(4) | An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. | Substantially Compliant | Yellow | 31/12/2025 |