

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, Dublin 8
Type of inspection:	Announced
Date of inspection:	20 May 2026
Medical Radiological Installation Service ID:	OSV-0007880
Fieldwork ID:	MON-0049747

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

St Luke's Radiation Oncology Network (SLRON) operates as a fully integrated network across three sites at St Luke's (SLH), Beaumont (BC) and St James's Hospital's. SLRON at St James's Hospital (SJH) treats approximately 1,600 patients per year with 22,000 ionising medical exposures. Its radiological equipment consists of four linear accelerators and two CT scanners. Treatment plans are prepared using Varian Eclipse TPS and Varian ARIA is used as an electronic patient record. A comprehensive quality assurance system exists to ensure all equipment operates optimally.

Governance at SLRON SJH is via the senior management team which report to the network executive management team and ultimately the Dublin & Midlands Regional Executive. SLRON has a single radiation protection advisor (RPA) who operates across the three sites and a single network radiation safety committee. Two radiation protection officers (RPO) operate on site in SLRON SJH. Incidents of unintended exposure or near misses are recorded through the incident reporting system, analysed by the local incident learning committee and reported to the network incident learning committee.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Wednesday 20 May 2026	09:30hrs to 15:45hrs	Margaret Keaveney	Lead
Wednesday 20 May 2026	09:30hrs to 15:45hrs	Noelle Neville	Support
Wednesday 20 May 2026	09:30hrs to 15:45hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

St. Luke's Radiation Oncology Network (SLRON) at St. James Hospital is one of three radiotherapy services in the St. Luke's Radiation Oncology Network, for which the Health Service Executive (HSE) is the undertaking. An inspection was completed at this service on 20 May 2026 to follow up on the compliance plan actions from the previous inspection of April 2022, and to assess the undertaking's ongoing compliance with the regulations in this service. It was evident that the undertaking had implemented several measures to address the gaps in compliance under Regulations 6 and 14 identified in the previous inspection. However, during this inspection, inspectors identified further gaps under Regulations 6 and 13.

Inspectors observed that the HSE, as the undertaking, had established governance and management arrangements at a network level, which provided oversight of the radiation protection measures at SLRON at St. James Hospital. It was evident that the undertaking's governance and management committees met regularly, and that there was a clear allocation of roles and responsibilities for a range of radiation protection measures in the service. However, some action was required by the undertaking to ensure that adequate human resourcing is available for these measures to ensure that they are sustainable. This is further discussed under Regulation 6 below.

A sample of electronic records for patients undergoing radiotherapy medical exposures were reviewed by inspectors during the inspection, and showed that appropriate persons, as per the regulations, were involved in referring for the medical exposures completed at the service. Inspectors were also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

During the inspection, inspectors saw that the undertaking had arrangements in place for the continuity of medical physics involvement and contribution in the service, which was commensurate with the radiological risk posed by the radiotherapy practices in the service.

Notwithstanding the areas for improvement identified over the course of the inspection, inspectors were assured that patients at SLRON at St. James Hospital were receiving safe and appropriate medical exposures.

Regulation 4: Referrers

From speaking with staff and a review of documentation, inspectors were assured that the medical exposures carried out at St. Luke's Radiation Oncology Network at

St. James Hospital were referred by individuals entitled to refer as per the regulations. Referrers in this service were appropriately registered medical practitioners for radiotherapy treatment and radiation therapists for treatment verification imaging exposures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors found that radiation oncologists and radiation therapists took clinical responsibility for individual medical exposures carried out in the radiotherapy department, which satisfied the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors observed that the undertaking had governance and management arrangements in place, to provide oversight of radiation protection measures in the radiotherapy service at SLRON at St. James Hospital. At a service level, a local incident learning group (LILG) met fortnightly to discuss all incidents, near misses and non-conformances that had occurred in the service. This meeting was attended by the radiation therapy services manager (RTSM), a radiation oncologist and a member of the medical physics team. This group reported into a network radiotherapy incident learning group (NRILG), which provided a forum for discussing all incidents that occurred across the SLRON and for sharing learning from such incidents. The NRILG subsequently reported into a network radiation safety committee (RSC) which had a wide multidisciplinary membership and met at least three times per year.

The RSC was responsible for monitoring radiation risks in the service and for discussing items such as equipment quality assurance (QA), clinical audits, incidents, and staff training and awareness of radiation protection. The committee was also responsible for approving new or revised policies and procedures and for coordinating and overseeing all queries and applications for the generic justification of new practices within the service. Inspectors saw that two queries on possible new practices were submitted to HIQA and responses appropriately actioned.

Inspectors noted that there were established lines of communication from the RSC upwards, via the Quality, Patient Safety and Risk Management Committee, to the network's executive management team (NEMT). The network manager was the chair of the NEMT and was responsible for informing the undertaking of key radiation protection matters in the service. They were also the designated manager

of the service. Inspectors were also informed of communication pathways between the RSC and the various staff groups, for example, to the Radiation Services Quality Group, radiation therapist staff meetings, radiation oncologist meetings and medical physics team meetings.

Since the previous inspection in April 2022, the undertaking had reviewed and updated documentation which ensured that key radiation protection responsibilities were clearly allocated to appropriate staff groups, such as the responsibilities of radiation therapists in their role as practitioners and also the responsibilities of medical physicists in various aspects of the service. The undertaking had also allocated roles and responsibilities for radiation protection measures in line with regulatory updates. However, inspectors were informed that in some areas the human resources for these allocations were not currently in place, which resulted in gaps in compliance with the regulations. For example, as outlined under Regulation 13 below, the undertaking did not have adequate human resourcing arrangements in place to ensure that the service's clinical audit strategy was sustained, as required by the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*.

Overall, while some improvements were required in the resourcing of allocated responsibilities, inspectors were satisfied that there were effective arrangements in place to ensure the radiation protection of service users in the radiotherapy department at SLRON at St. James Hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors noted that the undertaking had systems in place to ensure that only radiation oncologists and radiation therapists acted as practitioners in the radiotherapy department, and that all medical exposures took place under the clinical responsibility of these practitioners.

From a review of a sample of patient records and policies, such as *Optimisation and Justification procedure for Ionising Radiation Medical Exposures*, inspectors were satisfied that the optimisation of radiotherapy medical exposures involved radiation oncologists, radiation therapists and medical physicists. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for all individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors noted that the undertaking had arrangements in place to ensure the continuity of THE medical physics TEAM'S involvement and contribution at SLRON at St. James Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

During the course of this inspection, inspectors spoke with staff and established that the medical physics team were involved in all responsibilities outlined in Regulation 20.

Inspectors noted that the undertaking had arrangements in place to ensure that medical physicists gave advice on medical radiological equipment, prepared the technical specifications for such equipment and its installation and design, and were involved in the surveillance of the medical radiological installation, the selection of equipment required to perform radiation protection measurements and the training of practitioners and other staff in relevant aspects of radiation protection.

From a review of documentation, such as *Quality Assurance Programme Guidelines* and *Management of Radiation Incidents Procedure*, inspectors noted that medical physicists were also allocated key responsibilities in these radiation protection areas, such as dosimetry, contributing to the definition and performance of QA of medical radiological equipment and analysing events involving, or potentially involving, accidental and unintended medical exposures.

Judgment: Compliant

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

From the evidence gathered during the course of this inspection, inspectors were satisfied that the level of involvement of the medical physics team was appropriate and proportionate to the radiological risk associated with medical radiological practices at SLRON at St. James Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

During the course of the inspection, inspectors observed that the undertaking had many effective processes and procedures in place that ensured the radiation protection of patients and the safe delivery of medical exposures. It was also noted that since the previous inspection, the undertaking had effectively addressed gaps in compliance with Regulation 14, by implementing measures such as the use of log books on each treatment unit to record work performed or remaining after quality assurance testing. Since the previous inspection, the undertaking had also implemented measures to address gaps in compliance which ensured that many key radiation protection documents were now reviewed and updated. However, some gaps in compliance continue and are discussed below under Regulation 13.

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. Inspectors were also satisfied that the various medical exposures along the patient's radiotherapy pathway were justified in advance by a person entitled, as per the regulations, to take clinical responsibility for justification.

Inspectors noted a strong multidisciplinary approach to the optimisation of medical radiological procedures at SLRON at St. James Hospital. A QA programme for the medical exposure equipment was reviewed by inspectors, which included a range of comprehensive tests that were performed daily, monthly and annually by staff. Inspectors also observed good processes in place regarding the inquiring and recording of patients' pregnancy status and that there were effective systems in place for recording and reviewing incidents involving, or potentially involving, accidental or unintended exposures to ionising radiation.

The radiotherapy team had developed written protocols, procedures and guidelines to support the delivery of the standard medical exposures carried out in the service, which incorporated referral guidelines. However, inspectors noted that some of these documents required review to ensure that they continued to reflect day-to-day practice and support staff. Inspectors also noted that while the undertaking had implemented a clinical audit strategy in the radiotherapy service that met many of the requirements of the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, further action was required to ensure that the strategy was sustained and integrated into the network's overarching clinical audit strategy, which was in draft format and not yet implemented across the service.

Notwithstanding the gaps identified under Regulation 13, inspectors were satisfied that systems were in place to support the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

From speaking with staff and reviewing a sample of patient records for radiotherapy medical exposures, inspectors were assured that the undertaking had processes in place to ensure all individual medical exposures were justified in advance by a

practitioner and that a record of this justification was maintained. The radiotherapy management team had developed *Optimisation and Justification procedure for Ionising Radiation Medical Exposures* which clearly allocated the roles and responsibilities pertaining to the justification of medical exposures along the radiotherapy pathway.

All referrals reviewed by inspectors were available in writing, stated the reason for the request and were accompanied by sufficient medical data to allow the practitioner consider the benefits and the risks of the medical exposure during the justification process. Inspectors noted that a number of checklists were incorporated into the patient's electronic health record. They listed the medical data that was to be reviewed by referrers and practitioners during the justification processes along the radiotherapy pathway, and this was identified as an area of good practice in the service.

During a tour of the radiotherapy service, inspectors observed posters and treatment site-specific patient information leaflets, which provided patients with clear information relating to the benefits and risks associated with the radiation dose from the medical exposures, and met the requirements of this regulation.

Judgment: Compliant

Regulation 13: Procedures

During this inspection, inspectors reviewed a number of written protocols, procedures and clinical guidelines on the medical exposures commonly delivered in the service, and noted that they included national and international referral guidelines. Many of the clinical guidelines had been developed by multidisciplinary teams with expertise and knowledge on the specific treatment site, and this approach to the development of written protocols was identified as an area of good practice in the service. Inspectors also noted that the team had introduced a document management system that alerted relevant staff as document review dates were reached. Inspectors saw that many of documents were reviewed within their specified timeline due to improvements in human resources since the previous inspection in April 2022. However, inspectors noted, that similar to the previous inspection, a number of documents had not been reviewed by their review date. Therefore, the undertaking must continue to prioritise the review of key radiation protection documents to ensure that the established written protocols, procedures and clinical guidelines on the medical exposures are reviewed and updated within their set timelines.

During the review of patient records on medical exposures, inspectors observed that a discharge letter was generated after each patient completed their radiotherapy treatment, which included information on the treatment site and dose received by the patient, thereby meeting the requirements of Regulation 13(2).

Inspectors noted that significant work had been done by the radiotherapy team to implement HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* into St. Luke's Radiation Oncology Network at St. James Hospital. This included the development of a *Clinical Audit in Radiation Services Procedure* and the establishment of a Clinical Audit in Radiation Services (CARS) Group. A review of CARS meeting minutes and the audit strategy showed good commitment by the radiation therapists team to auditing a range of radiation protection measures along the patient's radiotherapy pathway. However, inspectors were informed that, due to human resourcing issues, the CARS group had not met since December 2025 and that this gap in resourcing had affected the ongoing implementation of the strategy and the timely implementation of audit recommendations and quality improvement plans. Inspectors also noted that *Clinical Audit in Radiation Services Procedure* pertained to radiation therapists only, and therefore were not assured that there was a multidisciplinary approach to audit throughout the service. In order to fully comply with Regulation 13(4), the undertaking must provide and maintain human resources for clinical audit and also ensure that the team involved in clinical audit in the service is multidisciplinary. The undertaking must also ensure that the radiotherapy services clinical audit strategy is considered in the overarching clinical audit strategy, which was in draft form at the time of the inspection.

Judgment: Substantially Compliant

Regulation 14: Equipment

During the course of the inspection, inspectors were informed of the various measures that the undertaking's team had in place to ensure that the medical radiological equipment was kept under strict surveillance regarding radiation protection. Many of these key measures were outlined in a procedure titled *Quality Assurance Programme Guidelines for Radiotherapy Equipment*, and included weekly, monthly and annual performance testing that was completed on the two CT units that were used during the planning of the treatment and on each of the four linear accelerators that delivered the radiotherapy treatment.

The medical physics team was allocated responsibility for developing and overseeing the QA programme, and had developed a QA tracker system, which included a traffic-light system that facilitated easy review of all QA completed and due. Inspectors saw that both the radiation therapists and the physics team were involved in carrying out the testing, and that on the day of the inspection all QA testing was up-to-date. From a review of records, inspectors also noted that the equipment manufacturers performed regular planned servicing of the equipment and that they were also available for any unplanned servicing that was required. Following the previous inspection in April 2022, the undertaking's team had committed to implementing logbooks for each linear accelerator, which would provide a clear summary and oversight of any outstanding work following routine performance tests and the repair of equipment faults. During this inspection,

inspectors noted that these logbooks had been implemented as planned. Inspectors also noted that quarterly testing was performed on the treatment planning system that is used to optimise individual treatments and this was identified as an area of good practice in the service.

During the review of the up-to-date inventory and QA records for the medical radiological equipment, inspectors noted that while all equipment was past their nominal replacement date, all had passed QA testing.

Overall, the undertaking ensured that the equipment in use in the service was kept under strict surveillance regarding radiation protection, by implementing effective measures to address gaps in compliance identified during the previous inspection and by maintaining an effective QA programme.

Judgment: Compliant

Regulation 15: Special practices

During the course of the inspection, inspectors were satisfied that the undertaking had given special attention to appropriate radiation protection practices for patients receiving radiotherapy treatment.

There was a good multidisciplinary approach to the radiation protection of patients receiving high radiotherapy doses. For example, all patients, potentially undergoing a type of radiotherapy treatment involving high doses known as Stereotactic Ablative Radiotherapy, were discussed at a multidisciplinary meeting prior to their treatment referral being processed. The procedure *Management of the Stereotactic Ablative Radiotherapy Multidisciplinary Meeting in SLRON* stated that at this meeting each patient's medical history was discussed by the radiotherapy team and, where relevant, other medical disciplines to ensure that all pertinent information was considered during the decision to treat process.

The undertaking's management team had also formed site-specific tumour groups across the network, whose membership was multidisciplinary and included radiation oncologists, radiation therapists, members of the physics team and other relevant disciplines. These groups were responsible for ensuring that the clinical guidelines under their remit contain evidence-based clinical indications for treatment, dose prescriptions, radiotherapy planning techniques such as target delineation, and the review of any new clinical trials relevant to the tumour site. The team had also formed a multidisciplinary group, which focused on developing, and reviewing evidence based imaging protocols for use during the verification of radiotherapy treatments. These groups contributed to the delivery of evidence-based and standardised radiotherapy to patients in the service.

During the course of the inspection, inspectors also spoke with staff in the radiotherapy treatment planning department, who informed inspectors that specific planning protocols were used for each treatment site to ensure that doses to normal

tissue were kept as low as possible while delivering the optimal treatment dose to the treatment area. From a review of documentation, inspectors also noted that site-specific procedures were in place to guide and support the radiotherapy team during pre-treatment imaging and to ensure safe delivery of patients' treatment.

Inspectors were also informed that a radiotherapy team of radiation oncologists, radiation therapists and medical physicists met weekly to review all treatment plans in advance of treatment commencing. The document *Planning Peer Review Guideline* outlined how these meetings were coordinated to ensure that individual treatment plans were peer reviewed which enhanced the radiation protection of patients in the service. This was identified as an area of good practice in the department.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed that multilingual notices were displayed in patient waiting areas throughout the radiotherapy department, which aimed to raise patients awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. The *Procedure for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures and for determining breast feeding status in Nuclear Medicine* provided guidance and support to the radiation oncology and radiation therapist teams on assessing and confirming the pregnancy status of patients undergoing radiotherapy CT planning and treatment.

From discussions with staff, inspectors were informed that patients were educated on the risks associated with potential irradiation to the unborn child during medical exposures, and that an information leaflet on these risks was posted to all relevant patients prior to them attending for their treatment planning CT. This was identified as an area of good practice within the service. Inspectors were also informed that practitioners enquired on and recorded the pregnancy status of relevant patients both prior to the planning CT scan and prior to first radiotherapy treatment being performed. From the review of a sample of patient records, it was evident that these enquiries were made by practitioners.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied that the undertaking had a system in place to record and analyse incidents involving, or potentially involving, an accidental or unintended

exposure to ionising radiation, which included the regulatory requirement to notify HIQA of any reportable incidents. This system, and the associated roles and responsibilities, were clearly outlined in the document *Management of Radiation Incidents Procedure*.

When an event occurred, it was recorded on an electronic incident reporting system that was accessible to all radiotherapy staff. Once recorded, the system notified the RTSM who informed other relevant parties such as the physics team and the referrer. All reported incidents and near misses were discussed at a monthly local radiation incident learning group (RILG), whose membership included the RTSM, the principal physicist and a consultant radiation oncologist. The RILG subsequently reported to the undertaking's network radiation incident learning committee (NRILC) which met on a monthly basis and subsequently reported into the RSC.

From a review of documentation, inspectors were satisfied that there was a good culture of incident and near miss reporting in the service, and that the NRILG actively monitored and reviewed incident trends. For example, inspectors reviewed a summary of incidents reported in 2025, which included details of the points in the radiotherapy pathway at which the incidents occurred. A similar report on events reported in the first quarter of 2026 was also available. Inspectors also reviewed a report, developed in January 2026, on the analysis of potentially serious incidents that occurred in 2025 but were not reportable to HIQA. This review identified some gaps in guidance documents and in radiotherapy processes that had contributed to the incidents, and also prioritised recommendations to address these findings. While this proactive approach to minimising the risk of potential serious risks occurring was identified as an area of good practice in the service, the undertaking should ensure that adequate resources are put in place to ensure that these recommendations are promptly actioned by the NRILG in order to further strengthen and enhance the radiation protection of patients in the service.

Inspectors also followed up on a number of incident investigation reports submitted to HIQA, and saw that appropriate measures had been implemented to minimise the risk of a similar incident occurring. These measures included, among others, the introduction of additional mandatory checks prior to a patient starting treatment.

Overall, inspectors were satisfied that the undertaking was meeting the requirements of this regulation for accidental and unintended exposures and significant events that occurred in the service.

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 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 at St James Hospital OSV-0007880

Inspection ID: MON-0049747

Date of inspection: 20/05/2026

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: Approve a SLRON Strategy for Clinical Audit of Radiological Procedures Involving Medical Exposure to Ionising Radiation, including the associated governance arrangements, defined roles and responsibilities, annual audit programme, and reporting and monitoring processes. Completion Date: 30 November 2026 Review clinical audit resources, including protected time, and escalate any requirements through the Executive Management Team. Completion Date: 30 November 2026 Establish a multidisciplinary Clinical Audit governance group for Medical Radiological Procedures either new, or aligned with current governance committees (CARS), with approved Terms of Reference and meeting schedule. Completion Date: 31 December 2026 Establish and implement the annual clinical audit schedule and programme, with audits commenced and monitored in accordance with the approved Strategy and Operational Plan. Completion Date: 01 January 2027	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures:	

Review and update all overdue radiation protection procedures, protocols and clinical guidelines.

Completion Date: 28 February 2027

Review clinical audit resources, including protected time, and escalate any requirements through the Executive Management Team.

Completion Date: 30 November 2026

Re-establish the CARS Group with appropriate multidisciplinary representation, or establish a new multidisciplinary governance group, to oversee the Clinical Audit Programme and monitor recommendations.

Representation will include relevant disciplines involved in radiological practices, including Medical Physics and Radiation Oncology.

Through the reestablishment of the CARS group, or equivalent, review clinical audit recommendations, assign responsible leads and monitor implementation.

Completion Date: 30 November 2026

Establish and implement the annual clinical audit schedule and programme, with audits commenced and monitored in accordance with the approved Strategy and Operational Plan.

Completion Date: 01 January 2027

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	01/01/2027
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for	Substantially Compliant	Yellow	28/02/2027

	each type of equipment for relevant categories of patients.			
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	01/01/2027