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, 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:	12 October 2021
Medical Radiological Installation Service ID:	OSV-0007377
Fieldwork ID:	MON-0031744

About the medical radiological installation:

St. Luke's Hospital first treated cancer patients 65 years ago and established St. Luke's Radiation Oncology Network (SLRON) over a decade ago. SLRON expanded its service in 2010 and opened two new radiation oncology centres on the campuses of Beaumont Hospital 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 Dublin Midland's Hospital Group Chief Executive Officer (CEO).

High specification linear accelerators (the main equipment used to treat cancer patients with external beam radiotherapy) are available across the SLRON. SLRON currently provides public radiotherapy cancer services for Dublin along with a range of specialist national radiotherapy services. Approximately 55% of radiotherapy patients in Ireland are treated in Dublin and 75% of these are treated in SLRON. 5,000 new cases per year are treated on 14 linear accelerators making SLRON one of the largest radiation oncology centres in Europe. Patients also benefit from access to clinical trials for multiple tumour types. In addition to external beam radiotherapy (the commonest form of radiotherapy to treat cancer), St Luke's Hospital provides Radiology services, both diagnostic and therapeutic Nuclear Medicine services and Brachytherapy services (a form of treatment where radiation sources are placed inside the body).

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 12 October 2021	09:30hrs to 16:30hrs	Agnella Craig	Lead
Tuesday 12 October 2021	09:30hrs to 16:30hrs	Maeve McGarry	Support
Tuesday 12 October 2021	09:30hrs to 16:30hrs	Patricia Hughes	Support

Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership, governance and management arrangements in place at St. Luke's Hospital (SLH), Rathgar, one of the three centres which make up the St. Luke's Radiation Oncology Network (SLRON). As part of this inspection, inspectors were provided with documents for all services in this hospital where medical ionising radiation exposures were conducted. This included the diagnostic imaging department, the nuclear medicine department and the radiotherapy department. On the day of inspection, inspectors visited the radiotherapy department and focussed on the external beam radiotherapy service and the brachytherapy service conducted in both the radiotherapy department and operating theatre.

The governance structures in place showed that oversight for radiation protection was provided by a Radiation Safety Committee (RSC) which reported to the Network Director and the Network Executive Management team through the Quality, Patient Safety and Risk Management Committee. A good example of radiation safety described to inspectors and seen in the reviewed documents related to the use of a local Incident Learning Committee (ILC) which operated in each of the three centres and also at network level. This Network Radiotherapy Incident Learning Committee (NRILC) facilitated learning to be shared across all centres within the network.

From the evidence gathered during this inspection, inspectors were assured that only those who are entitled to refer acted as referrers in this hospital. Similarly, only radiological specialists (radiologists and radiation oncologists) were considered practitioners in this hospital with respect to the regulations. Although the documentation could be updated to include the term Medical Physics Expert (MPE) where relevant, inspectors were assured that MPEs were available in this service and their level of involvement was in line with the level of risk posed by the complex procedures provided in this hospital. However, some tasks which should only be completed by practitioners were delegated to MPEs. Furthermore, practitioner tasks were also delegated to radiographers and radiation therapists although these individuals were not considered to be practitioners locally. Inspectors did not have any safety concerns in relation to this scenario as the regulations recognise both radiographers and radiation therapists as practitioners, however, the undertaking should review the current allocation of responsibilities to ensure there is alignment between practice, documentation of practice and adherence with regulations.

Regulation 4: Referrers

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

Policy documents reviewed by inspectors in advance of this inspection outlined the referral process in this facility for medical exposures for all types of services involving ionising radiation. These documents included a table which outlined the personnel who can refer patients for different procedures in the radiotherapy, nuclear medicine and diagnostic imaging departments. These referrals were received in either electronic or paper-based formats.

From the records reviewed in the brachytherapy unit on the day of inspection, inspectors were assured that only radiation oncologists referred patients for procedures. Similarly, from the records reviewed in the radiotherapy department, only consultant radiation oncologists and radiation oncology registrars referred patients for external beam radiotherapy.

Judgment: Compliant

Regulation 5: Practitioners

From reviewing documentation in advance of this inspection and speaking with staff on the day of inspection, inspectors found that only those who are entitled to act as practitioners took clinical responsibility for medical exposures in this facility.

Judgment: Compliant

Regulation 6: Undertaking

The governance structure in place for the radiation protection of service users within this facility was made available to inspectors in documentation provided in advance of inspection. This included a chart detailing the radiation safety organisation structure which showed how the local ILC reported to the NRILC, which in turn reported to the RSC. This structure facilitated discussion at both local level and network level which in turn facilitated learning across the network. The RSC reported to the Quality, Patient Safety and Risk Management Committee which in turn reported to the Network Director who is also the designated manager for this facility. On the day of inspection, the designated manager explained the pathway used to communicate with the Health Service Executive (HSE), who is the overall undertaking for this facility and therefore has ultimate responsibility for the service. From the information provided, inspectors were assured of the structures and systems in place to safeguard patients undergoing medical exposures in this facility.

Although the allocation of responsibilities was detailed in the documentation reviewed and this was known by staff, the specific documented responsibilities allocated to some personnel was not aligned with the regulations. For example, radiographers and radiation therapists were not considered practitioners in this

facility, however they were delegated some tasks which can only be carried out by those acting in a practitioner role. For many types of procedures, these tasks included making the enquiry about pregnancy, justifying the exposure in advance and evaluating individual exposures, for example, imaging used in advance of daily radiation treatments. There was a lack of awareness among some staff on the understanding that elements of practitioner responsibilities along the patient pathway can be shared among different personnel, accepting that overall clinical responsibility for a patient was held by one practitioner. However, inspectors had no concerns for the safety of patients as radiographers and radiation therapists are entitled to act as practitioners, as per the regulations. These findings were discussed with staff on the day of inspection and management staff accepted that some change is required in order to align the documented responsibilities with the day-to-day practice, which in turn should align with the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From reviewing the documentation and speaking with staff, inspectors found that all medical exposures took place under the clinical responsibility of a practitioner as defined in the regulations, with practitioner status assigned to radiologists and radiation oncologists in this facility. Inspectors were informed that radiation therapists, radiographers and medical physics experts were delegated the practical aspects of medical radiological procedures, however, a record showing this delegation was not available for review on the day of inspection. Additionally, some tasks that were delegated can only be completed by those recognised as practitioners. Therefore, improvements are required in order to come into compliance with this regulation.

Inspectors were informed that in theatre, most brachytherapy procedures were performed by radiation oncologists. In addition, MPEs were also present for prostate brachytherapy procedures and carried out certain practical aspects of the procedure. However, for some less common brachytherapy procedures, neither a radiation oncologist nor an MPE were present and the delegation of practical aspects was not defined. Inspectors were informed that these procedures were carried out by a non-radiological specialist who was not defined locally as a practitioner. Furthermore, examples of this practice were given to inspectors where the personnel involved had very little or no radiation protection training. Although the regulations permit registered medical practitioners to conduct medical exposures, the retention of specific personnel with training in radiation protection must be considered to ensure the radiation protection of patients, in the absence of new training requirements on radiation protection from the professional regulators as specified in Regulation 22.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

MPEs were sufficiently available to support this facility and inspectors were assured of the continuity of expertise in the diagnostic imaging, nuclear medicine and radiotherapy departments.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From documents reviewed prior to, and on the day of inspection, and from speaking with staff, it was evident that the MPEs take responsibility as detailed in the regulations. These responsibilities included: quality assurance (QA) and acceptance testing, dosimetry and dose audits, optimisation, reviewing diagnostic reference levels (DRLs), and training and education of staff. MPEs were also involved in analysing events involving or potentially involving ionising radiation and were represented on both the ILCs and the RSC. Although a non-compliance was not identified, relevant documentation should be updated to ensure the responsibilities of the MPE are clearly outlined as distinct from general physicist or radiation protection adviser (RPA) roles.

Judgment: Compliant

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

Inspectors were assured that the level of involvement of the MPEs was aligned to the level of radiological risk posed by the complex services provided in this facility as explained previously under Regulation 20.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place for service users undergoing medical exposures for external beam radiotherapy and brachytherapy in SLH. SLH demonstrated a good level of compliance with the assessed regulations and staff demonstrated a strong awareness on matters relating to radiation protection. This included evidence of the use of diagnostic reference levels (DRLs)

where relevant, providing information for service users regarding the risks associated with medical exposures and using methods to optimise treatments for patients. This included the special attention given to children undergoing radiotherapy which included the use of special paediatric immobilisation devices and customisation of imaging protocols for paediatric patients. An up-to-date inventory and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place and the equipment was kept under strict surveillance. A positive attitude to clinical audit was noted. The processes in place to create a culture of reporting and investigating incidents and near misses were also found to be effective in terms of the safe delivery of medical exposures across all services. A quality improvement project to assess staffs' perceptions of incident reporting was seen as a good example of how undertakings can assess and address issues related to incident reporting.

However, although the hospital had written protocols in place for procedures available in this facility, these should be reviewed to ensure they are up to date. Similarly, the process for enquiring about pregnancy and breastfeeding status should be reviewed to ensure these tasks are completed by those recognised as practitioners in the regulations. Notwithstanding the areas for review, overall inspectors were satisfied that SLH had effective systems and processes in place to ensure the safe delivery of medical exposures in all departments in this hospital.

Regulation 8: Justification of medical exposures

From the information gathered as part of this inspection, inspectors were assured that the risks and benefits of medical radiological procedures were considered in advance of medical exposures, and that sufficient medical data was available to satisfy the practitioner that the procedure, as stated in the referral, was justified.

However, the specific personnel allocated full responsibilities associated with justification should be reviewed in order to ensure full alignment between the regulations, practice and documentation. For example, from the details provided in the documentation, inspectors were informed that the radiologists and radiation oncologists, deemed practitioners in this hospital, had been allocated the responsibility of justification. This information was detailed in a chart included in the document *"Optimisation and Justification Procedure for Radiotherapy Ionising Radiation Medical Exposure"* which aligned the patient pathway in radiotherapy with the personnel who are assigned the specific roles and responsibilities of justification. This chart specified that by signing the treatment request form (TRF), the radiation oncologist has justified in advance the patient's planning scan or treatment. Similarly, by reviewing and approving the final treatment plan, the radiation oncologist justified the radiotherapy treatment course in advance with the associated protocol which detailed the type of, and schedule for, additional exposures to check and verify treatment (verification imaging). Radiation therapists,

who were delegated the practical aspects in this hospital, followed these protocols when carrying out any verification imaging. However, in order for the treatment to proceed or justify additional imaging within protocol, a clinical assessment of the adequacy of the exposure and the set-up must first be completed. As this task can only be completed by a practitioner, this hospital should review the day-to-day process and the documentation to ensure full alignment between the regulations and the documented practice.

Likewise, documentation for the diagnostic imaging department detailed the role of the radiographer in providing patients with information on risks and benefits, again a task which should be completed by practitioners. Therefore, the documentation would benefit from a review to ensure clarity on all aspects of roles and responsibilities.

Notwithstanding the areas needing review, inspectors were assured that justification of all medical exposures was considered by personnel who are entitled to act as practitioners as stated in the regulations.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke to staff on the day of inspection about the optimisation of radiotherapy procedures. Inspectors reviewed policies, procedures and guidelines which outlined optimisation per treatment site. In addition, the documentation included an overview of optimisation considerations throughout the patient pathway and the responsible personnel. Optimisation of dose to target and non-target volumes as well as medical exposures used for planning and verification purposes was outlined.

A sample of treatment plans in brachytherapy were reviewed and staff described how the plans were optimised. The treatment plans reviewed demonstrated that target volumes were individually planned. Inspectors were informed that doses to non-target volumes were kept as low as achievable, with planning aims and constraints applied based on international evidence. The planning system included a traffic light system to aid decision making around individual plan optimisation.

The verification of medical exposures was outlined in documentation reviewed by inspectors. The imaging used to guide and verify the delivery of treatment was outlined in site specific policies, for example one policy for prostate cancer patients and a separate one for breast cancer patients. In addition, policies outlined that routine quality control checks were performed throughout the patient pathway by radiation therapists and physics team members. Inspectors reviewed patient records which demonstrated that checks took place and that additional patient specific quality assurance (PSQA) was used to verify dose delivery for complex cases in advance of the first treatment.

Inspectors were informed how patients participating in clinical trial research projects involving radiotherapy and brachytherapy were informed in advance about potential risks. Patients were given the opportunity to consider their participation prior to consent. Inspectors were informed that for patients participating in research projects, individual dose levels and specific dose constraints were considered by the practitioner prior to the exposure taking place.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The "*Procedure for review of diagnostic reference levels in the Diagnostic Imaging and Nuclear Medicine Departments*" was reviewed by inspectors and detailed the procedure used to establish, review, implement and annually audit DRLs in X-ray imaging, fluoroscopy, CT scanning, and nuclear medicine.

From reviewing the table for diagnostic CT scanning, inspectors were assured that the local DRLs were lower when compared with the available national DRLs.

Judgment: Compliant

Regulation 13: Procedures

From the documents provided in advance of inspection, inspectors noted a significant number of written policies, procedures, protocols and guidelines were available for staff. Inspectors were informed that staff could usually access these documents by using searches on the hospital intranet. However, at the time of inspection, the intranet was unavailable as a consequence of the HSE cyber-attack earlier in the year and a new system was in the process of being developed. Staff had found a work-around which consisted of having hard copies available until the new system will become available. Inspectors noted the use of extensive references to inform these guidelines demonstrating the hospital's positive attitude to using the evidence base in terms of referral guidelines for radiotherapy. Staff also had access to referral guidelines for diagnostic imaging purposes. However, from the sample of clinical guidelines reviewed, inspectors noted that many documents had passed their identified review date. Inspectors were informed that this related to human resource issues but that this would be remedied shortly. Management should ensure that documentation is reviewed in line with local policy.

Inspectors were informed that information relating to the dose of radiation received by patients is included in treatment summaries which are produced once patients finish their treatment. Inspectors were informed that these summaries report the treatment dose received and the duration of treatment to other teams involved in

the patient's care.

A sample of clinical audits reviewed by inspectors showed good compliance rates. Examples of audits conducted included: an audit of referrers in the diagnostic imaging department which showed a 100% compliance rate and a pregnancy policy audit conducted in 2020 which showed a 98% compliance rate. An audit of justification in the radiotherapy department examined consent and the completeness of the *'Treatment Request Form'* and again good compliance (100%) was noted for each aspect.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided to HIQA in advance of this inspection.

From the evidence provided, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. Mechanisms used to facilitate surveillance included having policies for quality assurance for medical radiological equipment in all departments in the hospital. However, some policy documents would benefit from updating as they had passed the date identified for review, for example, the document titled "Quality Assurance Programme Guidelines for Radiotherapy Equipment" issued in November 2017, was due for review in November 2018. Reviewing these policy documents should take into account the terminology used in the current legislation, for example, the role of the MPE, rather than the RPA or physicist to ensure full clarity.

Judgment: Compliant

Regulation 15: Special practices

Inspectors found that special considerations were made for children undergoing radiotherapy treatment. The considerations described to inspectors and outlined in policy included the selection of ancillary equipment, the practical techniques used and the procedures to verify dose delivery.

Special considerations were made to optimise dose from exposures used to plan and guide treatment delivered to children. For the computed tomography (CT) scans carried out to plan treatment, parameters and features were used to reduce dose. In addition, staff informed inspectors that play therapists were often involved which benefited the patients and helped achieve the practical techniques of the exposure needed for treatment planning.

In addition, a specific paediatric image guidance protocol outlined how dose from imaging used to verify and guide the treatment delivery was optimised. The use of lower dose imaging protocols, the choice of imaging modality and how often the images were performed were considered.

Inspectors were informed that for paediatric patients specific ancillary equipment was used such as paediatric masks and other immobilisation devices needed for the practical aspects of the exposures.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From the documents reviewed and speaking with staff, inspectors were informed of the process for enquiring about and recording pregnancy status. Inspectors reviewed a number of records and found that, in most cases, this enquiry had been documented.

For patients undergoing external beam radiotherapy, the radiation oncologists and the radiation therapists were involved in enquiring and documenting pregnancy status. Details of the process including the point at which the enquiry is first made and when this is re-checked was provided in the documentation and was known by staff. However, although recognised in the regulations as practitioners, as radiation therapists are not considered practitioners in this hospital, the undertaking should review this to ensure daily practice and documentation is aligned and is compliant with the regulations.

In addition, inspectors noted some staff who enquired about pregnancy status for patients undergoing nuclear medicine procedures are not recognised as practitioners in the regulations, therefore the undertaking needs to take steps to come into compliance with Regulation 16(1)(a).

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documentation before inspection, and speaking with staff on the day of inspection, inspectors were informed of the measures taken within this facility to minimise the probability of accidental or unintended exposures. Oversight from senior management within this hospital was evident as radiation incidents and potential incidents are a standing item at a number of committee meetings including the RSC, the local ILC and the NRILC. These meetings provide an opportunity for the sharing of learning within this facility and between the facilities within the

SLRON.

Staff who spoke with inspectors provided details of a quality improvement project (QIP) which had been conducted to examine incident reporting and the perceptions of staff about the culture of incident reporting and learning. The findings from this project informed an implementation strategy which included education, additional resources and engagement. In addition, inspectors were informed that more staff were invited to attend the local incident learning group meetings and radiation therapists' involvement in incident management also increased. Although Covid-19 had impacted on the implementation of some of the QIP recommendations, inspectors were provided with the NRILC annual report for 2020 which provided evidence of some improvements in reporting of incidents and near-misses. In addition, samples of the quarterly newsletters produced and shared with staff was also provided to inspectors. The structure used to present information in the quarterly newsletter produced and shared with staff in December 2020 was notably different to previous newsletters provided and inspectors were informed that this change was made to make the data more visual and increase awareness. This QIP is a good example of how undertakings and facilities can take steps to firstly examine and subsequently improve the culture and environment of incident reporting**.**

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	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially 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-0031744

Date of inspection: 12/10/2021

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Procedure RS P 011 (justification and optimisation) has been amended to reflect that Radiation Therapists are acting in practitioner roles (with the associated responsibilities) when they acquire and assess on-board imaging exposures in advance of the delivery of daily radiation treatments, and when they confirm a patient's pregnancy status prior to CT sim and day 1 of radiotherapy. This document will be peer reviewed and approved by the Radiation Safety Committee at the next meeting March 2022.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: A practitioner procedure document will be developed to demonstrate the staff to whom a practitioner role applies and, or, to whom practical aspects have been delegated. This document will be peer reviewed and approved by the Radiation Safety Committee at the next meeting March 2022. In the case of less common brachytherapy case where the presence of a radiation oncologist and MPE were not present and the practical aspects had not been delegated will be addressed through specific radiation protection training of nursing in the practical aspects of handling the ocular sources in theatre.	

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The inspectors report commented that a number of the clinical guidelines are past their revision dates. The Quality Assurance in Radiotherapy (QART) Radiation Therapist role has recently been filled after a prolonged gap. This role is central to coordinating the revision of guidelines. The QART department have been notified by the Chair of the Radiation Safety Committee of the need to prioritise the coordination of this and the circulation of guidelines to lead authors. The consultant body will also be informed of the need to prioritise updating clinical guidelines when circulated at the next Consultant Meeting 2.12.2021	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: We have implemented an immediate change in practice whereby senior house officers (SHOs) have been provided with the required radiation protection training to perform the practitioner task of enquiry of pregnancy status for the in- and outpatient radionuclide examinations and therapies. This will be in place of the MPE making this enquiry. This change in practice will also be reflected in RS P 03 procedures which will be updated and brought in line with the terminology of the current regulations.	

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	16/03/2022
Regulation 10(5)	An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of	Not Compliant	Orange	16/03/2022

	the delegation, and shall provide such records to the Authority on request.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/12/2022
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Not Compliant	Orange	30/11/2021