



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	St Lukes General Hospital - Kilkenny
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Freshford Road, Friarsinch, Kilkenny
Type of inspection:	Announced
Date of inspection:	28 September 2021
Medical Radiological Installation Service ID:	OSV-0007376
Fieldwork ID:	MON-0030756

## About the medical radiological installation:

St. Luke's General Hospital, incorporating Carlow District Hospital, is a model 3 hospital which is part of the Ireland East Hospital Group and serves the population of Carlow and Kilkenny. The department of radiology is a teaching department for the University College Dublin undergraduate radiography degree programme. The following services are provided at St. Luke's Hospital Kilkenny; general radiography, mobile radiography, ultrasound, computed tomography (CT), dual-energy X-ray absorptiometry (DXA), fluoroscopy and magnetic resonance imaging. General radiography and CT services are provided on a 24/7 basis at the hospital.

## How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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 28 September 2021	09:00hrs to 16:30hrs	Kirsten O'Brien	Lead
Tuesday 28 September 2021	09:00hrs to 16:30hrs	Maeve McGarry	Support

## Governance and management arrangements for medical exposures

On the day of inspection, inspectors visited clinical areas at St. Luke's Hospital, Kilkenny where medical radiological procedures were carried out including general radiography (X-ray), fluoroscopy and computed tomography (CT).

Inspectors reviewed documentation outlining the allocation of responsibility to individuals for the radiation protection of service users at the hospital and spoke with staff and management to establish the reporting and oversight arrangements which existed for medical exposure to ionising radiation at St. Luke's Hospital, Kilkenny.

The general manager was the designated person responsible for ensuring the radiation protection of patients and other services users undergoing medical radiological procedures at the hospital. A radiation safety committee (RSC) had also been established as the main forum for the oversight of radiation protection at the hospital. The RSC reported to the both the radiology governance group and the quality and safety executive committee (QSEC) who in turn reported to the executive management team. However, inspectors found that radiation protection was not routinely discussed at the QSEC. Similarly, the designated manager was not a member of the RSC and inspectors found that the membership of the RSC differed between documentation reviewed.

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner. Similarly, practitioners and an MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. Inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. However, some day-to-day practices, such as justification, were not fully aligned with the hospital's policies and procedures. The practical aspects of medical radiological procedures were only conducted by persons entitled to act as practitioners and the hospital had retained the presence of a radiographer for all medical exposures as an additional radiation protection measure in the absence of updated training requirements, as per Regulation 22.

On the day of inspection, a medical physics expert (MPE) was found to be appropriately involved to act or give specialist advice in line with the level of radiological risk at the hospital. However, inspectors noted that medical physics expertise at the hospital was provided for by way of an informal legacy arrangement with another hospital. This should be formalised and strengthened to ensure the continuity of medical physics expertise at the hospital.

Overall, while inspectors were satisfied that governance and management arrangements were in place at St. Luke's Hospital, Kilkenny, a clear allocation of responsibility for all aspects of the radiation protection of service users should be consistently and clearly documented. Similarly the hospital should review and

strengthen arrangements to facilitate a more formalised oversight of radiation protection within the service.

#### Regulation 4: Referrers

Inspectors found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at the St. Luke's Hospital, Kilkenny.

Judgment: Compliant

#### Regulation 5: Practitioners

On the day of inspection, only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

#### Regulation 6: Undertaking

Inspectors reviewed local policies, procedures, guidelines and records and an organisational chart which described radiation protection governance at the hospital. Inspectors also spoke with staff and management at the hospital to establish the reporting and oversight arrangements which existed for medical exposure to ionising radiation at St. Luke's Hospital, Kilkenny. Documentation reviewed in advance of the inspection indicated that the general manager was the designated manager and was the person responsible for governance and management of the radiation protection of services users undergoing medial radiological procedures at the hospital.

An RSC had been established as the main forum of oversight for radiation protection policy at the hospital and reported to both the QSEC and the radiology governance group. Both of these groups reported to the executive management team (EMT). An annual report from the RSC to the QSEC was noted in the QSEC minutes reviewed and membership of the QSEC included the radiography services manager. However, from the minutes of QSEC meetings reviewed by inspectors, radiation protection of service users was not discussed regularly at the QSEC and was not listed as a standing agenda item.

Additionally, inspectors found an inconsistency in the membership of the RSC between hospital policies and other documentation and records reviewed. For example, the *Radiation Safety Procedures* for the hospital stated that the designated

manager of the hospital was a member of the RSC. However, the RSC terms of reference indicated that membership included a senior management representative rather than the designated manager. While inspectors were satisfied that a management structure was in place, the mechanisms by which the general manager, as the named designated manager for the service, maintains oversight of all aspects of radiation protection should be reviewed with a view to formalising and strengthening the governance and management arrangements for medical exposures at St. Luke's Hospital, Kilkenny.

Inspectors also reviewed documentation and spoke with staff regarding the role of individuals allocated responsibility for the radiation protection of service users. On the day of inspection, only individuals entitled to act as practitioners took clinical responsibility for medical exposures. However the scope of individuals' responsibility for conducting aspects of clinical responsibility was documented across a number of policies and may have contributed to the inconsistency between hospital policy and day-to-day practice which was identified in the justification of medical radiological examinations in fluoroscopy. For example, the role of the radiographer in justification was included in the hospital's *Radiation Safety Procedures, Procedure for the justification of X-rays for acute and outpatient referrals at St. Luke's Hospital Kilkenny* and *Understanding NIMIS vetting*. However, while inspectors were informed by staff that justification of fluoroscopy procedures was carried out by a radiographer, the *Understanding NIMIS vetting* and *Procedure for the justification of X-rays for acute and outpatient referrals at St. Luke's Hospital Kilkenny* policies stated that a consultant radiologist had been allocated responsibility for carrying out this role.

It is important that policies, procedures and guidelines clearly indicate the allocation of responsibility for radiation protection at St. Luke's Hospital, Kilkenny. Similarly documentation should be site specific, for example, the *Radiation Safety Procedures* included allocation of responsibility to practitioners for services and procedures that are not conducted at the hospital. Additionally while policies and procedures were accessible using a shared drive which could be accessed by radiology staff, the service would benefit from a hospital-wide documentation management system to ensure that all staff at the hospital involved in the medical exposures, such as referrers, had access to radiation protection policies.

While inspectors were satisfied that governance and management arrangements are in place to ensure the safe delivery of medical radiological procedures at St. Luke's Hospital, Kilkenny, the hospital could benefit for strengthening these arrangements and consolidating and streamlining documentation to ensure the clear allocation of responsibility for the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Additionally, the practical aspects of medical radiological procedures were only carried out at St. Luke's Hospital, Kilkenny by individuals entitled to act as practitioners in the regulations. As an additional assurance, the hospital had retained the presence of a radiographer for the practical aspects of all medical radiological procedures. In the absence of new updated training requirements, as per Regulation 22, this was viewed as a positive additional radiation protection mechanism for service users at the hospital.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

On the day of inspection, medical physics expertise at the hospital was provided by way of an informal legacy arrangement with another hospital. While inspectors were satisfied that this arrangement facilitated the involvement of an MPE at St. Luke's Hospital, Kilkenny, such arrangements should be formalised and strengthened to provide an assurance that the HSE, as the undertaking for the hospital, has the necessary arrangements in place to ensure that continuity of medical physics expertise at the hospital.

Judgment: Substantially Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff at the hospital and were satisfied that the hospital had arrangements in place to ensure that the involvement and contribution of an MPE were in line with the requirements of Regulation 20. The MPE took responsibility for dosimetry and gave advice on medical radiological equipment. Records reviewed by inspectors also demonstrated that the MPE had contributed to quality assurance (QA) and acceptance testing and was involved in optimising medical exposures at the hospital.

Judgment: Compliant



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

An MPE was found to be appropriately involved in all aspects of medical exposure to ionising radiation conducted at the hospital, in line with the level of radiological risk at this installation.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors reviewed documentation and spoke with staff and management to assess the safe delivery of medical exposures at St. Luke's Hospital, Kilkenny. Information leaflets were provided to patients undergoing medical exposures and posters containing information about the benefits and risks associated with medical exposure to ionising radiation were observed in waiting rooms.

While all referrals reviewed were in writing, inspectors found in instances where the record of justification in advance was not recorded using the Radiology Information System, such records were not retained as required by the regulations. Additionally, policies and procedures reviewed did not fully align with day-to-day practices communicated to inspectors regarding the justification of procedures in fluoroscopy.

Inspectors found that DRLs for medical radiological procedures were established, regularly reviewed and used at the hospital. However, on review of documentation provided to inspectors in advance of the inspection, an inconsistency in the grouping of paediatric DRLs to national guidance was identified. The hospital should review the groupings used for paediatric DRLs to allow for meaningful comparison of radiation doses with the national DRLs. This finding was discussed with management on the day of inspection.

Referrers and or practitioners at the hospital inquired about the pregnancy status of individuals, where appropriate. However, these inquiries were not always recorded in a manner consistent with local policies and procedures. In addition, although arrangements were found to be in place to record and analyse actual accidental and unintended exposures to ionising radiation, an opportunity to improve the reporting and recording of potential radiation incidents to facilitate learning on accidental or unintended exposures was identified.

Inspectors found that the hospital had a quality assurance programme, including performance testing, in place for general X-ray, fluoroscopy and CT. However, documentation outlining the procedure for the routine performance testing in fluoroscopy should be reviewed and updated to ensure that policies reflect day-to-day practice. Similarly while inspectors were satisfied that written protocols were established for standard medical radiological procedures, inspectors noted that

protocols were in both typed and hand-written formats. The hospital should review their document management processes to ensure that documents are managed in a controlled manner to reflect up to date changes to equipment, practice and version history.

Inspectors also found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2). The HSE, as the undertaking for St. Luke's Hospital, Kilkenny should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulations.

Noting the areas for improvement noted in this section, inspectors did not identify any significant risks regarding the conduct of medical exposure to ionising radiation of service users on the day of inspection at St. Luke's Hospital, Kilkenny.

### Regulation 8: Justification of medical exposures

On the day of inspection, all records of referrals reviewed were in writing and stated the reason for the medical radiological procedure. Inspectors spoke with staff and management about the justification process and found that justification in advance was carried out by a practitioner. However in clinical areas where the record of justification was not recorded using a Radiology Information System (RIS), such records were not retained as required by the regulations. This was acknowledged by management at the hospital during the inspection.

Additionally, policies and procedures reviewed did not fully align with day-to-day practices communicated to inspectors regarding the justification of procedures in fluoroscopy. Inspectors were informed that justification of fluoroscopy procedures was carried out by a radiographer. However, the *Understanding NIMIS vetting and Procedure for the justification of X-rays for acute and outpatient referrals at St. Luke's Hospital Kilkenny* documents stated that a consultant radiologist was the practitioner with clinical responsibility for carrying out this role. Documentation should clearly identify the allocation of roles and responsibilities to ensure that day-to-day practices and local policy accurately reflect each individuals' scope of practice locally.

St. Luke's Hospital, Kilkenny provided information leaflets about the benefits and risks associated with the radiation dose associated with medical radiological procedures to patients in advance of their appointment which was identified as an area of good practice. Additionally, this information was also available on posters were also available in the waiting areas.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

Inspectors found that DRLs for medical radiological procedures were established, regularly reviewed and used at the hospital. However, on review of documentation provided to inspectors in advance of the inspection, an inconsistency in the grouping of paediatric DRLs to national guidance was identified. The hospital should ensure that local DRLs are established in a manner consistent with the specific weight groupings used for the national DRLs to allow for a meaningful comparison of dose.

Inspectors were satisfied however that St. Luke's Hospital, Kilkenny had conducted reviews and implemented appropriate corrective actions where the radiation doses for a medical radiological procedure was identified as consistently exceeding the established local DRL for that procedure.

Judgment: Substantially Compliant

## Regulation 13: Procedures

On the day of inspection, inspectors were satisfied that written protocols were established for standard medical radiological procedures. However, when reviewing the documentation which was available in hardcopy, inspectors noted that protocols were in both typed and hand-written formats. While protocols were available, the hospital should review their document management processes to ensure that such protocols are managed in a controlled manner to reflect version history, approval and updated changes. The hospital should consider conducting systematic reviews and updating of protocols, with involvement of appropriate staff, which would provide a assurances that all medical radiological procedures are optimised.

Inspectors found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2). The HSE, as the undertaking for St. Luke's Hospital, Kilkenny, should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulations.

A programme of clinical audit was established and inspectors reviewed a sample of clinical audits conducted at the hospital. Referral guidelines for medical imaging were also available for referrers on hospital computers.

Judgment: Substantially Compliant

## Regulation 14: Equipment

Inspectors reviewed documentation and records and spoke with staff and management at the hospital. An up-to-date inventory of equipment was also provided to HIQA in advance of the inspection. On the day of inspection, an appropriate QA programme had been implemented at St. Luke's Hospital, Kilkenny which included an assessment of radiation dose. Annual QA testing was carried out by an MPE and records reviewed also demonstrated that acceptance testing was carried out before the first clinical use of the equipment.

While a policy was in place outlining performance testing which should be carried out on a regular basis, inspectors found that this policy was not up-to-date and did not fully align with current practice. For example, the *In-House Quality Assurance Checks* policy indicated that the fixed fluoroscopy performance testing protocol was not currently implemented, however staff informed inspectors that regular performance testing of the fluoroscopy equipment was carried out. Additionally, inspectors were also informed that in some instances regular performance testing was delayed due to ongoing issues external to the hospital, for example the recent cyberattack.

On the day of inspection, some medical radiological equipment at the hospital was identified as being past nominal replacement dates. Inspectors also reviewed records of equipment downtime and noted that the equipment in question was listed as part of the national equipment replacement scheme. This has been escalated by hospital management to the HSE, and some interim measures had been put in place. The introduction of a prospective equipment replacement programme by the undertaking for medical radiological equipment would be a positive measure which would provide an additional assurance to the HSE, as the undertaking, of further optimisation of medical exposures in line with the technological advancements in medical radiological equipment.

Judgment: Substantially Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Due awareness for the protection of pregnant women was in place at the hospital through the use of multilingual public notices in appropriate places, such as in the waiting area. Inspectors were also satisfied that a referrer or practitioner inquired regarding pregnancy status and recorded the answer to the inquiry in writing. However, a sample of records of the answer to the inquiry were reviewed on the day of inspection and inspectors found that the answer was not recorded in line with local hospital policy. This finding had been identified by local management and was consistent with the outcome of previously conducted clinical audits which were reviewed on the day.

Judgment: Substantially Compliant

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

St. Luke's Hospital, Kilkenny had arrangements in place to record and analyse accidental and unintended exposures to ionising radiation. However, inspectors spoke with staff and management and found that the reporting and analysis of potential accidental and unintended exposures to ionising radiation was an area for improvement at the hospital.

The consistent recording and trending of potential accidental and unintended exposures offers an opportunity for learning and would assist management in identifying and taking appropriate measures to minimise the probability and magnitude of actual incidents. In addition, the hospital could improve evidence of reporting and put in place arrangements to increase staff awareness of reporting and opportunities to record potential accidental and unintended medical exposures to ionising radiation.

Judgment: Substantially 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
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

# Compliance Plan for St Lukes General Hospital - Kilkenny OSV-0007376

Inspection ID: MON-0030756

Date of inspection: 28/09/2021

## 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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiation Protection will now be routinely discussed by the RSM at each QSEC meeting starting immediately. The Radiation Protection of the service user will be on the standing agenda.</p> <p>The Radiation Safety Committee terms of reference will now include the designated manager to be represented by a senior member of management if the designated manager is unable to attend.</p> <p>There will be an education piece for Radiographers on the justification policy with a specific focus on the justification of Fluoroscopy examinations and other high dose examinations. Timeline is 4 weeks (10 December 2021)</p> <p>Documentation will be reviewed to demonstrate clear allocation of roles and responsibilities to ensure that day to day practice accurately reflects each individual scope of practice. This will be augmented by an education piece as part of shared learning. Timeline to be completed in is 4 weeks (10 December 2021)</p> <p>There is a document control system currently under review by the undertaking.</p>	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: The service level agreement is currently under review by the undertaking. Timeline</p>	



10/02/2022

Regulation 8: Justification of medical exposures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:

This quality improvement plan will result in the permanent record of justification of the radiological examination. Timeline 10/12/2021. This will be achieved by recording that the justification process has occurred on RIS or by scanning in the document. This will be measurable via audit. The Audit will be carried out after 3 months (10 March 2022) and be retrospective.

The second QIP within this regulation will be an education piece for all staff on the justification process for Fluoroscopy procedures. The justification protocol documentation will emphasise this. The timeframe for this QIP to be implanted is by the 10th of December 2021.

Regulation 11: Diagnostic reference levels

Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

This QIP will result in the grouping of paediatric DRLs consistent with the specific weight groupings used for the national DRLs to allow for a meaningful comparison of dose. This process is currently being reviewed by a Radiographer for general x-rays and Fluoroscopy procedures, and CT.

Going forward, the weight of all children under 16 will be required as part of the requesting information prior to the examination. This will apply to all CT and Fluoroscopy examinations. This will apply to chest x-rays, abdomen x-rays, Spine x-rays, humeri, and femurs.

We aim to have the required numbers to form local DRLs in 6 months ( 10 May 2022)

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:  This QIP will result in the elimination of hand written protocols. These will be replaced with typed protocols. These protocols will include version history, approval and updated changes. All protocols will be available on a shared G drive for all staff to see. A recording system will be put in place to ensure all protocols are reviewed and updated at the right time. The time frame for this is 3 months (10 February 2022).  There is a document control system currently under review by the undertaking.</p> <p>The undertaking is currently investigating how to add a comment relating to the dose received by the patient to the final report. Timeline is 16 May 2022.</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:  The in-house Quality Assurance Checks protocol for performance testing will be reviewed and updated by the MBE. Timeline 8 weeks (11 January 2022)</p> <p>There is a prospective equipment replacement programme in place and the equipment in question is on the priority list for being replaced. Timeline Ongoing</p>	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:  There will be an education piece on the LMP documentation and form. Timeline is 4 weeks (10 December 2021). This will be monitored and reviewed by Audit, Timeline 12 weeks (4 February 2022)</p>	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: Education piece for all staff on the recording and trending of potential accidental and unintended exposures will be facilitated as part of ongoing shared learning of Radiation Safety within the department. Timeline 4 weeks (10 December 2021)</p>	

## 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	10/12/2021
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any	Substantially Compliant	Yellow	10/12/2021

	medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Orange	10/12/2021
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	16/05/2022
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for	Substantially Compliant	Yellow	10/02/2022

	each type of equipment for relevant categories of patients.			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	16/05/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	16/11/2021
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	11/01/2022
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years	Substantially Compliant	Yellow	10/12/2021

	and provide such records to the Authority on request.			
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	10/12/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	10/02/2022