



**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:	Limerick Clinic
Undertaking Name:	Galway Clinic Doughiska Unlimited
Address of Ionising Radiation Installation:	Raheen, Limerick
Type of inspection:	Announced
Date of inspection:	15 August 2024
Medical Radiological Installation Service ID:	OSV-0007394
Fieldwork ID:	MON-0042306

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

The Limerick Clinic is under the governance of Galway Clinic Doughiska Unlimited. The clinic provides X-ray, Ultrasound and Magnetic Resonance Imaging (MRI) services. The MRI service is complimented by the availability of complimentary X-ray service for pre MRI screening. X-ray imaging is performed on referrals from the consultant rooms, the adjoining VHI Swiftcare facility and general practitioners. In 2023 there were 10, 619 X-ray procedures performed at Limerick Clinic

## How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector<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:

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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.

## **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
Thursday 15 August 2024	09:30hrs to 13:50hrs	Emma O'Brien	Lead
Thursday 15 August 2024	09:30hrs to 13:50hrs	Kay Sugrue	Support

## Governance and management arrangements for medical exposures

Inspectors completed an inspection of the medical radiological services at Limerick Clinic on 15 August 2024, to follow up on the compliance plan actions from the previous inspection on 21 January 2020, and to also assess the undertaking's ongoing compliance with the regulations. During this inspection, inspectors visited the general radiography X-ray room in this facility.

On the day of the inspection it was evident that the Galway Clinic Doughiska Unlimited, as the undertaking, had implemented measures to address the gaps in compliance identified during the previous inspection, to comply with Regulations 4, 6, 8 and 13. However, during this inspection, inspectors identified gaps in compliance with Regulations 10, 11 and 17 and further gaps under Regulation 6.

Inspectors observed that since the previous inspection in January 2020, the undertaking, Galway Clinic Doughiska Unlimited, had strengthened governance and management arrangements, to improve oversight of the radiation protection measures in the service provided at Limerick Clinic. From a review of documents and from speaking with staff on the day of the inspection inspectors were satisfied that there were appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day to day operations in the facility up to the undertaking.

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

The inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures and were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

While inspectors acknowledged the strengthened governance and management arrangements since the previous inspection, further improvements are required to ensure that all aspects of the clinical responsibility of a practitioner are appropriately allocated to the correct group of professionals as required by Regulation 10(1). Also, improved oversight by the undertaking of the establishment and review of diagnostic reference levels (DRLs) is required in order to meet compliance with the requirements of the regulations.

## Regulation 4: Referrers

From discussions with staff in the radiology department in Limerick Clinic and from the sample of records reviewed, inspectors were satisfied that Limerick Clinic only accepted referrals from appropriately recognised referrers. In addition to medical practitioners, radiographers and advanced nurse practitioners were also considered referrers in this facility. The specific circumstances in which radiographers could act as secondary referrers was clearly outlined in local policies and articulated to inspectors by staff. Information identifying individual nurse referrers and their scope of practice was observed by the inspectors and this information was made available to the relevant staff in the clinical area.

Judgment: Compliant

## Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures at Limerick Clinic.

Judgment: Compliant

## Regulation 6: Undertaking

Documentation reviewed by the inspectors prior to and during the inspection demonstrated that there were clear lines of communication within the clinical governance and management structures in Limerick Clinic. These documented arrangements aligned with those described by staff to the inspectors. The radiation protection unit (RPU) was responsible for communication and discussion on all day to day matters relating to radiation safety and legislation compliance. This forum met quarterly and was attended by the radiation services manager (RSM) from Limerick Clinic, the departmental radiation protection officer (RPO), the head of physics, the MPE and it was chaired by the lead RPO. Items such as staff training, clinical audits, equipment QA and incidents were among the issues considered by the RPU. The RPU subsequently reported into the radiation safety committee (RSC).

The RSC provided oversight for radiation protection arrangements in the service, and met twice a year to discuss items such as radiation safety incidents, clinical audit and the radiological equipment quality assurance programme. Inspectors noted that these meetings were attended by the radiology clinical director, the allied health executive, the lead RPO, departmental RPO's, the RSM, MPE's, the QPS coordinator, and the chief executive officer (CEO), who was the undertaking representative. Inspectors also reviewed other documentation that evidenced well

established lines of communication from the RSC upwards, via the clinical governance committee, to the board of directors. Inspectors were satisfied that issues relating to the radiation protection of service users were escalated appropriately and managed effectively. For example, inspectors viewed minutes from a clinical governance committee meeting where an issue in relation to radiation protection training of staff was escalated from the RSC. This issue was discussed by the executive management team and a quality improvement plan agreed at the meeting to address the issue.

Despite these strengthened governance and management structures, inspectors noted that improvements were required in the allocation and oversight of roles and responsibilities in some areas of radiation protection within the service. For example; although inspectors were assured that only those entitled to act as a practitioner as per the regulations took clinical responsibility for individual medical exposures, not all aspects of the clinical responsibility of a practitioner had been allocated by the undertaking, specifically the clinical evaluation of the outcome of the exposure. The allocation of all aspects of clinical responsibility of a practitioner must be reviewed and allocated appropriately to ensure the radiation protection of service users. Additionally, inspectors were not assured that the undertaking had appropriate arrangements in place to ensure that the establishment and regular review of DRLs was completed by staff responsible for this task. DRLs must be established for all common radiological procedures and regularly reviewed to ensure that they are contributing to dose optimisation for adult and paediatric patients undergoing a medical exposure of ionising radiation.

Improvements in the document quality management arrangements were also required to ensure that the procedures and protocols available to staff in the department were regularly reviewed and, when required, updated by the appropriate personnel. For example, and as discussed under Regulation 8, the justification policy should be updated to outline the process of justification for all systems in use at Limerick Clinic.

Overall, despite areas for improvement in relation to the allocation and oversight of roles and responsibilities and document management, inspectors were satisfied that a culture of radiation protection was embedded at Limerick Clinic to ensure the radiation protection of service users.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

Inspectors were satisfied on the day of the inspection that the justification process of individual medical exposures involved the practitioner and the referrer and that the optimisation process involved the practitioner and the MPE.

However, as discussed under Regulation 6, inspectors were not assured that all aspects of the clinical responsibility of a practitioner, specifically the clinical evaluation of the outcome of the medical exposure, had been appropriately allocated to the correct group of professionals. As discussed with management staff on the day of the inspection the professionals recognised as a practitioner at Limerick Clinic should be reviewed to ensure that all aspects of the clinical responsibility of a practitioner are allocated by the undertaking and are being completed by the most appropriate individuals.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Limerick Clinic.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors viewed the professional registration certificate of the MPE engaged by the undertaking to provide specialist advice to Limerick Clinic, as appropriate, on matters relating to radiation physics, and this met the requirements of Regulation 20(1). Evidence viewed in documentation and discussions with staff demonstrated to inspectors that the MPE fulfilled a range of responsibilities as per Regulation 20(2) relevant to the practice. These included optimisation, QA of medical radiological equipment and training of practitioners.

Judgment: Compliant

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

Inspectors were satisfied that the MPE was appropriately involved in Limerick Clinic, and that the level of involvement was commensurate with the level of radiological risk posed by the service.

Judgment: Compliant



## Safe Delivery of Medical Exposures

Inspectors visited the general x-ray unit, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Limerick Clinic. While Regulations 8, 13, 14 and 16 were compliant, inspectors noted that there was further work required to bring Regulations 11 and 17 into full compliance.

In relation to Regulation 8, inspectors found that improvements had been made since the previous inspection to ensure that justification in advance is recorded and that previous diagnostic imaging is routinely checked for all patients undergoing medical exposure to ionising radiation. A review of records on the day of inspection showed that there was a written referral from a recognised referrer for each medical radiological procedure which contained sufficient clinical information to inform justification in advance by a practitioner. Pregnancy enquiries were made by a practitioner in advance of each examination, documented and uploaded onto the electronic system demonstrating compliance with Regulation 16.

Inspectors were satisfied that written protocols were available for every type of standard medical radiological procedure for both adults and paediatrics and that information relating to patient exposure formed part of the report of the medical radiological procedure. Good practices were evident in relation to the conduct of clinical audit in this service and inspectors acknowledged the work that had been done to implement the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*.

In relation to Regulation 14, the evidence gathered by inspectors demonstrated that staff at this facility ensured that the strict surveillance of medical radiological equipment in use was maintained in line with the QA programme established by the MPE.

Even though inspectors were satisfied that all reasonable measures are taken at Limerick clinic to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure and that an appropriate system for the recording and analysis of these events was in place, improvements are required to ensure that events that have the potential to involve accidental or unintended exposure are recorded and managed.

Inspectors noted that although local facility DRLs had been established for common adult radiological procedures performed at Limerick Clinic there was no evidence to suggest that appropriate reviews were being carried out, where for a given examination or procedure, doses exceeded previously established local DRLs. Additionally, while paediatric x-ray procedures were routinely performed at Limerick Clinic, paediatric DRLs had not been established. The process for establishing and reviewing local DRLs for all radiodiagnostic examinations, for both adults and

paediatrics, must be addressed by the undertaking to ensure the optimisation of these procedures and regulatory compliance of the service.

Notwithstanding the gaps identified under Regulations 11 and 17, inspectors were satisfied that systems were in place to support the safe delivery of medical exposures in this service.

## Regulation 8: Justification of medical exposures

On the day of the inspection, all referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data to enable the practitioner to adequately consider the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of information leaflets and posters in waiting areas.

Inspectors observed that since the previous inspection, two prompts had been added to the radiology information system (RIS) for staff to confirm that justification has been completed and that previous diagnostic imaging has been sought in advance of a medical radiological procedure. This was identified as an effective improvement initiative as all records viewed on the day showed a record of justification in advance by a practitioner and that previous diagnostic information had been sought to avoid unnecessary exposure.

While meeting the requirements of this regulation, inspectors noted that the *Justification of the use of ionizing radiation in radiology* policy only included the process for recording the justification of individual medical exposures received from internal referrers. A separate system and different process were used for recording justification from external referrers which was not included in local policy and therefore this omission, as detailed under Regulation 6, should be addressed to provide clarity for all staff involved in the justification process.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

Inspectors observed that DRLs had been established for common adult radiological procedures completed at Limerick Clinic, and were comparable to national DRLs, where established, and displayed in the clinical area. However, while no local facility DRLs exceeded national diagnostic reference levels there was a protracted delay in the MPE's annual review, namely DRLs established in January 2024 were not signed off by the MPE until June 2024.

Additionally, the *Recording of Patient Doses from Radiology Procedures* document outlined that for any local DRLs that exceed national DRLs or previously established local DRLs an investigation should be undertaken by the MPE. However, through a review of local facility DRLs inspectors noted that some of the 2023 DRLs for a number of procedures were trending upwards from the previous year and there was no evidence on the day of inspection that this upward trend had been acknowledged and was being investigated. In order to ensure that appropriate reviews and corrective actions, where necessary, are taken without undue delay the undertaking must ensure that DRL reviews are completed in a timely manner.

Inspectors were informed that paediatric x-ray procedures were regularly performed at Limerick Clinic, however, paediatric DRLs had not been established. In order to reach compliance with Regulation 11(5), and assist staff in optimising the radiation protection of paediatric patients who are subject to medical exposures at this facility, paediatric DRLs should be established and reviewed regularly.

Judgment: Not Compliant

### Regulation 13: Procedures

Since the previous inspection in January 2020, inspectors noted that the undertaking had implemented a number of improvements to meet the requirements of Regulation 13. In addition to standard adult medical radiological procedures, written protocols for standard paediatric radiological procedures had been established and were available to staff in the clinical area. Limerick Clinic had also implemented an interim measure to meet the requirements of Regulation 13(2) and inspectors observed that information relating to the patient exposure formed part of the reports viewed on the day of the inspection. Inspectors were also satisfied that referral guidelines were available as required by Regulation 13(3).

Inspectors acknowledged the significant work that had been done by the undertaking to implement the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*. Inspectors viewed the *Radiation Services Clinical Audit Strategy 2024* and minutes from the recently developed radiation services audit strategy group and were satisfied that the undertaking had implemented an effective framework for clinical audit in this facility. Inspectors viewed a number of clinical audits that were ongoing and complete at Limerick Clinic, including quarterly LMP audits and radiographer peer review audits. Inspectors were also informed that a clinical audit had recently been initiated after a trend in inadequate or incorrect information on referrals had been observed by staff. The use of clinical audit to drive improvement in the radiation protection of service users was identified as an area of good practice in the service.

Judgment: Compliant

## Regulation 14: Equipment

Inspectors were satisfied that an appropriate QA programme was in place to ensure that medical radiological equipment at Limerick Clinic was kept under strict surveillance. An up-to-date inventory was provided to inspectors as requested in advance of the inspection. Limerick Clinic had implemented a quality assurance programme which included an annual quality assurance assessment by the MPE and monthly and quarterly testing of the equipment by the departmental RPO.

Inspectors viewed the *Equipment Maintenance and Quality Assurance in Radiology* policy and noted that QC test results that are unusual or out of tolerance should be reported to the medical physics department and recorded in the QA master spreadsheet. On the day of inspection inspectors saw evidence that this policy was being adhered to and that performance issues with the medical radiological equipment was actioned immediately and addressed by the MPE. This oversight provided assurance to the inspectors that the medical radiological equipment at Limerick Clinic was maintained in good working condition.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

In advance of this inspection, inspectors viewed the *Policy on Irradiating Female Patients of Child Bearing Age* which outlined specific staff responsibilities, for example, the practitioner role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. Inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors observed information posters in the waiting area of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

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

Inspectors observed that the process for reporting radiation incidents was outlined in detail in the *Radiation Safety Procedures* document. Staff demonstrated awareness of this process and of their individual role in the incident management pathway. Minutes from the RPU and RSC meetings reviewed demonstrated that incidents were discussed as a standard agenda item. Inspectors were assured from the evidence gathered that measures were taken to minimise the probability and

magnitude of accidental and unintended exposures of individuals subject to medical exposure.

From discussions with staff inspectors were made aware of an ongoing issue with incorrect or inadequate information on a significant number of referrals sent into the service. While staff were aware of this trend, and a clinical audit had recently been initiated to address this issue, the individual instances of these near misses were not being captured on the incident management system.

While inspectors were satisfied that a system was implemented for the record keeping and analysis of events involving accidental or unintended medical exposures, improvements are required to ensure that all potential incidents and near misses are recorded so that early risk management actions can be implemented and the risk of potential harm to the patient minimised.

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, as amended. 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	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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

# Compliance Plan for Limerick Clinic OSV-0007394

Inspection ID: MON-0042306

Date of inspection: 15/08/2024

## 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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <ul style="list-style-type: none"> <li>• All relevant policies have been updated to provide clear allocation of responsibilities for the protection of patients. The definition of clinical responsibility, which includes clinical evaluation of outcome, has been added and policies edited to identify the following as practitioners 'Radiographers, Radiologists, Cardiologists, Surgeons and Pain specialists.</li> <li>• The 'policy on recording of patient's doses from Radiology Procedures' has been updated to add a timeline for review and sign off. The responsibilities section has been edited to add-The MPE and Lead RPO are responsible for ensuring DRLS are reviewed and signed off within the required time frame.</li> <li>• The specific justification process for VHI patients in Limerick Clinic has been added to the 'Justification of the use of ionising radiation in Radiology' policy.</li> <li>• The Radiation Safety Procedure document has been updated to add that procedures and protocols available to staff in the department are to be reviewed by RSM, lead RPO and MPE on an annual basis and updated when necessary.</li> <li>• All Radiology staff have been informed of these updates.</li> </ul>	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities:	



- All relevant policies have been updated to provide clear allocation of responsibilities for the protection of patients. The definition of clinical responsibility, which includes clinical evaluation of outcome, has been added and policies edited to identify the following as practitioners 'Radiographers, Radiologists, Cardiologists, Surgeons and Pain specialists.

Regulation 11: Diagnostic reference levels	Not Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

- Paediatric DRLS have been calculated for 2023 and will be reviewed annually.
- The 'policy on recording of patient's doses from Radiology Procedures' has been updated to add a timeline for review and sign off DRLs. The responsibilities section has been edited to add-The MPE and Lead RPO are responsible for ensuring DRLS are reviewed and signed off within the required time frame.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

- A communication has been sent to all radiographers informing them of the need to ensure that all potential incidents and near misses (as well as incidents) are reported on Q pulse. The HCI knowledge portal is installed on each PC for ease of access.

## 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	15/10/2024
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	15/10/2024

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.	Not Compliant	Orange	15/10/2024
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Substantially Compliant	Yellow	15/10/2024
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping	Substantially Compliant	Yellow	15/10/2024

	and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			
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