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:	University Hospital Kerry
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Rathass, Tralee, Kerry
Type of inspection:	Announced
Date of inspection:	05 June 2024
Medical Radiological Installation Service ID:	OSV-0007357
Fieldwork ID:	MON-0042265

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

The Radiology Department in the University Hospital Kerry (UHK) provides a diagnostic imaging service to in-patients, out-patients, the Emergency Department (ED) and Acute Medical Assessment Unit, Orthopaedic Theatre, and access to general practitioners (GPs). Radiology services play a pivotal role in the provision of healthcare diagnostics in the hospital. The hospital provides a 24/7 service 365 days a year for ultrasound, computed tomography (CT), X-rays and interventional procedures, fluoroscopy cases and theatre emergencies. A standard working week is 9am-5pm Monday-Friday, but continual out of hour's service is provided by both radiologists and radiographers (on-site). There is a 24 hour emergency on-site "on-call" radiographer in-house service arrangement for both the general radiography examinations and CTs to facilitate hospital in-patients and the ED. The department offers an appointment system for GP access to diagnostic imaging, general x-ray and ultrasound imaging. GPs have access to radiology via electronic system Health link. Routine referrals aim to have a wait time of four weeks, and all urgent referrals are accommodated within one to two weeks.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

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

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 5 June 2024	09:30hrs to 14:45hrs	Kay Sugrue	Lead
Wednesday 5 June 2024	09:30hrs to 14:45hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

An inspection was carried out at University Hospital Kerry (UHK) on 5 June 2024 to assess compliance against the regulations. On the day of inspection, inspectors reviewed documentation and records and spoke with staff working in different modalities within the radiology department.

Inspectors reviewed the governance and management arrangements in place to ensure good oversight of the radiation protection of service users and found that the radiology governance structure remained largely unchanged since the previous inspection in 2022. The hospital's radiology governance structure included the radiation safety committee (RSC), the radiology governance group (RSG), and various sub-committees and working groups. These forums ensured issues and risks associated with the radiology service were communicated effectively up to the executive management board UHK, the UHK general manager (GM) and upwards to the undertaking at the Health Services Executive (HSE). Inspectors noted that, similar to the previous inspection, the chair of the RSC was not filled by a consultant radiologist in line with the terms of reference of this committee. Management informed inspectors that this was due to resource deficiencies which were also evident during the previous inspection. Staff identified to inspectors that additional resources, once in place, should provide greater support to staff and quality assurance for the service. While some progress has been made, management informed inspectors that work continued towards improving resources and a plan to improve the radiology service delivery model and operational function of the radiology service was underway.

From the evidence gathered, inspectors found that all medical exposures took place under the clinical responsibility of a practitioner and were only carried out on the basis of a referral from a recognised referrer in line with the regulations. The undertaking had ensured that medical physics expert (MPE) responsibilities were appropriately allocated to a medical physicist for this facility and continuity arrangements of medical physics expertise had been improved since the previous inspection and now met the requirements of Regulation 19(9).

While many aspects relating to the allocation of responsibilities were in place, some improvements were required. For example, improvement regarding the allocation of responsibility for monitoring compliance with Regulation 13(2) and Regulation 8 was identified by inspectors. In addition, the process for justification should be clear to all staff and individuals allocated with responsibility for completing justification in day-to-day practice in line with hospital procedures.

Non-compliances identified during this inspection related to gaps in documentation and did not pose a patient safety risk. Inspectors noted that staff at the hospital were committed to the radiation protection of service users and had implemented

corrective actions to improve compliance following the inspection carried out in 2022.

Regulation 4: Referrers

Inspectors found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at University Hospital Kerry. From discussions with radiology staff and records viewed by inspectors, referrers were clearly identifiable in each of the referrals reviewed.

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 at University Hospital Kerry.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation that outlined the radiation protection governance arrangements at University Hospital Kerry, in addition to speaking with staff and management. The radiation safety committee (RSC) in place reported into the radiology governance group (RGG), which in return reported to the hospital's quality and patient safety committee. Inspectors were informed that a member of the senior hospital management team attended both the RSC and RGG which was verified in minutes viewed. Inspectors noted additional committees and working groups in place within the radiology governance structure which were described by management as useful and effective to ensure there was adequate oversight of the radiation protection of service users. These communication pathways ensured that issues relating to the radiation protection of service users were being communicated upwards to the hospital's executive management board, the general manager who was also the designated manager, the hospital group and finally the undertaking at Health Services Executive (HSE) level.

Minutes viewed from the various committees and working groups within the radiology governance structure showed that there was improvement in multidisciplinary attendances at these forums since the previous inspection. However, similar to a finding from 2022, the RSC was not chaired by a consultant radiologist in line with the hospital's terms of reference. Staff informed inspectors

that the radiation protection officer generally chaired this forum in the absence of a clinical lead for the radiology service. This meant that the action outlined in the compliance plan submitted following the last inspection to address this issue had not been completed. Management informed inspectors that despite multiple recruitment initiatives taken to fill this position and increase on-site consultant radiologists resources, radiologist resources remained below approved levels for the hospital. At the time of this inspection, the hospital remained heavily reliant on outsourced radiology reporting and on-call support which has remained unchanged since the previous inspections. The lack of a clinical lead in radiology was recorded on the hospital's risk register and escalated appropriately via established reporting lines and management at the hospital continued to work towards addressing resource issues identified in this service.

In relation to the allocation of responsibilities, inspectors found that referrals were only accepted from individuals recognised under Regulation 4. Similarly, medical exposures carried out at the hospital took place under the clinical responsibility of a practitioner as per the regulations. Management at the hospital had also established practices to ensure a radiographer was present for all medical exposures conducted in this facility. A suite of policies, procedures, guidelines and protocols were available to staff that outlined individual roles and responsibilities in relation to medical radiological practices and the radiation protection of service users. Formal arrangements were in place by the undertaking to ensure the continuity and appropriate involvement of MPE advice and input for medical radiological practices. While noting that many aspects relating to the allocation of responsibilities for medical exposures to ionising radiation were met, some improvements were required to comply with Regulation 6(3).

Inspectors found that the since the last inspection, management had implemented corrective actions to address the non-compliances identified. However, despite the actions taken to comply with Regulation 13(2) since previous inspections, compliance with this regulation remained an issue. Staff at the hospital were not aware that the solution implemented at the hospital to ensure that information relating to patient exposure formed part of the report as required by Regulation 13(2) had not been consistently applied in each setting within the service. Inspectors found that the allocation of responsibility for monitoring compliance with this regulation should be clearer, and improved, to ensure the solution provided at the hospital is consistently applied in each report as per the regulations. Additionally, the allocation for justifying computed tomography (CT) cardiology procedures, as discussed under Regulation 8, did not fully align with the hospital's procedure for justifying procedures in the CT setting. Therefore, the allocation of responsibility for justifying these procedures should be reviewed to ensure that day-to-day practices are consistent with documented procedures.

While noted that improvements were required as outlined above, inspectors were satisfied that the appropriate personnel were carrying out radiation protection measures and that service users in the radiology department received safe exposures of ionising radiation.

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. The practical aspects of medical radiological procedures were only carried out in this facility by persons entitled to act as practitioners as per the regulations. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposures to ionising radiation. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Following a review of documentation and discussion with staff and management, inspectors were satisfied that management at University Hospital Kerry had taken further action to ensure the continuity of medical physics expertise at the hospital as required under Regulation 19(9). Continuity of medical physics expertise at the hospital was available through arrangements made with both the Cork University Hospital (CUH) group and a private MPE resource. These arrangements had been maintained and strengthened since the 2022 inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed professional registration certificates of the medical physicists providing specialist advice on matters relating to radiation physics, documentation and spoke with staff including the medical physicist to assess compliance with this regulation.

From the evidence gathered, inspectors were satisfied that MPE responsibilities had been allocated in line with those set out under Regulation 20 and covered a range of responsibilities across the radiological service. For example, documentation showed that a medical physicist carried out acceptance testing of all new equipment installed and commissioned since 2019 and provided advice on medical radiological equipment. Annual QA of equipment was also performed by a medical physicist. There was documentation to demonstrate MPE involvement in the development of

diagnostic reference levels (DRLs) and associated reviews as required. Evidence viewed showed MPE involvement in optimisation, staff training on radiation protection and advice, dose calculation for radiation incidents and attendance at RSC and radiation protection compliance group meetings. In addition, from discussions with the medical physicist on the day, it was clear to inspectors that there was regular engagement between the private and CUH medical physicists. There was also regular communication with the radiation protection advisor (RPA) at CUH as required under Regulation 20(3).

Judgment: Compliant

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

From the evidence gathered during the review of documentation and speaking with staff and the medical physicist, inspectors were satisfied that the level of MPE involvement was proportionate to the radiological risk posed by the service provided at this facility, as per the regulations.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited several clinical areas including general radiography, the fluoroscopy room, CT and dual energy X-ray absorptiometry (DXA) services within the radiology department at the hospital. In addition, inspectors spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at University Hospital Kerry. Since the previous inspection, corrective actions implemented resulted in compliance with Regulation 11. Inspectors also found Regulations 9, 14 and 16 were compliant and Regulation 17 was sub-compliant. Despite the measures implemented to achieve compliance with the regulations and the associated improvements observed by inspectors, further action was required to achieve compliance with Regulations 8 and 13.

From the evidence gathered, inspectors noted that compliance with Regulation 11 had improved and staff provided examples of how facility DRLs were reviewed appropriately when found to be consistently above national DRLs. Inspectors noted that there was a strong commitment demonstrated by staff towards the optimisation of medical exposures and the radiation protection of service users. The evidence gathered demonstrated compliance with Regulation 9. Good practice was seen regarding Regulation 16 where there was evidence to show that appropriate inquiries were made by a practitioner to establish and record the pregnancy status

of individuals to whom this regulation applies. Inspectors were satisfied that medical radiological equipment was kept under strict surveillance in line with Regulation 14.

The hospital had implemented a solution to comply with Regulation 13(2) which was evident in the majority of medical radiological procedure reports viewed by inspectors in the areas visited. This demonstrated that progress had been made to come into compliance, however a sample of reports viewed did not contain information relating to the patient exposure. Consequently, despite efforts made by staff at the hospital to comply with this regulation, it remains an ongoing issue since it was first identified in the 2021 inspection.

In relation to Regulation 8, inspectors noted that justification in advance was not consistently recorded in some medical radiological records viewed. Therefore, greater assurance and more action is needed to ensure that all individual medical exposures carried out at the hospital are justified in advance and that records evidencing this are retained to achieve compliance with Regulations 8(8) and 8(15). Finally, while there was systems and processes at the hospital to identify and manage all radiation incidents, inspectors found the levels of reporting of incidents that do not meet reporting thresholds and near misses could be improved, given the levels of activity within this facility.

Overall, while noting that improvements were required to achieve full compliance with the regulations, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors visited several clinical areas during this inspection and reviewed medical radiological procedure records in each area visited. From a review of these records, inspectors found that corrective actions implemented to comply with Regulation 8 since the last inspection had not achieved the expected outcome as non-compliances against Regulations 8(8) and 8(15) were again identified. Justification in advance of a procedure by a practitioner was not consistently evident to inspectors in records of medical radiological procedures performed in the DXA and theatre fluoroscopy services.

Hospital procedures outlined the process for the justification of CT procedures. This was described as a joint approach to justification performed in two steps where firstly, the radiologist protocolled the procedure at the vetting stage and secondly, the radiographer completed the final justification in advance of the procedure. The records showed that while justification by a radiographer was evident in the samples viewed, vetting by a radiologist was not consistently documented and in some records was completed by an individual other than a radiologist. This did not align with local procedures viewed by inspectors.

Inspectors noted that justification audit reports were regularly carried out across a range of services. The results achieved in these audit did not consistently demonstrate 100% compliance in the majority of areas audited. This was despite actions taken to address deficiencies identified in these audits. Furthermore, in discussions with inspectors, it was noted that not all staff were familiar with the justification process or the persons allocated with the responsibility for justifying medical radiological procedures.

Compliance with the process of justification is a regulatory requirement, therefore, the undertaking must ensure that monitoring of compliance with this regulation is improved to build staff awareness of the need to consistently adhere to the process of justification in line with hospital procedures and to meet regulatory requirements.

Judgment: Not Compliant

Regulation 9: Optimisation

From discussions with staff and a review of documentation, inspectors were satisfied that there were appropriate processes in place to ensure that the doses delivered for each individual medical exposure to ionising radiation were kept as low as reasonably achievable (ALARA) consistent with the intended outcome.

Hospital procedures viewed outlined the measures in place for each modality to ensure that the medical radiological procedures in the service were optimised. These included but were not limited to collimation, the selection of the appropriate imaging protocol, accurate positioning of the patient prior to the procedure, regular QA of equipment and adjusting exposure parameters in consideration of individual patient characteristics. It was clear to inspectors following discussions with staff, that established facility DRLs were available to staff when carrying out medical radiological procedures and these were viewed in each of the control rooms visited. Corrective actions described under Regulation 11 demonstrated a proactive approach to reducing facility DRLs that were consistently above national DRLs.

During discussions with inspectors, staff described the multidisciplinary approach taken in developing protocols to optimise procedures and had cross referenced information with radiology staff in another acute hospital that has a similar CT scanner when developing CT protocols specific to University Hospital Kerry. This was noted as good practice by inspectors.

From the evidence gathered, inspectors were satisfied that staff were focused on the optimisation of medical exposures carried out in this facility to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Since the previous inspection, inspectors found that the undertaking had taken sufficient action to comply with this regulation. For example, facility DRLs for each modality were established and reviewed each year. In line with good practice, action had been taken by staff at the hospital, where sufficient data allowed, to establish weight-based paediatric facility DRLs for standard medical radiological procedures.

Inspectors were informed of measures implemented to address facility DRLs that exceeded national DRLs, including reducing the pulse rate on the C-arm in the orthopaedic theatre which resulted in a reduction to the dose associated with the procedure. Issues identified relating to higher than expected doses found in a recently installed orthopantomogram (OPG) unit were also investigated and required the inputted parameters to be revised to align with those provided by the manufacturer. The evidence provided following discussion and review of documentation demonstrated compliance with Regulation 11.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for adult and paediatric standard radiological procedures provided at University Hospital Kerry were available and viewed by inspectors. While found to be compliant with Regulation 13(1), it was noted by inspectors that protocols for DXA had recently passed the date for review and therefore should be updated to ensure they continue to align with best practice.

Inspectors saw evidence to show that the system implemented by the undertaking to ensure that dose information relating to patient exposure was included in the majority of medical radiological reports viewed. However, this was not the case in all reports viewed. Staff who spoke with inspectors were not aware that this information was not available on some of the reports. Noting ongoing gaps in compliance with respect of Regulation 13(2) in previous inspections, and despite actions taken to date, the undertaking must provide greater assurance that corrective measures taken to comply with the Regulation 13(2) are consistently applied by all staff.

Referral guidelines were available to staff on desktops at work stations located in each clinical area as per regulations.

Inspectors found that there was a clinical audit programme in place and work was underway to ensure that clinical audit practices aligned with the National Procedures published by HIQA.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided as requested in advance of the inspection which was verified by inspectors on the day. Documentation viewed by the inspectors provided evidence that quality assurance testing of the medical radiological equipment had been completed. However**,** inspectors found that contingency arrangements could be improved to ensure that the time lines detailed in the quality assurance (QA) programme are consistently met for each piece of equipment, particularly, for equipment where MPE access may be limited due to high activity levels in the service.

Acceptance testing and performance testing including maintenance and quality control checks of the equipment had been completed in line with Regulation 14(3). Inspectors viewed maintenance logs in the emergency department, general X-ray room and the CT control room that contained details and actions taken to address faults and issues relating to medical radiological equipment.

Overall, inspectors were satisfied that the medical radiological equipment at this facility was kept under strict surveillance as per Regulation 14(1).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Notices to raise awareness of the special protection to be applied for relevant service users who may be pregnant were observed in waiting areas and procedure rooms of each area visited by inspectors. Inspectors reviewed a sample of medical radiological procedure records for women of childbearing years across a range of modalities. The records showed an inquiry had been made in advance of each procedure by the practitioner which was signed by the service user confirming their pregnancy status. This record was uploaded and maintained on the radiology information system. The evidence demonstrated the undertaking's compliance with Regulation 16.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following a review of documentation and discussion with staff, inspectors found that significant events that met the threshold for reporting to HIQA were managed appropriately and reported in line with the timelines in HIQA guidance. There was also evidence in minutes of meetings viewed to show that radiation incidents were regularly discussed at committees within the radiology and hospital governance structures.

Although there was a system in place to record and analyse radiation incidents and potential incidents, the level of radiation incidents and near misses reported was quite low when considered in the context of the numbers of medical exposures carried out in the hospital each year. Therefore, inspectors found that reporting of potential incidents and near misses could be improved to comply with Regulation 17(1)(c).

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially 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 University Hospital Kerry OSV-0007357

Inspection ID: MON-0042265

Date of inspection: 05/06/2024

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: The hospital has amended the terms of reference for the radiation safety committee to appoint the general manager as the chairperson of the committee in the absence of a clinical lead for radiology. The hospital has written to staff informing them of their responsibility to include information relating to patient exposure in the radiology report. Furthermore, this activity will be included in the clinical audit schedule, reviewed by the RSC to ensure compliance with Regulation 13(2). The justification policy has been updated to include the cardiologist role and responsibility in justifying procedures in the context of cardiac CT to align with daily practice and comply with Regulation 8.	
Regulation 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: The justification policy has been reviewed and updated to include the following: DXA: All DXA referrals are vetted in advance using the vetting module on RIS by radiographers who have completed training in DXA. The justification process is performed by the radiographer for every patient and the radiographer must	

ensure all documents are scanned onto RIS.

Theatre: Radiographers will complete a justification form prior to the medical exposure which will then be scanned onto RIS.

CT: CT procedures are vetted by a radiologist or an entitled radiographer using the vetting module on the RIS. Cardiac CT procedures are manually vetted by the cardiologist and scanned onto RIS.

An information poster for staff on justification process and responsibility has been developed. This will be circulated to all staff and displayed in the clinical areas to improve staff awareness to consistently adhere to the process of justification. In addition, the undertaking will ensure monitoring of compliance is undertaken with increased audit activity.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:

The DXA protocols have been updated and will be reviewed at the next RSC meeting.

The hospital has written to staff informing them of their responsibility to include information relating to patient exposure in the radiology report. Furthermore, this activity will be included in the clinical audit schedule, reviewed by the RSC to ensure compliance with Regulation 13(2).

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

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

The policy on reporting of accidental and unintended exposures and significant events has been updated to include the reporting of all near misses.
All staff will be briefed on the necessity for reporting of near misses as well as incidents at the next staff meeting. This topic will be included in the audit schedule to allow monitoring of compliance by the undertaking.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/07/2024
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Not Compliant	Orange	31/07/2024

	specific objectives of the exposure and the characteristics of the individual involved.			
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	31/07/2024
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	31/07/2024
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	31/07/2024