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:	01 March 2022
Medical Radiological Installation Service ID:	OSV-0007357
Fieldwork ID:	MON-0035835

About the medical radiological installation:

University Hospital Kerry (UHK) is a Model 3 acute teaching hospital, providing comprehensive medical and surgical services for adults and children and maternity services to women in the surrounding catchment area. UHK serves a population of approximately 150,000 in Co. Kerry and additionally to a proportion of the populations of West Limerick and North Cork. In addition, the Kerry area has quite a large visiting population with approximately 2 million tourists visiting the region annually, principally during the summer months. Demographically the average age of the population is increasing, with 14% of the current population >85yrs and the average age is expected to rise in the category of >65yrs and >80yrs.

The Radiology Department in UHK provides a diagnostic imaging service to in-patients; out-patients; the Emergency Department and Medical Assessment Unit; the orthopaedic theatre; and direct access to General Practitioners (plain X-rays). UHK is a 377 bed hospital servicing Kerry and areas of Cork and Limerick. UHK provides 24 hr service for computed tomography (CT) imaging, general X-ray and theatre with 1 on-site CT and 1 on-site general radiographer during out of hours.

Modalities and services provided are:

- 2 CT scanners
- 3 Ultrasound Rooms
- 4 General X-ray rooms
- 1 Fluoroscopy Interventional suite
- 2 Image Intensifier in Theatre
- 1 dual-energy X-ray absorptiometry (Dexa) scanner
- 1 General x-ray room in Cahersiveen Community Hospital
- 1 Orthopantomography (OPG) Dental

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 1 March 2022	09:05hrs to 15:00hrs	Maeve McGarry	Lead
Tuesday 1 March 2022	09:05hrs to 15:00hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection took place at University Hospital Kerry (UHK) on 1 March 2022 to follow up on the outcomes of an inspection carried out on 28 July 2021. The previous inspection identified that considerable improvement was required with respect to radiology governance structures, MPE responsibilities and the level of MPE involvement within the service. This re-inspection focused on regulations which were previously deemed not compliant or substantially compliant, Regulations 6, 11, 20 and 21.

Inspectors found that progress had been made since the last inspection in relation to clarification of the governance structures and representation at governance meetings. A revised organogram reviewed by inspectors outlined that the Radiation Safety Committee (RSC) reported into the Radiology Governance Group, which in turn reported into the hospital Quality and Patient Safety Committee. An additional Radiation Protection Compliance Committee was recently established as an operational sub-committee of the RSC. Inspectors were informed that this group met monthly, as the twice yearly RSC meetings were deemed too infrequent for ongoing radiation safety related issues.

According to the terms of reference, the RSC should be chaired by a radiologist and inspectors found that this was yet to be progressed by the hospital. However, there was improved representation at meetings in line with terms of reference since the last inspection by radiologists and representatives from senior hospital management. This improved attendance should be sustained by the hospital to ensure multidisciplinary input and clinical oversight at governance level and that the priority assigned to radiation safety issues is maintained.

While there was as evidence of improved involvement of the radiologists in local governance meetings, inspectors were informed that recruitment campaigns for permanent radiologists were still underway and not all posts were filled. The radiologist staffing compliment had increased from three to four since the last inspection, with the increase facilitated by locum staff. However, as per the previous inspection only one of the radiologists was in a permanent post. Furthermore, the hospital remained reliant on additional outsourcing to external providers for certain reporting and on call services to meet deficits in local resourcing.

Since the last inspection, the hospital had engaged a private Medical Physics Expert (MPE) to supplement existing resources provided by Cork University Hospital (CUH). Staff informed inspectors that increased MPE resources with on-site presence had a positive impact on the overall radiology services. Inspectors found that the additional MPE resource had addressed some of the non-compliances identified in the previous inspection. Inspectors were informed that the arrangement with the private MPE was for a six month period initially, with a view to a further six month extension if required. While the allocation of responsibilities of an MPE had improved, the temporary nature of the arrangement did not provide assurance of

the long term sustainability of MPE resourcing at the hospital.

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner. Since the last inspection, there was improved clarity regarding radiographer's entitlement to adapt and perform secondary referrals. This was reflected in policy documentation and was articulated by staff. However, the shared practitioner responsibilities for justification of medical exposures for various modalities should be strengthened in documentation to ensure they are clearly allocated. Inspectors noted an improvement in the ratification of recently approved local policies which used a consistent template and included multidisciplinary review including MPE and a radiologist.

Overall, inspectors found the hospital had put measures in place to address some of the non-compliances identified in the previous inspection. There was improvement in clinical oversight, participation in governance meetings and the allocation of MPE responsibilities. The hospital had addressed immediate resourcing deficits by outsourcing and with temporary staffing arrangements but this reliance is nonetheless a vulnerability in the service. The undertaking needs to progress recruitment of specialist resources to ensure a long term and sustainable staffing model for both MPEs and radiologists to support to the service at UHK.

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. Radiographers could act as referrer for secondary and adapted referrals as per the local scope of practice of diagnostic radiographer's document. Referrals for certain procedures were also accepted from advanced nurse practitioners (ANPs), and inspectors were informed of the process in place for these referrers to maintain competency.

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 local policies, procedures, guidelines and documentation which described radiation protection governance at University Hospital Kerry. Inspectors also spoke with staff and management who outlined the reporting structure and arrangements in place. Inspectors reviewed an organisational chart which had been revised since the last inspection, and found that this revision improved clarity on the reporting of radiation safety related issues to senior hospital management. The revised reporting structure saw the dual reporting of the Radiation Safety Committee (RSC) clarified, which now reported into the Radiology Governance Group, which in return reported to the hospital's Quality and Patient Safety Committee via an annual report. Inspectors were informed that the quality manager attends both RSC and Radiology Governance meetings and that operational issues were escalated via the operations manager. While inspectors found the revised reporting structure improved clarity, staff acknowledged that the frequency of an annual report from the Radiology Governance Group upwards could be potentially increased to ensure a focus is maintained on radiation safety related issues.

Inspectors reviewed minutes of meetings and the terms of reference of the RSC and Radiology Governance Group which had been recently updated. Inspectors noted an improvement in clinical representation by radiologists at recent meetings. In addition, there was senior management representation by the Deputy Hospital Manager at the Radiology Governance Group in December 2021. The improved attendance by radiologists and senior management provided assurance around clinical oversight and governance of radiation safety which needs to be maintained and sustained by the hospital. Furthermore, the hospital should continue to progress the involvement of radiologists to ensure that the terms of reference of the RSC are met. For example, a meeting which took place in December 2021 was not chaired by a radiologist as per the terms of reference.

Inspectors also reviewed documentation and spoke with staff regarding the roles and responsibilities allocated for the radiation protection of service users. Since the last inspection, a scope of practice document for diagnostic radiographers had been developed. This helped to improve clarity around the scope within which radiographers can act as referrer.

Regarding justification of medical exposures, there were some inconsistencies between day-to-day practice and documentation reviewed. For example, the *Scope of Practice of Diagnostic Radiographers* stated that radiographers perform justification for each procedure, whereas *Justification and Optimisation of Radiological Procedures* Policy stated that the radiologist ensures justification for CT and fluoroscopy. The undertaking should ensure that shared practitioner responsibilities are clearly outlined in documentation and understood by staff.

The allocation of MPE responsibilities by the undertaking had improved since the last inspection. On the day of inspection MPE services at UHK were provided by both resourcing from CUH and by a private MPE provider who has been engaged by the undertaking for a six month period initially. Inspectors were informed that this arrangement can be extended by further six months. Both the private MPE and an MPE from CUH met with inspectors and outlined the approach taken to share the

allocated responsibilities. The recently engaged MPE, developed an additional sub-committee of the RSC, the Radiation Protection Compliance Committee. Inspectors were informed that this committee would meet on a monthly basis and would maintain a focus on regulatory requirements matters relating to radiation safety.

Since the last inspection progress regarding increasing radiologist resourcing has been limited, with no new permanent members of staff since the July 2021 inspection. The staffing levels of radiologists had increased from three to four: one permanent radiologist, two locum radiologists and one registrar. Management informed inspectors that the radiologist compliment should be five, in addition to a lead radiologist for the South South/West Hospital Group. Inspectors were informed that campaigns for posts were progressing but not yet filled and management were evaluating ways to make the posts more attractive to applicants by exploring the inclusion of other imaging modalities and specialist services to the job description. Inspectors were informed that certain reporting and on call support was also outsourced, however, minutes of meetings reviewed by inspectors indicated that there had been capacity limitations within the outsourcing. Management informed inspectors that this was for a short period and had been resolved and that key performance indicators had improved since the last inspection. However, the reliance on outsourcing and locum staff was determined to be a short term solution and an approach to maintain a sustainable model should be considered.

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. Inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. In addition, the practical aspects of medical radiological procedures were only carried out by individuals entitled to act as practitioners in the regulations.

Furthermore, practitioners and the MPE were found to be involved in the optimisation process. The input of the MPE in optimisation had improved since the previous inspection and included diagnostic reference level (DRL) development, review of optimisation for certain interventional procedures and review of CT protocols.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The hospital had adapted arrangements for MPE resourcing since the last inspection. At the time of re-inspection, a formal arrangement had been put in place with a private MPE provider, in addition to MPE support from Cork University Hospital. Inspectors were informed that cover for the private MPE was agreed in principle when the individual was not available or absent, but this was not included in formal arrangements. Therefore, the formal arrangement should be updated to ensure continuity of expertise, particularly around MPE involvement in Regulation 17. The current arrangement with the private MPE provider was for six months and while inspectors were informed that this could be extended, the HSE as the undertaking for the hospital, should have the necessary arrangements in place to ensure the sustained continuity of medical physics expertise.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors met with a representative MPE from Cork University Hospital and the private MPE who outlined how the responsibilities as per Regulation 20 were delineated. Inspectors also reviewed documentation including the service level agreement with the private MPE. Inspectors were informed that the CUH MPEs would retain responsibility for quality assurance, any commissioning and acceptance testing and advice on new equipment. The private MPE had an on-site presence and the responsibilities were focused on optimisation, DRLs, involvement in protocol and policy development and approval, and analysis of any accidental and unintended exposures. Inspectors noted the provision of education by the MPE had commenced and should be progressed to all practitioners. Overall, inspectors were satisfied that the delineation of roles and responsibilities between the MPE resources was understood and that the arrangement was in line with the requirements of Regulation 20.

Judgment: Compliant

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

On the day of inspection, 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. Sustainability of the involvement of an MPE in the service as outlined under Regulation 19 should be considered by the undertaking to ensure the appropriate level of involvement seen on the day of inspection is maintained.

Judgment: Compliant

Safe Delivery of Medical Exposures

Overall, inspectors found that improvements were evident and that the undertaking was working towards compliance where gaps had been identified in the previous inspection in relation to Regulations 11 and 17. Inspectors were satisfied that the undertaking had put measures in place to ensure MPE availability to meet the requirements of Regulation 17. In line with the findings from the previous inspection, good practice was noted in relation to the conduct of audit which was carried out regularly in the radiology services. Furthermore, the hospital was found to keep medical radiological equipment under strict surveillance and an appropriate QA programme was in place and up-to-date.

Inspectors found that local DRLs were on display, used by staff and had been recently reviewed by an MPE. A review of a fluoroscopy procedure which was significantly above the national level was ongoing since the time of the previous inspection, but low patient numbers meant that the review had not concluded. The MPE presented inspectors with an action plan which was underway but the hospital should ensure that concluding this review is prioritised to fully meet the requirements of Regulation 11.

Inspectors identified an area for improvement in relation to recently developed documentation outlining the process of justification at the hospital. The documentation should be reviewed to ensure any discrepancies are rectified and that the allocation of responsibilities is clearly outlined for staff working in the service.

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 University Hospital Kerry should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulations.

Noting some areas for improvement outlined in this section, inspectors were satisfied that the hospital had effective systems and processes in place to ensure the safe delivery of medical exposure to ionising radiation.

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of medical radiological procedures in general radiology, CT and fluoroscopy and spoke with staff involved in the justification of medical exposures. In general radiology and CT, inspectors found that there was a system in place for justification in advance of the medical exposure and that this was documented. However, staff and management communicated to inspectors that

for interventional radiology the radiologist was responsible for justification but this was sometimes done verbally and was not always recorded. To ensure full compliance with this regulation, the hospital should ensure that all medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

Inspectors reviewed a recently developed justification and optimisation document and a scope of practice for radiographers. However, there were some discrepancies in these policies which did not fully align with the day-to-day practices outlined by staff. For example, documents reference that radiographers perform justification for each procedure yet justification of certain procedures such as CT and fluoroscopy is performed by the radiologist. Furthermore, an audit was carried out of justification by the radiographer for fluoroscopy which was not in line with the justification process described by staff. Documentation should clearly outline the allocation of roles and responsibilities to ensure that policy accurately reflects day-to-day practice. This finding was acknowledged by hospital management.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors found that DRLs for medical radiological procedures were established and used at the hospital. The DRL policy which was in draft at the time of the previous inspection, had since been approved for use. A review of a local DRL in fluoroscopy which was significantly higher than the national levels which was identified at the last inspection was still underway. The MPE provided a report on the corrective actions taken thus far including a review of patient data and phantom testing. However, the review was not yet completed and would be concluded when sufficient patient numbers would allow an assessment of optimisation in conjunction with the vendor. Given that this review is ongoing since prior to the July inspection, the undertaking should ensure that corrective actions are taken without undue delay in line with Regulation 11(6).

On the day of inspection, inspectors were informed that paediatric dose levels were grouped based on age, as opposed to weight based as per national guidance. However, the hospital had rectified this following on from the inspection and furnished HIQA with facility paediatric DRLs for one general radiography room which were weight based. The hospital should ensure that going forward, local DRLs are established in a manner consistent with the specific weight groupings used for the national DRLs where relevant, to allow for a meaningful comparison of dose.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors were informed that there was improved involvement in protocol development by MPEs since the last inspection. The MPE informed inspectors that protocols for DXA, CT and fluoroscopy had been reviewed. Furthermore, a hospital wide algorithm on ratification of documentation had been drafted.

Similar to the findings of the 2021 inspection, good practice was evident in relation to levels of audits carried out. Examples of audits reviewed included the documentation of justification and triple identification check. Recommendations to improve audit findings included staff meetings, education at induction programme and re-education for current staff. Another audit example was the adequacy of certain X-rays in the emergency department which identified room for improvement in the practical aspects of the exposure and an action plan was underway to address findings.

Compliance with respect of 13(2) however remains unchanged, as inspectors found that information relating to patient exposure did not form part of the report of medical radiological procedures. The HSE, as the undertaking for University Hospital Kerry should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulations.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was provided to HIQA in advance of the inspection. Documentation reviewed by inspectors showed that appropriate quality assurance (QA) programmes, including regular performance testing had been implemented and maintained for each piece of medical radiological equipment in the inventory. Inspectors reviewed a log book used for recording and communicating faults and equipment issues which was in use by staff in the general X-ray area. QA testing for equipment which exceeded nominal replacement was up-to-date and had been reviewed by an MPE. Overall inspectors were satisfied that equipment was kept under strict surveillance regarding radiation protection.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were informed that access to an MPE for the analysis of events had improved since the last inspection and that the reporting timeline to HIQA of three working days would now be achieved. Furthermore, a recently developed algorithm for how to report an accidental or unintended exposure was on display in clinical

areas and staff articulated the process of reporting. Inspectors were satisfied with the changes made by the undertaking and the systems put in place to meet compliance with this regulation.
Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for University Hospital Kerry OSV-0007357

Inspection ID: MON-0035835

Date of inspection: 01/03/2022

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: 1. Radiology Governance Committee is now scheduled to report bi-annually to QPS committee meetings. 30th May 2022 2. A consultant radiologist will chair the RSC meeting. 23rd June 2022 3. Both Radiologists and Radiographers shared roles and responsibilities in the justification process is clarified & clearly defined in a revised version of "Justification and Optimisation of Radiological Procedures" Policy. 6th April 2022 4. The Scope of practice for radiographer's policy has been revised to reflect the shared roles in justification. 6th April 2022 5. Both revised policies have been shared with all stakeholders, agreed and ratified at the Radiology clinical governance. 6th April 2022 6. The justification process by both the radiographers and radiologists will be audited and reported to the Radiology Quality & Audit Committee .30th June 2022 7. The Undertaking has extended the formal contract with the private MPE until CUH Diagnostic Medical Physics department recruits adequate permanent staffing to fully support UHK. Completed 8. Recruitment of permanent & temporary Radiologists will continue. Outsourcing of some plain films and CT on-call duties will continue in the interim to support the service until recruitment is finalised. on-going 9. All Radiologists are invited to attend the RSC and Radiology Governance meetings. Completed	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of	

medical physics experts:
1. The SLA between the undertaking (UHK) and private MPE has been amended by agreement to include a formal contingency plan whereby a certified MPE will take over the private MPE duties in the event of an absence or non-availability of private MPE. Completed
2. The Undertaking, has extended the formal contract with the private MPE until CUH Diagnostic Medical Physic department recruits adequate permanent staffing to fully support UHK. Completed

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
1. All IR Fluoroscopy procedures are vetted/ justified by the performing Consultant Radiologist on the NIMIS system in advance of radiographic imaging -Completed This will be subject to audit and reported to the Quality & Audit Committee. 30th June 2022
2. Both Radiologists and Radiographers shared roles and responsibilities in the justification process is clarified & clearly defined in a revised version of "Justification and Optimisation of Radiological Procedures" Policy. 6th April 2022
3. The Scope of practice for radiographer's policy has been revised to reflect the shared roles in justification. 6th April 2022
4. Both revised policies have been shared with all stakeholders, agreed and ratified at the Radiology clinical governance. 6th April 2022
5. The justification process by both the radiographers and radiologists will be audited and reported to the radiology Quality & Audit Committee. 30th June 2022

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
1. The following recommendations have been made upon completion of the investigation of the Local DRL for Barium Enema procedures:
• Barium Enema procedures have not been carried out since December 2021 due to non-availability of enema kits nationwide. Irrespective of this supply issue, UHK have suspended this procedure at the hospital. Completed
• Additionally, 2 separate protocols have been developed to address a) the

average patient weight and b) the patient exceeding 80kg in weight as the MPE identified that a significant percentage of patients exceeded the recommended weight categorisation for establishment of DRLs. The vendor will attend on the 7th June 2022 to set up both protocols. 7th June 2022 2. The Radiology department has introduced weighing scales for the General, CT and Fluoroscopy to facilitate compliance with paediatric weight-based DRLs. Completed

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: On 21.03.22 Change Healthcare issues official information in regard to the Introduction of Compliance Solutions for SI256 and a medium term solution for Article 13 (2) – Radiological Procedures i.e. recording of the dose in the medical report, is now in PRODUCTION. This has circulated to all Radiologists in UHK for use- Completed	

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	06/04/2022
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	Substantially Compliant	Yellow	06/04/2022

	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	06/04/2022
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.	Not Compliant	Orange	07/06/2022
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of	Not Compliant	Orange	06/04/2022

	five years from the date of the review, and shall provide such records to the Authority on request.			
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	Yellow	06/04/2022
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	06/04/2022