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:	28 July 2021
Medical Radiological Installation Service ID:	OSV-0007357
Fieldwork ID:	MON-0028533

About the medical radiological installation:

University Hospital Kerry is a 300 Bed hospital servicing Kerry and areas of Cork and Limerick. The hospital provides 24 hour service for computed tomography (CT) imaging, general x-ray and theatre modalities. Radiology services provided at the hospital include: two CT scanners, three ultrasound rooms, four general x-ray rooms, one fluoroscopy interventional suite, two image intensifiers in the Theatre Department, one dual energy X-ray absorptiometry (DXA) scanner, one general x-ray room in Cahersiveen Community Hospital and one orthopantomography (OPG) dental scanner.

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
Wednesday 28 July 2021	09:10hrs to 15:35hrs	Kay Sugrue	Lead
Wednesday 28 July 2021	09:10hrs to 15:35hrs	Noelle Neville	Support
Wednesday 28 July 2021	09:10hrs to 15:35hrs	Bairbre Moynihan	Support

Governance and management arrangements for medical exposures

Inspectors found that University Hospital Kerry had established governance arrangements for the radiation protection of service users which were understood by staff and management who spoke with inspectors. This included a Radiology Governance Group and a Radiation Safety Committee (RSC), both of which reported into the hospital Quality and Patient Safety Committee. Dual reporting arrangements for both these committees described to inspectors were not fully aligned to the documented arrangements presented in the hospital organogram and therefore need to be updated. The Radiology Services Manager (RSM) chaired both the RSC and the Radiology Governance Group and inspectors viewed evidence of regular reporting relating to the radiology service from the RSM to senior hospital management providing assurance that day to day operations, issues and risks were communicated appropriately to management.

However, records of minutes from meetings reviewed by inspectors demonstrated that the hospital had not consistently met its own terms of reference with respect to defined quorums required for these meetings to proceed with subsequent decision making. Noting that the hospital did not have a lead radiologist, attendances at these forums also demonstrated a notable absence of clinicians and radiologists at meetings held in 2021. Deficiencies in radiologist resources meant that the hospital was heavily reliant on external support from locum, agency and contracted services. Discussions with staff on the day of the inspection identified that the radiology service was negatively impacted as a result of prolonged and current radiologist resource deficiencies. These included the lack of clinical oversight and participation of radiologists at governance meetings, lack of input into the development of radiation protection related policies and protocols and the ability to consistently meet some internal radiology quality key performance indicators relating to peer review audit and report turn around. Inspectors were informed that efforts to recruit additional radiologists including a clinical lead radiologist had proved challenging and was taking longer than expected, however, recruitment was ongoing and progressing.

Furthermore, from discussions with staff and documentation reviewed, inspectors identified additional scope to improve the allocation of responsibility for the radiation protection of service users. Inspectors were assured that referrals were only accepted from appropriate professionals entitled to refer under the regulations and all medical radiological procedures conducted at the hospital took place under the clinical responsibility of a recognised practitioner. However, greater clarity was required in relation to radiographer entitlement to refer and practical application of radiographers as practitioners to include the scope of practice in this regard. This lack of clarity was found in local policies and in discussions with staff. Inspectors also identified scope to improve the process to develop, review, update and ratify local policies for the radiation protection of service users. Policies viewed needed to be revised to align with current regulations and there was also scope for greater

multidisciplinary input for policy development and approval.

Access to Medical Physics Expert (MPE) resources was an area of improvement also identified by inspectors. The hospital had access to MPE services provided by the Cork University Hospital Physics Department. MPE resources available to the hospital were described by staff to inspectors as relatively restricted due mainly to resourcing limitations. The need for more MPE involvement in the radiology service was consistently articulated in discussions with staff, including the MPE met with on the day. Inspectors identified that there was scope for further involvement in the optimisation process for medical exposures. As a result, inspectors determined that not all regulatory requirements were met with respect of Regulation 10, Regulation 20 and Regulation 21 of this report.

Overall, inspectors found the hospital had governance arrangements and reporting lines in place for the radiology service ensuring that there was appropriate communication of operational activity up to hospital senior management. However, established governance arrangements needed to be strengthened. The hospital should address representation and attendance at its radiology governance meetings to ensure at a minimum that quorums as set out by terms of reference are consistently met. Based on the composite nature of these findings relating to deficiencies in radiologists staffing resources, the lack of clinical lead in radiology, inspectors determined that significant improvement was required to ensure compliance with Regulation 6. In response to these findings, the hospital should implement measures to ensure appropriate clinical oversight and input from specialist resources as a matter of urgency to ensure regulatory compliance and to provide greater assurances relating to the radiation protection of service users.

Regulation 4: Referrers

Inspectors viewed a sample of referrals for medical radiological procedures at the time of the inspection. The referrer was clearly identifiable in all referrals viewed and were requested from registered medical practitioners in line with regulatory requirements. Inspectors spoke with a number of staff who demonstrated an understanding of the referral process and the means in place to readily identify recognised referrers.

However, there was a lack of clarity demonstrated by some staff who spoke with inspectors in relation to radiographer entitlement to adapt referrals or perform secondary referrals for medical exposures if required. Additionally, the scope of practice in which radiographers may be entitled to act as referrers was not clearly defined in radiation safety procedures reviewed by inspectors. While the hospital met the requirements of Regulation 4, there was scope to improve documentation to ensure clarity on persons entitled to refer within the hospital.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors spoke with staff in the Radiology Department and reviewed a sample records and found that only persons entitled to act as practitioners had taken clinical responsibility for individual medical radiological procedures. Inspectors found that while the hospital was compliant with this regulation, greater clarity was needed in documentation viewed to ensure the scope of those that can act as practitioner for medical exposures is more clearly defined.

Judgment: Compliant

Regulation 6: Undertaking

Documentation relating to the leadership, management and governance arrangements for radiology services at University Hospital Kerry was reviewed by inspectors. In addition, governance, reporting lines and oversight were described by staff and hospital management to inspectors during the inspection. The hospital general manager was the designated manager for radiological services. The hospital had a Radiology Governance Group and RSC. Both committees had responsibility for ensuring the hospital's compliance with current regulations.

The Radiology Governance Group met each quarter and had overall responsibility for monitoring the quality of the service and supporting clinical governance within radiology diagnostic imaging services. This committee reported to the hospital's Quality and Patient Safety Committee and the Executive Management Board. Responsibility for implementing recommendations from this group rested with senior management and the Executive Management Board. The RSC met twice a year. Inspectors were informed by senior management that the RSC had a dual reporting line up to the Radiology Governance Group and the hospital Quality and Patient Safety Committee. Staff who spoke with inspectors were familiar with reporting lines as outlined above, however, these arrangements did not fully align to documented reporting structures in the hospital organogram provided. This finding was acknowledged by senior hospital management on the day of the inspection. Inspectors reviewed evidence of a comprehensive report from 31 March 2021 from the RSM to the Quality and Patient Safety Committee demonstrating that there was an effective reporting line to senior management.

In accordance with its terms of reference, the RSC's function was to review, monitor, advise and report on issues relating to the radiation safety of patients in the hospital. This committee had a clinical sub-audit committee and a radiation incidents sub-committee listed in its terms of reference. However, inspectors found on the day of inspection that the latter did not exist. Inspectors found on review of the terms of reference for the RSC and the Radiology Governance Group that the hospital had not consistently adhered to its own terms of references for these

forums. For example, defined quorums to enable decision making were not consistently met as essential members were not always present in minutes reviewed by inspectors. Furthermore, on review of minutes from both committees, inspectors identified a notable absence of consultant radiologists or other clinicians at scheduled meetings which did not provide sufficient assurance pertaining to the clinical governance and oversight of the radiology service.

Inspectors reviewed the allocation of responsibility for the protection of service users undergoing medical exposure which were outlined in the hospital policies and found that improvements were required. For example, greater clarity was needed with respect to the role of radiographer as practitioners and the scope in which radiographers at the hospital were entitled to refer. There was also a lack of clarity relating to the practitioner role of radiographers in the justification policy viewed. Additionally in discussions with staff, inspectors found that not all staff demonstrated awareness in their entitlement to perform adapted or secondary referrals. The allocation of responsibility should reflect day-to-day practices and be accurately reflected in policies, procedures and guidelines. In addition, radiology governance structures should also be updated to reflect reporting arrangements in place as described to inspectors.

In documentation viewed by inspectors, the hospital had identified deficiencies in radiologists in staffing resources including a clinical lead radiologist as a concern and had escalated and recorded on the Corporate Risk Register. Acquiring appropriate level of resources was identified by the hospital as key to ensuring the quality of the service. Inspectors found that the hospital was heavily reliant on agency, locum and external services to support its radiology services and maintain on call out of hours service. On the day of the inspection, inspectors were informed that consultant radiologist resources were limited and two of its five consultant radiologists had recently left the service. Radiologist resources on the day of the inspection included one permanent whole time equivalent radiologist, one locum and one registrar. The impact from the lack of consultant radiologist resources over a prolonged period of time was further emphasised in discussions with staff who articulated that these deficiencies impacted on the department's ability to meet some of its internal key performance indicators including turn around times related to a number of reports and peer review audits.

Inspectors reviewed a sample of policies aimed to support staff in ensuring the radiation protection of patients and found that improvements were required. Policies viewed by inspectors required revision to clearly outline the allocation of responsibility for the radiation protection of patients and align with current regulations. Additionally, inspectors also identified scope to improve the process for developing and ratifying local policies relating to radiation protection to ensure consistent clinician involvement.

Inspectors discussed these concerns with hospital management. As an interim measure to provide clinical leadership and support to University Hospital Kerry radiology services, inspectors were informed by the hospital manager that recruitment of additional radiologists and a clinical lead for radiology was underway. Furthermore, the hospital and South South/West Hospital Group were in the process

of engaging an external consultant radiologist support to fill the current gap until such time as a lead consultant radiologist was in post.

Overall, inspectors were not satisfied that the allocation of responsibility aligned to the documentation reviewed. While inspectors found that medical exposures were carried out under structures that reported to executive management, deficiencies in clinical involvement to include clinical oversight and decision making at management forums and practitioner involvement in policy generation was evident. In order to achieve compliance with this regulation, University Hospital Kerry must ensure clear allocation of responsibilities in practice for the radiation protection of service users undergoing medical exposure to ionising radiation.

Judgment: Not Compliant

Regulation 10: Responsibilities

Following review of documentation, medical exposure records and discussion with staff, inspectors were satisfied that the hospital met the requirement of Regulation 10(1). Inspectors found that all medical exposures took place under the clinical responsibility of persons entitled to act as practitioners. However, inspectors found that greater clarity was needed in delineating aspects of clinical responsibility within the medical exposure pathway. Documentation should be reviewed and updated to ensure clarity in this regard.

Inspectors were consistently informed by radiology staff, including the MPE spoken with on the day, that the involvement of the MPE by the undertaking in the optimisation process for all medical exposures could improve. Input from the MPE at the hospital was described by staff to inspectors as mainly relating to the annual quality assurance programme and acceptance testing of radiological equipment. While MPE advice was accessible by phone during normal working hours, on site presence was limited. MPE involvement in establishing diagnostic reference levels (DRLs), review of internal DRLs exceeding national DRLs and involvement in the development and review of protocols for each medical radiological procedure was not evident.

Medical exposure records reviewed by inspectors demonstrated that the undertaking had ensured that a practitioner and referrer was involved in the justification process in line with this regulation. Additionally and in line with regulatory requirements, practical aspects of each medical exposure were conducted by persons entitled to do so under Regulation 10(4).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that registered MPE cover was provided by a team of off-site MPEs from Cork University Hospital. The arrangements described by staff and the MPE to inspectors provided an assurance that appropriate contingency arrangements were in place for the continuity of MPE services at University Hospital Kerry.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records and documentation reviewed by inspectors demonstrated that MPEs provided specialist advice at University hospital Kerry. MPEs carried out annual quality assurance (QA) testing as part of the hospital's quality assurance programme. This included acceptance testing which was evident in records viewed for new equipment commissioned for use in 2021. Minutes from the RSC viewed by inspectors showed that an MPE attended each scheduled RSC meeting. MPEs advised on equipment if required and also provided advice in relation to the analysis of events involving or potentially involving accidental or unintended medical exposures. However, staff described a situation where delays in accessing advice on the assessment of dose delivered to a service user following a significant event resulted in the hospital not meeting HIQA timelines for submitting this notification.

Following discussions with staff and the MPE on the day of the inspection, inspectors identified that there was scope to improve MPE contribution and involvement in relation to a number of aspects of this regulation. MPE input was described by staff as limited mainly to QA of equipment and advice via the phone if required. Inspectors were informed that this was mainly due to deficiencies in overall MPE resources which were subject to multiple competing demands for the service within the broader remit of the hospital group. The need for an increase in medical physics support was identified in a Radiology Service Report to the Radiology Governance Group and the hospital Quality and Patient Safety Committee which was dated 31 March 2021. This report also indicated that business cases for additional support had been escalated to the hospital group level.

Areas identified by staff in which MPE involvement and contribution must be improved were in relation to the responsibility for dosimetry, the optimisation of exposures particularly relating to the design, development and review of protocols and the establishment and application, use of DRLs and the comprehensive oversight of DRLs that exceeded national DRLs. Limitations of MPE involvement also impacted on staff training in relevant aspects of radiation protection. Inspectors were informed that the last training provided by an MPE at the hospital was in 2018.

Inspectors found that the assignment of MPE resources to University Hospital Kerry and associated involvement required improvement to achieve compliance with this

regulation.

Judgment: Not Compliant

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

From discussion with staff and documentation reviewed, inspectors were not assured that the level of involvement of the MPE was commensurate to the radiological risk posed by medical exposures involving potentially high doses and high activity levels such as those seen in the CT service. MPE advice was accessible by phone during normal working hours but on site presence was limited.

MPE staff acknowledged that there was scope to improve the level of involvement in relation the evaluation of the dose delivered to service users, the application and use of DRLs, the design, development and review of protocols for medical exposures and other areas identified in Regulation 20.

Judgment: Not Compliant

Safe Delivery of Medical Exposures

Notwithstanding areas for improvement identified in the governance and management section of this report, inspectors found that University Hospital Kerry had systems in place to ensure the radiation protection of service users undergoing medical exposure to ionising radiation on an operational basis. Overall, inspectors found the hospital was compliant with Regulation 8 and Regulation 14. Some areas for improvement were identified for some sub-regulations, namely Regulation 11, Regulation 13 and Regulation 17.

Areas of good practice identified by inspectors related to the process of justification which is a key principle of radiation protection. Inspectors saw documentary evidence that justification was completed in advance for each medical radiological procedure by a recognised practitioner. Adherence to the hospital justification policy was regularly audited and audit results reviewed by inspectors demonstrated high levels of compliance providing additional assurance locally on the hospital's compliance with Regulation 8.

An up-to-date inventory of equipment and quality assurance reports were provided to inspectors which showed that an appropriate QA programme was in place. Regular quality checks were performed in line with manufacturers instructions and inspectors saw evidence that when issues arose, they were reported and addressed in a timely way.

Overall, inspectors were satisfied that there was an ongoing process for the replacement of equipment past its nominal date of replacement which remained a priority at the hospital. Inspectors found that much work had been done in recent years to update ageing radiological equipment. For example, documentation viewed demonstrated that five pieces of equipment had been replaced in 2020. Older equipment identified as beyond nominal dates of replacement was subject to quality assurance and sign off as safe for clinical use by an MPE.

In respect of Regulation 17, inspectors found from documentation viewed that there was an appropriate system for the identification, analysis, tracking, trending and recording of radiation incidents and near misses at the hospital. This process was articulated by staff to inspectors. It was evident from minutes reviewed that incidents found were reported and discussed within the hospital radiology governance structures. Some examples in relation to the follow up and implementation of corrective actions resulting from incidents reported were found by inspectors. These examples provided assurance that learning from incidents and near misses were actively addressed and the implementation of corrective measures regularly monitored. Inspectors found that some improvement was required by the hospital to ensure that notifications of significant events were submitted to HIQA within specified timelines.

Inspectors found that the hospital had established DRLs for each modality and had a draft policy in place which had yet to be formally approved. DRLs were developed by the Radiation Safety Officer. Discussions with staff and review of documentation demonstrated that some areas of improvement in relation to Regulation 11 were required. The review of local DRLS found to consistently exceed national DRLs needs to be reviewed in a timely manner and actions are taken without undue delay for the radiation protection of patients.

The hospital demonstrated examples of good practice relating to the clinical audit of processes relating to medical exposure. A sample of clinical audit conducted in recent years were viewed by inspectors and demonstrated that the hospital was committed to improving the radiation protection of service users. Referral guidelines available to referrers in line with regulation. Inspectors found some areas of improvement in relation to Regulation 13(1). Inspectors viewed a sample of written protocols accessible to staff in the clinical area and found that quality assurance relating to the process for establishing, reviewing, revising and approving protocols needed review. There was also scope to improve the input from specialist staff such as radiologist and the MPE on protocol development. Furthermore, the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure to ensure compliance with Regulation 13(2).

Overall, inspectors identified some examples of good practice relating to the safe delivery of medical exposures. However, areas identified by inspectors for review and improvement outlined above should be addressed to provide greater assurances relating to the radiation protection of service users.

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of medical radiological procedures and referrals from a number of modalities and also spoke with staff responsible for justifying procedures in advance. Documentation and records reviewed demonstrated that medical exposures were appropriately referred and justified in advance in line with regulatory requirements.

Staff consistently described how each medical exposure was justified and how justification was recorded for each procedure. Inspectors were informed that the hospital had introduced a process for recording justification which also included documentation of adherence to the triple identification process on this record. Compliance with both these processes were regularly audited with high compliance levels demonstrated in audit results reviewed.

Staff demonstrated to inspectors how previous diagnostic information was accessed on the hospital's radiology information system. Inspectors were informed by radiology staff that the importance of reviewing clinical data prior to conducting a medical exposure was an area of justification strongly emphasised to staff within the facility.

Information on the benefits and risks associated with radiation was available in posters on walls in patient waiting areas and changing cubicles. Information leaflets were available on request but were removed from communal waiting areas since the onset of the COVID-19 pandemic.

The hospital justification policy was reviewed by inspectors. Inspectors found on review of the hospital's justification policy that greater clarity was required in relation to the role of the practitioner. For example, radiologists, radiation oncologist or dentists were listed as practitioners, radiographers were not included on this list yet were identified along with radiologists as entitled to justify medical exposures. This policy also needed to be revised to align with current regulations. Members of the radiology management team acknowledged this finding on the day of inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were informed that the Radiation Safety Officer develops and completes hospital DRLs for each modality which are approved by the RSC and the MPE. Inspectors were provided with DRLs developed locally for all modalities, the most recent of which were updated in flouroscopy and CT in July 2021. Inspectors observed recent hospital DRLs displayed alongside national DRLs in each control room within the areas assessed. A draft hospital DRL policy was provided to

inspectors for review but had yet to be formally approved.

Inspectors noted that some DRLs in flouroscopy exceeded national DRLs. Following discussions with staff, inspectors were not satisfied that the measures taken as described provided comprehensive assurance that sufficient corrective action had been taken in a timely way to determine whether the optimisation of protection and safety for patients was required. To ensure compliance with Regulation 11(6), the hospital must ensure that appropriate reviews are undertaken without delay in situations where procedure doses or activities consistently exceed the relevant DRL.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols were available in hard copy and accessible to staff in the clinical area. Inspectors reviewed a sample of protocols in CT, flouroscopy and general X-ray and were informed that protocols were developed locally by radiographers. The process described by staff for reviewing, updating and approving protocols did not provide adequate assurance relating to clinical oversight. Additionally, inspectors were informed that protocol development would benefit from MPE and radiologist input.

A sample of reports of completed medical radiological procedures were reviewed by inspectors who found that information relating to the patient exposure was not routinely included in the reports viewed. Inspectors were also informed by radiology staff that this was not current practice at the facility.

Inspectors were informed by staff that referral guidelines for medical imaging were available and accessible on desktops in each clinical area.

Documentation provided to inspectors for review demonstrated that the hospital had processes in place for the oversight and the conduct of clinical audit within the Radiology Department. A summary of audits provided to inspectors demonstrated some good examples of clinical audit practice. For example, the hospital had assessed appropriateness of referrals for a number of radiographs in the emergency department since November 2020 including plain abdominal radiographs and scaphoid referrals. Other audits undertaken included the exclusion of eye lens exposures in CT brain scans and adherence to the hospital triple identification and justification policy. Clinical radiology audits were the responsibility of the audit committee. From minutes reviewed, reports of audits undertaken were discussed within hospital radiology governance structures and reported upwards to the hospital Quality and Safety Committee

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors reviewed documentation relating to the QA programme for medical radiological equipment at Kerry University Hospital and found that there was an appropriate QA programme in place which was performed by a MPE. QA of equipment was maintained and was up to date. Inspectors saw documented evidence that routine performance testing was undertaken in line with manufacturer's guidelines.

Inspectors spoke to staff relating to the process for reporting issues or faults identified with equipment and found that the process articulated was clearly understood. This included emailing their line manager or person in charge on the day and reporting the fault to the manufacturer or engineer responsible for the preventative servicing and maintenance of the relevant piece of equipment. Maintenance records were sent to the RSM and were available electronically for inspectors to view. Inspectors found that individual equipment logs with all relevant information including records of faults, service and maintenance records for each piece of radiological equipment were not available within each imaging area. This meant that relevant information and service history for equipment was not readily accessible to staff using, testing or maintaining the equipment at any time on a day-to-day basis. This should be considered as an area of improvement following this inspection. Overall, inspectors were satisfied that processes were in place to ensure that appropriate actions were taken to take equipment out of service where necessary for patient safety.

Inspectors viewed records demonstrating that progress had been made in replacing equipment past their nominal replacement dates. For example, the up-to-date inventory of medical radiological equipment viewed by inspectors indicated that seven pieces of equipment had been replaced since 2019, five which were replaced in 2020. Equipment beyond nominal dates of replacement had met QA testing requirements and had been signed off for continuing clinical use by an MPE. Staff informed inspectors that equipment replacement was an ongoing priority and had been escalated to senior management. Evidence of communication to hospital management in relation to equipment replacement was provided to inspectors to view in addition to a sample of business cases submitted to the Health Service Executive (HSE) for equipment yet to be replaced.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following review of documentation and discussion with staff, inspectors were satisfied that there was a system in place to record all radiation safety incidents and evidence of discussion at committees within the radiology and hospital governance structures. Records demonstrated that incidents, near misses and reportable events

were recorded. Inspectors found that recommendations made following a notifiable incident submitted to HIQA in 2020 were in progress. For example, a poster for 'pause and check' was observed on the wall of an X-ray room and compliance with triple identification checks and the justification policy were audited. Recent audits conducted in June and July 2021 demonstrated high levels of compliance in both these areas. Inspectors were informed by staff that a protocol to mitigate the risk of an equipment failure caused by a power outage during the conduct of an X-ray was developed following a small number of reported near misses. These examples demonstrated areas of good practice in a quality improvement cycle.

HIQA received one significant event from University Hospital Kerry in 2020 which did not meet the required reporting timelines of within three working days from the date the incident was discovered. Inspectors were informed that some delay was experienced in accessing MPE services in addition to a difficulty in sharing information relating to the radiation dose to the service users to the main hospital within the group due to to different electronic information systems.

Overall, inspectors determined that regulatory requirements for this regulation were met for most aspects of the regulation but the hospital needs to ensure that timelines for submitting notifications of significant events are complied with to achieve full compliance with Regulation 17.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	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	Substantially Compliant

Compliance Plan for University Hospital Kerry OSV-0007357

Inspection ID: MON-0028533

Date of inspection: 28/07/2021

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: 1. Familiarise all staff with most recent Organogram- complete 17.09.2021 2. Develop schedule for PPPG review, develop SOP for ratification process to ensure full MDT involvement - 31.12.2021 3. Implement use of standardised PPPG template within the Radiology department - 31.12 2021 4. Continue recruitment process for additional Consultant Radiologists- fourth Radiologist commencing 01.11.2021 (on-going recruitment) 5. Expand roles and responsibilities piece on existing and future PPPG's – 31.12.2021 6. Engage with current radiologists to ensure attendance at Radiology Clinical Governance- attendance to be contained within Radiology report to the Quality and Patient Safety Committee - 16.09.2021 7. Review reporting lines within RSC Terms of Reference - 31.12.2021 8. Additional Process put in place to improve oncology CT turnaround times-completed - 10.09.2021 9. SSWHG in process of engaging external Consultant Radiologist to support Radiology services in UHK - 31.03.2022	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: 1. Expand roles and responsibilities piece on existing and future PPPG's for Radiographers – 31.12.2021 2. Additional onsite Medical Physics support from an external MPE company 'I Photon' for one day a week onsite support to commence on November 15th 2021. The Medical Physics Department at Cork University Hospital will also provide back up support as	

required.
3. Ratify draft DRL policy in consultation with MPE - 31.12.2021
4. MPE to review PPPG's if required - 31.12.2021
5. Develop & ratify Optimisation policy – 31.12.2021

Regulation 20: Responsibilities of medical physics experts	Not Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:
1. Additional onsite Medical Physics support from an external MPE company 'I Photon' for one day a week onsite support to commence on November 15th 2021. The Medical Physics Department at Cork University Hospital will also provide back up support as required.
2. Cork University Hospital are immediately progressing the recruitment for two (2) new MPE positions who will have an onsite commitment to University Hospital Kerry. The hospital will continue to utilise external MPE support until the two new positions are filled.
3. Private provider to undertake MPE training on site in UHK 31.12.2021
4. Notifiable incidents to be reported immediately and de-escalated if required once reviewed by MPE- complete 25.08.2021
5. Schedule of staff training by MPE (private provider)to be developed 31.03.2021

Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
1.Additional onsite Medical Physics support from an external MPE company 'I Photon' for one day a week onsite support to commence on November 15th 2021. The Medical Physics Department at Cork University Hospital will also provide back up support as required.
2.Cork University Hospital are immediately progressing the recruitment for two (2) new MPE positions who will have an onsite commitment to University Hospital Kerry.The hospital will continue to utilise external MPE support until the two new positions are filled.
3.MPE assistance for policy development and staff training as required 31.03.2022

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
1.TOSH medical and MPE to review next barium enema examination in fluoroscopy room to establish cause of high DRL.- 31.12. 2021
2.Scope use private MPE for PPPG input-31.12. 2021
3.Draft DRL policy to be ratified 31.12.2021

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
1.An annual review of all protocols (to assess need of update) will be completed with MDT involvement 31.12 2021
2.Scope private MPE availability to review PPPG's if required 31.12.2021
3.Patient exposures will be included in stage 3 of NIMIS- Senior project manager NIMIS National Team has given assurances to UHK via email that a meeting with the NRPC is taking place on 24th September 2021 to decide on phase 3 rollout of NIMIS- escalated to the National team 31.12.2022

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:
1.Notifiable incidents to be reported to HIQA immediately and de-escalated if required once reviewed by MPE - complete 25.08.2021
2.Radiology Incident reporting algorithm to be developed and displayed in clinical areas- 30.09.2021

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.	Not Compliant	Orange	31/03/2022
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Orange	31/03/2022

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	31/12/2021
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	12/09/2021
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/12/2021
Regulation 13(2)	An undertaking	Not Compliant	Yellow	31/12/2022

	shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.			
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and	Not Compliant	Yellow	30/09/2021
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Orange	31/03/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1)	Not Compliant	Orange	31/03/2022

	contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements;			

	and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Orange	31/03/2022
Regulation 21(2)(b)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c), a medical physics expert shall be involved, and	Not Compliant	Orange	31/03/2022