



## 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 Limerick
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	St Nessian's Road, Dooradoyle, Limerick
Type of inspection:	Announced
Date of inspection:	22 September 2021
Medical Radiological Installation Service ID:	OSV-0007379
Fieldwork ID:	MON-0030679

## About the medical radiological installation:

University Hospital Limerick (UHL) is a Level 4 Hospital in the University of Limerick Hospitals Group (ULHG). The radiography governance at UHL incorporates Croom Orthopaedic Hospital and the Maternity Hospital. The Radiology Department is primarily demand driven, serving all of the departments within UHL, Croom and Maternity Hospitals. There is a limited out-patient service across most modalities. There are Clinical Specialist Radiographers in all of the modalities and these radiographers run the operational side of the service. The imaging modalities using ionising radiation include: General X-ray including dental X-ray, Computed Tomography (CT), Mammography, Nuclear Medicine, Interventional Radiology, Interventional Cardiology Suites (Cardiac Cath Labs), Dual-energy X-ray absorptiometry (DEXA) Scanning and a Fluoroscopy service.

## How we inspect

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

As part of our inspection, where possible, we:

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

## About the inspection report

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

### **1. Governance and management arrangements for medical exposures:**

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<sup>1</sup> Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

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

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

<sup>4</sup> Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

**2. Safe delivery of medical exposures:**

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

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

**This inspection was carried out during the following times:**

Date	Times of Inspection	Inspector	Role
Wednesday 22 September 2021	10:10hrs to 16:16hrs	Kay Sugrue	Lead
Wednesday 22 September 2021	10:10hrs to 16:16hrs	Maeve McGarry	Support
Wednesday 22 September 2021	10:10hrs to 16:16hrs	Noelle Neville	Support

## Governance and management arrangements for medical exposures

University Hospital Limerick (UHL) is a Model 4 hospital in the University of Limerick (UL) Hospitals Group. This inspection was carried out to follow up on a short notice announced inspection by HIQA at University Hospital Limerick on 11 June 2020 in which a number of non-compliances were identified. These non-compliances were mainly related to deficiencies in medical physics staffing levels which were found to have a negative impact on the radiology service at that time. This inspection was undertaken on 22 September 2021 to assess the level of compliance following actions taken as outlined in the compliance plan submitted by the hospital following the 2020 inspection.

Inspectors reviewed information submitted prior to the inspection and on the day of inspection and reviewed practices in a number of modalities. Inspectors also spoke with a number of staff within the multidisciplinary team working in the radiology department and with members of the UHL management team. Overall, inspectors found that the hospital had taken significant steps to come into compliance with the regulations inspected against in 2020.

Radiology governance arrangements including sub-delegation from the Chief Executive Officer (also the designated manager) to a general manager within each directorate had been finalised since the last inspection. Staff who spoke with inspectors were familiar with these updated arrangements. Radiation safety procedures including local rules outlining roles and responsibilities in relation to radiation safety and the radiation protection of service users had been updated and aligned with regulations. Discussions with staff demonstrated a strong awareness of their allocated roles and responsibilities with respect of radiation protection and these were in line with regulatory requirements. Inspectors noted from engagement with staff that there was local ownership, enthusiasm and a strong commitment among staff to improving the radiation safety and protection for all service users. This was not only evident in discussions with staff but also observed by inspectors in respect to document development, participation in clinical audit and overall awareness of matters relating to radiation protection. Inspectors were satisfied that sufficient measures had been taken to comply with Regulation 6 requirements.

Assessment of compliance regarding Regulation 19, Regulation 20 and Regulation 21 demonstrated improvement in overall compliance had been achieved mainly through outsourcing of the majority of the Radiation Protection Advisor (RPA) function including the annual quality assurance (QA) programme to external providers and increasing UHLG medical physics resourcing. However, the continuity and sustainability of the medical physics service, while evident on the day of inspection, was not assured in the medium and long term. This was due to planned statutory leave and the ending of a temporary contract which had the potential to reduce medical physics resources to below 2020 levels.

Staff and management informed inspectors that establishing medical physics

resources to a level that enables in house maintenance of its annual QA programmes was the optimal model for its service. This would also facilitate and increase RPA and MPE expertise locally without the need to rely on external contractors. The hospital had a strategy in place regarding medical physics resource requirements which needs to be implemented and regularly revised in line with its rapidly expanding service. Hospital management informed inspectors that there were plans in place to improve medical physics staffing which were underway but had yet to be finalised. Therefore, the undertaking needs to continue its efforts to maintain medical physics resources currently, in addition to increasing MPE capacity in the medium and long term in line with its own identified resource needs and to ensure compliance with regulations.

Overall, inspectors were satisfied that the strong leadership, management and local ownership demonstrated by radiology staff during the inspection provided assurance on the radiation protection of service users undergoing medical radiological procedures at UHL.

#### Regulation 4: Referrers

Inspectors reviewed the hospital's radiation safety procedures which stated that only referrals from appropriately recognised referrers as per Regulation 4 were accepted by the Radiology Department at UHL. Referral documentation and discussions with radiography staff satisfied inspectors that the processes in place were applied when validating referrers prior to conducting medical radiological procedures. For example, inspectors viewed referral records which routinely contained medical council registration numbers. In addition, inspectors observed lists of approved nurse referrers displayed in the control rooms within the radiology department. Radiology staff informed inspectors that this list was regularly updated as required.

Judgment: Compliant

#### Regulation 5: Practitioners

Inspectors reviewed a sample of records in relation to medical exposures on the day of inspection in computed tomography (CT), general radiology, nuclear medicine and dual-energy X-ray absorptiometry (DXA) scanning and found that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures as per the regulations.

The hospital's radiation safety procedures were applied from a hospital group wide perspective. These procedures identified practitioners as radiographers, radiologists, dentists and medical practitioners with relevant training, knowledge and practical experience in medical radiological practice and radiation protection. Inspectors were

satisfied that following review of documentation and discussions with staff that only persons entitled to act as practitioners had taken clinical responsibility for individual medical exposures as per the regulations.

Judgment: Compliant

## Regulation 6: Undertaking

Documentation relating to reporting lines, governance structures, clinical governance and the allocation of responsibilities for the radiation protection of services users undergoing medical exposure to ionising radiation were reviewed by inspectors. Inspectors were satisfied from documentation viewed and discussions with staff and hospital management that these arrangements were understood by staff and applied in day-to-day operations and practice.

The Chief Executive Officer (CEO) of University of Limerick Hospital Group (ULHG) was the designated manager and a member of the hospital's Radiation Safety Committee (RSC). This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which reported upwards to the Executive Management Committee and from this committee to the Hospital Board.

University Hospital Limerick had worked to address gaps and non-compliances in governance arrangements identified in the previous HIQA inspection in June 2020. For example, comprehensive radiation safety procedures viewed by inspectors had been updated by medical physics and were formally approved by the ULHG RSC in December 2020. These procedures clearly outlined the allocation of responsibility for the protection of patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research from medical exposure to ionising radiation and incorporated local rules for each modality. In addition, documentation outlining sub-delegation from the ULHG CEO to the Chief Operating Officer to the general manager of each directorate within the hospital group was viewed by inspectors which was completed and approved in the interim since the last inspection.

To ensure further oversight of regulatory compliance, the hospital had implemented a multi-disciplinary task force for this purpose. Documentation viewed by inspectors demonstrated that there had been positive progress in development of local policies, procedures and guidelines. This was evident in recently approved policies on justification, carers and comforters, pregnancy protocols and diagnostic reference levels (DRL). Inspectors saw evidence of multidisciplinary approval from key stakeholders identified within the radiation protection governance structures in the approval and validation process for these policies. Inspectors were informed that there was a greater awareness amongst staff across all directorates within the ULHG on matters relating to radiation protection and the hospital would continue to build

on improvements made to date.

Overall, inspectors were satisfied that the hospital had a clear allocation of responsibilities for the radiation protection of services users undergoing medical exposure to ionising radiation.

Judgment: Compliant

### Regulation 10: Responsibilities

Systems and processes were in place in the hospital to ensure that all medical exposures took place under the clinical responsibility of a practitioner. Individual responsibilities for referrers, practitioners, medical physics experts (MPE), radiation protection officers, radiographers and the radiology services manager relating to radiation protection were outlined in the hospital's radiation safety procedures. Key personnel were involved in the optimisation and justification of all medical exposures in line with the requirements of this regulation. For example, inspectors spoke with staff who described their role in the justification of general radiography procedures and high dose procedures which was in line with local guidance and day-to-day radiological practices. Additionally, inspectors noted good practice in ensuring radiology staff were fully aware of individual roles and responsibilities in the conduct of CT imaging in the hospital's emergency department. Staff informed inspectors that regular simulated scenario training in CT procedures was undertaken for this purpose.

Inspectors found that delegation of the practical aspects of a medical exposure at the hospital was documented in local policy. In discussions with inspectors, staff demonstrated an understanding on the process of delegation and the persons to whom the practical aspects of a medical exposure could be delegated. With the exception of DXA scanning, inspectors were informed that it was hospital policy that all medical exposures took place with a radiographer practitioner present. The practical aspects of medical exposures undertaken in DXA scanning were undertaken by an appropriately registered nurse with required radiation safety and protection training which was verified by inspectors in documentation viewed.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The Medical Physics Department provided Medical Physics Expert (MPE) services at University Hospital Limerick and also to the hospitals within the wider hospital group. On the day of the inspection, the hospital had two MPEs on staff, one of which was the Chief Physicist. Two senior physicists working on site were awaiting



registration in the voluntary register of medical physics experts maintained by the Irish College of Physicists in Medicine. A basic grade physicist post had been filled after a long recruitment process. Specific work-related requirements meant that there was only one MPE available on site in the short to medium term.

While continuity of the MPE service was assured at the time of the inspection, inspectors were not assured that MPE resources as described to inspectors could be consistently maintained and increased in a sustainable way in the short or medium term. Inspectors were informed that planned statutory leave and the end of a temporary contract of one senior physicist was due to occur in the early part of 2022. This issue had the potential to impact on the continuity of MPE services and was discussed with the senior hospital management at the time of the inspection. Senior management acknowledged this risk and informed inspectors that the hospital was working to address this issue and increase MPE resources to future proof and improve MPE resources. To increase capacity with MPE services, inspectors were informed that the Radiation Protection Advisor (RPA) role was contracted to an external service. Furthermore, the hospital was in the process of engaging an additional external provider for RPA and potentially MPE resources in the future in addition to agreeing outsourcing some aspects of the 2022 annual QA programme.

Inspectors noted that while arrangements were in place to address RPA requirements through outsourcing, finalised arrangements were not in place at the time of the inspection to fully address deficiencies identified in MPE resources to a sustainable level. Therefore to ensure full compliance with Regulation 19(9), the undertaking must ensure that the hospital strategy for improving MPE resources is advanced which should take account of the increasing activity, growing needs and the complexity of the expanding service. In addition, the limitations of external contracted MPE/RPA services should be recognised and incorporated into regular assessment on the needs of the radiology service.

Judgment: Substantially Compliant

## Regulation 20: Responsibilities of medical physics experts

Documentation viewed by inspectors found that the hospital had two MPEs registered on the register of MPEs which remained unchanged since the last inspection on 11 June 2020. From discussions with staff and review of documentation, inspectors found that the undertaking had improved its overall compliance against this regulation, however, inspectors identified that more work was required to ensure there is adequate medical physics resources to ensure appropriate MPE involvement in all aspects of medical exposures as per the regulations. The resources needed were outlined in documentation viewed by inspectors and indicated that current medical physics resources fell well below projected needs of the ULHG radiology service.

Inspectors noted that increases in medical physics staffing resources since 2020 had facilitated more input and involvement of the MPE in medical radiological practices at the hospital. This was achieved through outsourcing of 80% of the annual quality assurance programme and other RPA roles to external providers to supplement existing MPE resources. Additionally, two senior physicist roles had been filled, one permanent and one on specific term contract. Hospital management acknowledged that further additions to existing medical physics staffing levels was needed and recruitment was ongoing at the time of the inspection.

Inspectors found improvements in aspects of MPE responsibilities in relation to training and optimisation. Documentation viewed and discussions with staff demonstrated to inspectors that an MPE was available to give advice on medical radiological equipment, contributed to dose audits and the establishment and review of DRLs at the hospital. While noting the significant progression evident in the establishment of DRLs for common medical radiological procedures within the hospital, inspectors found that CT DRLs had yet to be formally approved by the undertaking. In addition, inspectors were informed that more MPE input was required in relation to assessment of doses used in biomedical research projects involving medical exposures to ionising radiation which was currently undertaken by the radiation protection officer (RPO).

Additional resources facilitated the allocation of medical physics resources to areas of potential higher risk such as interventional cardiology. However, inspectors identified during the assessment of the nuclear medicine service that further MPE input was required to support the service. This gap was also identified in documentation viewed and in discussions with staff.

Medical physics continued to contribute to the annual QA programme and had responsibility for following up on any issues identified during annual QA performed by outsourced QA testing services and manufacturers' service engineers. While generally meeting this requirement, inspectors identified scope for the undertaking to improve medical physics staffing to ensure equipment fault logs and issues requiring MPE input are addressed within required timelines. Other areas for improvement identified was contribution to the preparation of technical specification for new medical radiological equipment and input into the development of protocols. Inspectors were informed that lack of input into technical specification for one piece of equipment contributed to the need to terminate the procurement process.

Overall, while noting the positive effect that increases in medical physics resources had on the radiology services, inspectors found that the undertaking should ensure MPE resources are at a level to ensure the appropriate level of involvement commensurate with the medical radiological risk of the service provided.

Judgment: Substantially Compliant

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

Following review of documentation and discussions with staff, it was acknowledged that the hospital and ULHG had completed major projects in the radiology services which resulted in an expansion of the service and upgrade of radiological equipment at an unprecedented rate since 2019. Inspectors were informed that these projects required significant input and involvement from medical physics in the construction and commissioning phases in addition to extra demands placed on the service from the COVID-19 pandemic. The high volume of projects within a relatively short period of time had placed additional demands on limited medical physics resources. Despite the challenges faced by Medical Physics Department to date, inspectors were satisfied from documentation reviewed and discussions with management and staff that an MPE was available for consultation and advice on matters relating to radiation protection concerning medical exposure. Inspectors found that improvements in MPE involvement in medical radiological practices correlated with increases in medical physics staffing. For example, a medical physics resource was allocated to interventional cardiology. This demonstrated prioritisation of resources to one area of high risk which is an example of good practice in the context of limited onsite medical physics resources.

However, while noting the progress made since the last inspection, inspectors found that there was further scope to improve MPE involvement in nuclear medicine and other modalities to support the radiological practices and service development. Inspectors reviewed protocols for medical radiological procedures which were developed by clinical specialist radiographers for each modality and found that MPE input into the development of protocols particularly for high dose procedures would provide greater assurances on the radiation protection of patients undergoing procedures with increased risks associated with medical exposure to ionising radiation. This finding was acknowledged by staff during the inspection.

In order to comply fully with the requirements of this regulation, the undertaking should prioritise medical physics resourcing to enable greater MPE involvement in the service.

Judgment: Substantially Compliant

## Safe Delivery of Medical Exposures

Inspectors found from the regulations reviewed that the hospital had measures in place to ensure that safe and effective medical exposures were provided to service users in compliance with the regulations. This included the establishment of facility diagnostic reference levels (DRLs) in the majority of areas although further work was required to finalise DRLs for the CT service. The progress attained in establishing DRLs since the last inspection demonstrated the hospital's commitment to improving compliance with Regulation 11.

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, which, due to limited available resources within the hospital medical physics department, the majority of which was outsourced to an external provider for 2021. On the day of the inspection, inspectors found that, in general, the QA programme was meeting projected time lines for completion outlined in the programme. Inspectors were informed that a proportion of the QA programme for 2022 also needed to be outsourced and discussions were due to be initiated by the hospital with an external service. Inspectors found on inspection of the nuclear medicine service that the undertaking needs to ensure there is adequate medical physics staffing to ensure input and oversight of nuclear medicine services and to ensure compliance with Regulation 14.

Inspectors were satisfied following review of documentation and discussions with staff that medical radiological procedures in the radiology department were justified in advance by a person entitled in the regulations to take clinical responsibility for justification. Higher dose procedures were justified by a consultant radiologist in line with local rules. While there was sufficient evidence viewed by inspectors that justification in advance was consistently performed and recorded prior to conducting medical exposures, inspectors found that the hospital was not compliant with Regulation 8(15) as records of justification in general radiography were not maintained by the hospital.

Inspectors found evidence of a strong multidisciplinary approach to radiation protection and the optimisation of medical radiological procedures. This was evident in the hospital's clinical audit programme for radiology services which had resulted in the implementation of quality improvement initiatives following a number of audits that reduced the dose to the patient cohort and increased efficiency of the service. This was particularly evident in the CT service. In addition, the hospital had allocated dedicated medical physics staff to work in potentially high dose areas such as interventional cardiology.

Inspectors found that the hospital was fully compliant with the regulatory requirements of Regulation 16 and Regulation 17.

Noting that there were areas for improving compliances regarding Regulation 8, Regulation 11, Regulation 13 and Regulation 14, inspectors were satisfied that the hospital had appropriate systems and processes in place to ensure that effective and safe medical exposures based on the regulations reviewed as part of this dimension.

## Regulation 8: Justification of medical exposures

On the day of inspection, inspectors spoke with radiographer and radiologist practitioners who explained how medical exposures are justified in advance of the medical exposure. Inspectors also reviewed a sample of records and found all referrals reviewed were available in writing and included the clinical indication for the request with accompanying medical data. The hospital had a recently updated

justification policy with multidisciplinary approval which was aligned with current regulations.

Records viewed also demonstrated that justification was documented for procedures carried out at the hospital on the day of the procedure. For example, responsibility for justifying a high dose medical radiological procedure in radiology was shared by the radiologist and the radiographer that was carrying out the practical aspects in line with hospital policy. Justification of these procedures was documented using an electronic record by the radiologist which was reviewed by inspectors. Justification for procedures conducted in general radiology was performed and recorded on the triple identification form in advance of a procedure by a radiographer, however these forms were not retained. To ensure compliance with Regulation 8(15), the hospital should ensure that records evidencing compliance with the justification of medical exposures in advance should be kept for a period of five years from the date of the medical exposure.

Information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure from radiology staff and on posters in the waiting area of the Radiology Department.

Judgment: Substantially Compliant

### Regulation 11: Diagnostic reference levels

Inspectors viewed a comprehensive hospital policy on the process for the establishment and review of diagnostic reference levels (DRLs). Inspectors found that the establishment of DRLs for common procedures had progressed significantly since 2020 and noted that much work had been done to improve compliance with respect of this regulation. Facility DRLs were observed by inspectors in the control rooms visited during the inspection and documentation reviewed demonstrated that DRLs were established for common procedures in most modalities. However, staff informed inspectors that while data had been collated for 2021 DRLs in the CT service, these had yet to be finalised by the undertaking. Therefore the establishment of facility DRLs should be completed as a priority by the hospital to ensure compliance with this regulation.

Following discussions with staff, inspectors were satisfied that staff were aware of the process for reviewing DRLs that consistently exceed established DRLs. Inspectors were informed by staff in the emergency department CT service that a log of projected doses in CT was kept. The system alerted the user where dose thresholds were exceeded. The log and system aided to ensure that corrective actions were taken following on from the identification of doses exceeding DRLs and examples of such were provided to the inspectors.

Staff informed inspectors of a quality improvement initiative resulting from the process of developing and establishing DRLs. Dose audits undertaken to collect

patient dose data had identified that patient doses from a number of CT and X-ray procedure for lower limb procedures were assessed as well below national DRLs. This finding in turn, led to a review of image quality in lower limb medical radiological procedures with a focus on the optimisation of medical radiological procedures. Inspectors found this to be an example of good practice.

Judgment: Substantially Compliant

### Regulation 13: Procedures

Hardcopy written protocols were available in the clinical areas inspected for each type of medical radiological procedure. Inspectors noted that protocols were developed by clinical specialist radiographers in each service. Discussions with staff identified that there was potential to increase multidisciplinary input into protocol development to provide greater assurance in relation to radiation protection and optimisation processes.

Inspectors reviewed a sample of reports of medical radiological procedures and found that information relating to the patient radiation dose was included in DXA and nuclear medicine reports. However this information was not consistently in reports viewed in general radiography and CT services. Instead, inspectors observed a commentary in these reports which was described by staff as an interim solution to the regulatory requirements of Regulation 13(2). To ensure compliance with Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the procedure in line with considered approach by the HSE as undertaking.

Inspectors viewed referral guidelines for medical imaging which were accessible to referrers in electronic format on desktops in each clinical area.

From discussions with staff and documentation viewed, inspectors were satisfied that the hospital had processes in place for conducting clinical audit of the radiological services. Inspectors noted a positive culture and proactive approach towards clinical audit with multidisciplinary involvement evident. Inspectors were informed of a number of audits conducted which were focused on the optimisation of medical radiological procedures and the reduction of patient dose. Examples of clinical audits undertaken included reviewing weight loss as a indication for referral for CT and the optimisation of CT Kidney, Ureter and Bladder (KUB) scans.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection and noted, from the details provided, that equipment was kept under strict surveillance regarding radiation protection.

Through discussions with staff and documentation reviewed, inspectors were satisfied that the hospital had an appropriate quality assurance programme in place, the majority of which was outsourced in 2020 and 2021 and likely to continue for 2022. On the day of the inspection, documentation viewed by inspectors demonstrated the annual QA programme was being carried out in line with projected timelines with 47% of the programme already completed for 2021. Follow-up of any issues identified during the annual QA programme was the responsibility of the ULHG Medical Physics Department.

Inspectors identified that due to capacity issues and competing priorities leading to reduce medical physics availability, monthly QA in nuclear medicine was performed by nuclear medicine radiography staff. Inspectors were informed that the lack of physics resources for nuclear medicine had been escalated to hospital management as a concern. Inspectors found that the undertaking needs to ensure there is adequate medical physics resourcing to ensure input and oversight of nuclear medicine services and to ensure compliance with this regulation.

Following discussions with staff and hospital management, it was clear to inspectors that the long-term plan was to manage annual QA by staff within UHL as this was seen as the optimal way of managing annual QA. Overall, inspectors found that while annual QA was in hand for 2021, the annual QA programme requires future proofing to ensure the maintenance and continuity of an appropriate quality assurance programme for medical radiological equipment is in line with regulatory requirements.

Judgment: Substantially Compliant

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

Inspectors were satisfied that there was an established process to determine the pregnancy status of service users and this process was documented in local policy. Records reviewed showed that radiographers had responsibility for making enquiries as to pregnancy status and these records were uploaded to the radiology information system.

Inspectors observed posters in the service user waiting area with the aim of increasing the awareness of women to whom this regulation applied. Risks from ionising radiation during pregnancy were included in patient information leaflets available in patient waiting areas within the radiology department.

Judgment: Compliant

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

From documentation viewed and discussions with staff, inspectors were satisfied that there were appropriate systems and processes in place for the management of accidental and unintended exposures and significant events. In addition, non-reportable incidents and near misses were also tracked and trended. These processes were consistently articulated to inspectors demonstrating a clear understanding of the process which was in line with local policy. Significant events were reported to HIQA within the required timelines. Overall, inspectors found that the undertaking met the requirements of 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
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for University Hospital Limerick OSV-0007379

Inspection ID: MON-0030679

Date of inspection: 22/09/2021

## Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

## Section 1

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

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 19: Recognition of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:            There are currently 2 MPE registered with the ICPM in the ULHG.</p> <p>In addition, the Senior Physicist who is on a 12 month Special Purpose Contract submitted documentation for MPE Registration to the ICPM in September 2021. The ICPM confirmed on the 21/9/21 that some responses had been received from the reviewers and that they were recommending that she be accepted onto the register as an MPE. Awaiting receipt of certificate from ICPM.</p> <p>Furthermore, the permanent senior physicist will submit their portfolio to the ICPM by end of December 2021.</p>	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:            Staff Complement:            UHLG Based staffing on International Guidance for Medical Physics Staffing. (EUROPEAN COMMISSION RADIATION PROTECTION NO 174, EUROPEAN GUIDELINES ON MEDICAL PHYSICS EXPERT, Annex 2, Medical Physics Staffing Levels in Europe, Directorate-General for Energy Radiation Protection, 2014).</p> <p>Current staffing complement : 6 WTE</p>	

Chief Physicist (permanent), Senior Physicist X 3 (2 permanent and 1 temporary) and Basic Grade Physicist X 2 (permanent). A Senior Physicist who is due to go on Statutory Leave in December and a Basic Grade Physicist are both required to work from home as advised by The Occupational Health Department.

Additional Capacity created through outsourcing:

1 WTE (x 2 External RPA'S ) + 0.5 WTE (Outsourcing of QA)=1.5WTE

Staffing complement post recruitment campaigns: 7 WTE

Chief Physicist (permanent), Principal Physicist (permanent), Senior Physicist X 3 (2 permanent and Basic Grade Physicist X 2 (permanent).

Additional Capacity created through outsourcing :

1 WTE (x 2 External RPA'S) + 0.5 WTE (Outsourcing of QA) =1.5 WTE

Two external RPA companies (1WTE) have been engaged by the CEO to support the 5 HSE Hospitals in 2021 and the Chief Physicist continues to provide RPA advice to St. John's Hospital. QA outsourced to external provider to create additional Capacity (1 WTE).

Sustaining MPE resources in the Short and Medium Terms (Strategic Plan) :

Planned statutory leave will occur in early December and the temporary contract will cease at the end of February. The CEO confirmed in November that 1WTE was approved for the duration of Maternity Leave (12 months) to address continuity of the permanent MPE service. The position was offered to candidates on the active ULHG Senior Physics panel, however the National Recruitment Service was "unable to fill" this position and it was closed on 22/11/2022. A request for VAP approval will now be submitted to progress this with an agency recruitment service.

In addition, a 12 month Special Purpose Contract (SPC) Senior Physicist post was reapproved by the ECC to replace the existing contract which ends in February. Following VAP approval, the recruitment process will commence with an agency recruitment service.

The National Recruitment Service confirmed for the Hospital that it was "unable to fill" the Principal Physicist on the 8/9/21. The NRS were requested to reactivate this position on the 15/10/21. They confirmed for the Chief Physicist on the 18/11/2021 that a new campaign will be initiated shortly.

Contingency Plan:

Agreement with an external company, to provide on-going Medical Physics Expert support and input as required by UHLG. This initiative will provide additional capacity within the Medical Physics Department. Additional WTE provided will be determined retrospectively once output quantified.

Specific Short term plans indicating how it is intended to come into compliance with specific tasks identified by HIQA during the inspection (Operational Plan):

CT DRL data for 2021 has been collated and was discussed with the Clinical Specialist Radiographers on 18/11/21. It will to be reviewed by the relevant radiologists and approved by the 30/11/21. A significant amount of work has been undertaken by medical physics staff to configure one of the two dose management systems in UHL. This has

helped with the establishment of the 2021 CT DRLs and will assist in the collation of future DRLs.

A Senior Physicist has been assigned to the Nuclear Medicine service from November 1st until end of February when their contract will end. This will ensure MPE support is provided to the service which has been absent since April 2021 due to a deficit in on-site resources. The newly appointed Senior Physicist will take up these duties when in post.

A more robust system has been set up in the Medical Physics Department to track faults identified during QA assessments. It will also capture non-routine faults reported to the Medical Physics Department. These faults will be followed up by the Medical Physics staff ensuring issues identified are addressed in a timely manner and that systems are retested prior to clinical use, where appropriate.

Senior physics staff have been assigned to contribute to and/or review technical specifications for new and replacement equipment projects planned for 2022 i.e. Cath labs, Mini C-arm and dental Cone Beam CT.

Medical Physics staff will continue to estimate doses as required until the temporary senior physicist contract ends on the 28/2/2022. The new Senior and Principal Physicists will be assigned to support the clinical trials and biomedical research projects when in post.

Subject to a positive recruitment campaign for the two 12 month SPCs, the annual QA programme will be completed by the ULGH. If there are delays in the recruitment process and/or the campaign is not successful, the contingency plan will include outsourcing a minimum of 50% of the 2022 annual QA programme.

Sustaining MPE resources in the Long Term (Strategic Plan):

A combined model including recruitment of additional staff and external outsourcing will be utilised to ensure adequate MPE input within UHLG.

The CEO is committed to ensuring the Medical Physics Department is adequately staffed and recruitment campaigns continue to be initiated.

Agreement with an external company, OnePhoton to provide on-going Medical Physics Expert input as required by UHLG will stay in place to ensure adequate MPE support.

The priority is to maintain the staff complement of 7 WTEs to continue the development of the service in line with the Strategic Plan for the ULHG.

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
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<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:  While Medical Physics staff currently have a limited role in the development and review of clinical imaging protocols, they are involved in the investigation of unusually low or high DRL values. Further to appointment, the new Senior and Principal physics staff will contribute to the review and development of imaging protocols.  Medical Physics Experts are consulted and involved in the investigation of significant deviations from DRL's together with the other key stakeholders e.g. radiographers, radiologists, cardiologists, service engineers, etc.</p>	
<p>Regulation 8: Justification of medical exposures</p>	<p>Substantially Compliant</p>
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:  As noted on the day of inspection, justification of high dose ionising radiation exposure is completed by Radiologists when vetting and by Radiographers prior to exposure.  In General x-ray the studies are justified and are documented on the triple ID sheets.   As mentioned during the inspection, ULHG is the first Hospital Group to implement CRIS, the new RIS system, in 2022. This new system should include a more seamless method of justifying exposures.   In the interim regular audits will continue to be carried out to ensure compliance with legislation.</p>	
<p>Regulation 11: Diagnostic reference levels</p>	<p>Substantially Compliant</p>
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:  The 2020 UHL CT DRLs were approved on the 9th October 2020. CT DRL data for 2021 has been collated and was discussed with the Clinical Specialist Radiographers on 18/11/21. It will be reviewed by the relevant radiologists and approved by the 30/11/21.</p>	

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Communication was issued by Dr. Ciaran Browne, Co-chair of the HSE National Radiation Protection Committee on the 23/2/21 to Hospital Group CEOs outlining changes that will take place to the RIS/PACS system to address justification in advance of procedures and information relating to patient dose recorded on the medical report.</p> <p>The HSE NIMIS Programme Team plan to introduce the technical changes on a phased basis and will engage with the relevant experts in the hospital to facilitate the process. The changes will be accompanied by guidance developed by the NRPC to support implementation which will be circulated by the HSE NIMIS Programme Team at each stage of the process. We await an update from the NRPO on this matter.</p> <p>In the interim all protocols are reviewed by the Multi-Disciplinary Radiology Team to ensure input from all stakeholders including Consultant Radiologists, Physicists, Radiographers and Nurses as required prior to sign –off. Contribution of the different disciplines will be indicated on the front page of the policy.</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: Subject to a positive recruitment campaign for the two 12 month SPCs, the annual QA programme will be completed by the ULGH. If there are delays in the recruitment process and/or the campaign is not successful, the contingency plan will include outsourcing a minimum of 50% of the 2022 annual QA programme.</p> <p>Onsite medical physics staff have been assigned to the Nuclear Medicine service from the 1st of November while the temporary Medical Physicist is in-situ. One of the newly recruited Senior Physicists will be appointed to this role when they take up the position. This will permit Medical Physics staff to undertake the monthly QA programme which had to be assigned to radiography staff due to lack of resources.</p>	





## Section 2:

### Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 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	Yellow	30/11/2021
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	31/12/2021
Regulation 13(1)	An undertaking	Substantially	Yellow	31/03/2022

	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.	Compliant		
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	30/11/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	31/12/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	01/06/2022
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1)	Substantially Compliant	Yellow	01/06/2022

	takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) 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	Substantially Compliant	Yellow	01/06/2022

	<p>equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>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.</p>	Substantially Compliant	Yellow	01/11/2021
Regulation 21(2)(b)	<p>In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised</p>	Substantially Compliant	Yellow	01/11/2021

	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			
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