



## 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:	Short Notice Announced
Date of inspection:	11 June 2020
Medical Radiological Installation Service ID:	OSV-0007379
Fieldwork ID:	MON-0029586

## 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 as the priority for the hospital is inpatient activity due to demands on inpatient beds. There are Clinical Specialist Radiographers in all of the modalities. These radiographers run the operational side of their service. The imaging modalities using ionising radiation include:

General x-ray: including dental x-rays

Computed Tomography (CT)

Mammography

Nuclear Medicine

Interventional Radiology

Interventional Cardiology Suites (Cardiac Cath Labs)

Dual-energy X-ray absorptiometry (DEXA) Scanning  
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
Thursday 11 June 2020	10:58hrs to 15:02hrs	Kay Sugrue	Lead
Thursday 11 June 2020	10:58hrs to 15:02hrs	John Tuffy	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 short notice announced inspection was initiated due to non-compliances identified during a routine announced inspection at Nenagh Hospital on 12 February 2020. The extent of medical physics staffing levels impacted regulatory compliance at Nenagh Hospital with possible greater implications on compliance at its parent hospital UHL, given the scale and complexity of the services provided there.

Inspectors found the level of Medical Physics Expert (MPE) resources available for UHL and the wider hospital group was not appropriate for the level of radiological services provided. At the time of the inspection, the Medical Physics Department located at UHL had two MPEs and one basic grade physicist for consultation and specialist advice on matters relating to radiation physics. Inspectors noted that the Medical Physics Department at UHL was established in January 2018 but had not been adequately resourced from the outset.

Inspectors found through documentation review and discussion with staff that there was a strong awareness amongst staff of the substantive issues related to medical physics staffing and resulting effects on compliance with regulations. Medical physics staffing deficiencies had been recorded as a high level risk on the corporate risk register since 2017. Inspectors saw sufficient documentary evidence to show the gaps in medical physics staffing were escalated through radiation protection governance structures and upwards to hospital group and Health Service Executive (HSE) level. However, efforts to increase the identified deficiencies since 2017 had been limited up to the time of this inspection. In discussions with staff, inspectors were told that a recruitment process to increase MPE resources was ongoing with plans to increase medical physics staffing levels by two whole time equivalents by the end of 2020. In addition, the hospital also planned to outsource the quality assurance (QA) of medical radiological equipment for 2020 with the aim of alleviating pressure on the Medical Physics Department.

Inspectors found that areas significantly impacted by deficiencies in medical physics staffing levels related to continuity of MPE service. Staff stated that contingency arrangements were not in place for the continuity of MPE expertise should the need arise.

Capacity issues were also found to impact on the MPE involvement in medical radiological practices. Staff stated that there was potential to expand the involvement of the MPE in line with the requirements of Regulation 21 should the MPE resource deficiencies be addressed. In addition, further improvements were required with respect of Regulation 20 relating to MPE responsibilities to ensure full regulatory compliance. Inspectors found there was scope to improve MPE role in optimisation, diagnostic reference levels, training and a prospective QA programme

of equipment. This finding was acknowledged and accepted by staff and management during discussions held at the time of the inspection.

Inspectors found that governance arrangements at UHL had evolved in a significant way since 2019. Inspectors were satisfied that overall responsibility for radiation protection at the hospital and for the wider UHL Group was at the appropriate level resting with the Chief Executive Officer (CEO). From discussions with staff, it was clear to inspectors that staff were very aware of recently revised governance and reporting structures at the hospital and within the hospital group. However, it was apparent that the re allocation of governance responsibilities and oversight was an evolving process and more work needed to be done. For example, membership of the Radiation Safety Committee (RSC) needed to be finalised to ensure appropriate clinical and directorate representation and attendances at the RSC meetings. Draft RSC terms of reference reflecting these changes were due to be approved at the next scheduled RSC meeting.

Inspectors found that hospital radiation safety procedures needed to be revised to ensure alignment with current regulations and be reflective of updated governance arrangements and expanding radiological services provided at the hospital. Following on from this inspection, these local procedures should be updated as a priority for the benefit of radiology staff and to ensure the radiation protection of service users within the hospital.

Overall, inspectors found that the deficits in regulatory compliance identified were weighted towards MPE staffing deficiencies. Staff and senior management at the hospital acknowledged these deficiencies and there was general agreement that compliance levels should improve in tandem with increasing MPE resources.

## Regulation 6: Undertaking

Inspectors found that under updated governance arrangements, the CEO was the nominated designated manager for the purposes of the regulations. This role was sub-delegated to the Deputy CEO who was also the Chief Operating Officer (COO). The UL Hospital Group RSC was the radiation protection governing body for five of the six hospitals within hospital group and reported into the Quality and Safety Executive Committee (QUALSEC) and upwards to the UL Hospital Group CEO and HSE as undertaking.

From discussions and minutes viewed by inspectors, the CEO and COO were also members of QUALSEC and had attended the RSC meeting as observers on 6 May 2020. Under recently revised draft RSC terms of reference viewed by inspectors, the CEO and COO were to become new members of this committee once approved at the next RSC meeting. Further sub delegation from the general managers within each of the UL Hospital Group directorates was required to finalise governance arrangements for the radiation protection of patients. Improvements

were also under review relating to the clinical representation on the committee with plans to seek clinical directors from each directorate to attend future meetings.

The Medical Physics Department was supporting six sites within UL Hospital Group and was established in early 2018. It was clear from discussion with staff that MPE resource issues were ongoing from the outset. The hospital had documented this issue on its corporate risk register since 2017. A local assessment of the resources needed by the department had been completed by the chief physicist which had factored in resources needed for a growing and increasing demand on its service. This needs assessment had been presented to senior management. From documentation viewed by inspectors, it was clear that identified resource deficiencies had been escalated at hospital and group level and upwards to the undertaking at HSE level. However, while inspectors were satisfied that there was awareness at appropriate levels within the organisation, this did not translate in to addressing the resource deficiencies in an appropriate and timely way. Staff stated that efforts had been made to recruit two additional staff to bolster medical physics resources and this was still ongoing at the time of the inspection. Additional resource were expected to be in place by the end of 2020. Overall, inspectors were not satisfied with the progress made since 2017 to supplement existing medical physics resources.

Inspectors found that centrally developed UL Hospital Group Radiation Safety Procedures referred to as 'Local Procedures' were out of date and had not been revised since January 2018. These procedures viewed by inspectors did not reflect the regulations or changing governance arrangements at the hospital. Despite the gaps in documentation identified, these local procedures were re-approved for use by the RSC on 18 June 2019. Staff stated that the completion of risks assessment for all installations within the radiological service was a prerequisite to updating local procedures. Delays in completing risk assessments and updating the procedures were attributed to deficiencies in medical physics staffing and increased demands on MPE involvement into recently approved capital projects during the COVID -19 pandemic. Inspectors were not satisfied with the proposed nine month timeframe allocated for updating these procedures given their importance to radiation protection for service users and management should ensure that these local procedures are updated as a priority.

Overall, while improvements had been made in the governance arrangements for the radiation protection of service users, inspectors found that more improvements were needed. To ensure the radiation protection of service users, governance arrangements should be finalised to provide clarity to staff. Deficiencies identified by the hospital within its Medical Physics Department and updating of supporting radiation safety procedures must be addressed as a priority following on from this inspection.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Through discussions with staff and documentation reviewed, inspectors were not satisfied that the necessary arrangements required under Regulation 19(9) were in place to ensure the continuity of medical physics expertise. As a consequence, UHL was not meeting regulatory requirements, a finding acknowledged by senior management at the time of the inspection.

At the time of the inspection, medical physics resourcing amounted to two MPEs and one basic grade physicist. Inspectors were informed that there was a deficit in workforce planning in place and locum cover for unplanned medical physics leave had not been provided at the time of the inspection. Furthermore, there was a concern that the ongoing reliance on external medical physics experts resourcing to provide QA of equipment was not sustainable and must be addressed urgently.

Overall, inspectors found that the Medical Physics Department resource planning should be prioritised to ensure continuity to MPE service is assured. Management at UHL must initiate short and medium term strategies to address immediate deficits identified in this report and enact a long term strategy to build on the resourcing requirements identified for the future needs of the service.

Judgment: Not Compliant

## Regulation 20: Responsibilities of medical physics experts

The hospital had two MPEs registered in the Register of Medical Physics Experts. From discussions with staff, inspectors were satisfied that MPE responsibilities relating to the surveillance, acceptance testing, selection of equipment and evaluation of technical specification relating to medical radiological equipment were being met. This was evident in the recent workload performed by Medical Physics Department in its involvement in capital projects initiated in 2020. Inspectors were informed that funding to proceed with building works at UHL and another ULHG site had become available in March 2020. As a consequence, radiation safety risk assessments were required to update building plans as a priority. Inspectors noted that MPE input required for these new builds was not factored in at the planning stage which was acknowledged by senior management.

Inspectors were also assured that there was appropriate contribution by an MPE in the analysis of events involving accidental or unintended medical exposures. Discussion with staff highlighted the need for more MPE involvement in the training of practitioners and other staff in relevant aspects of radiation protection and would be a focus for improvement subject to increased MPE resources in the future.

Inspectors found areas of improvement were required relating to responsibility for dosimetry and optimisation of the radiation protection of service users. Inspectors noted that the collection of data for the establishment of diagnostic reference levels (DRLs) was evident in documentation reviewed, however facility DRLs were not

established for most of the procedures provided at the hospital. In addition, staff acknowledged that there was a lack of MPE involvement in the development of protocols underpinning optimisation of medical exposures as required in Regulation 10(2) and more needed to be done in this regard. Urgent improvements were also identified in relation to the ongoing quality assurance programme of medical radiological equipment which will be discussed further under Regulation 14.

To help mitigate potential risks, inspectors were informed that radiography staff provided additional supports to the MPE service. For example, staff stated that the Radiation Protection Officer (RPO) was responsible for the training of staff in relevant aspects of radiation protection and both the Radiation Services Manager and RPO were involved in the development of protocols.

Inspectors found that the hospital was meeting some requirements of Regulation 20 however deficits noted in related to the management of an appropriate QA programme and the establishment of a comprehensive suite of DRLs for the hospital and the wider group should be prioritised as a matter of urgency.

Judgment: Substantially Compliant

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

From discussions with staff, inspectors found that capital projects and the COVID-19 pandemic had placed additional demands on an already under resourced Medical Physics Department. As a consequence, inspectors were not satisfied that there was an appropriate level of MPE involvement commensurate with the radiological risk posed by the service which included Nuclear Medicine and interventional radiology practices. Management at UHL should ensure that allocation and resourcing of medical physics expertise should be urgently prioritised to meet the deficits identified under Regulation 20.

Judgment: Not Compliant

### Safe Delivery of Medical Exposures

This risk based inspection focused on Regulation 11 and Regulation 14 based on issues identified at Nenagh Hospital. Inspectors found that improvements were required at UHL to ensure regulatory compliance with Regulations 11 and 14. This included the establishment and use of facility diagnostic reference levels and a more proactive approach to ensuring an appropriate ongoing quality assurance programme was in place to help ensure the safety and effectiveness of the service.

Inspectors identified that urgent improvements were required in relation to the processes in place for ensuring an ongoing appropriate quality assurance programme for medical radiological equipment. Deficiencies in MPE staffing meant that annual QA of equipment needed to be outsourced for 2019 and 2020. From review of documentation provided and in discussions with staff, inspectors found that the 2019 QA programme, although completed, had not been formally signed off by the hospital at the time of the inspection. In addition, outsourcing of the QA programme for 2020 had not been finalised and scheduled. However, documentation submitted since this inspection provided assurance that outsourcing had subsequently been agreed for the majority of equipment and would be completed by the end of 2020.

Inspectors found that substantial work was required to advance the establishment of diagnostic reference levels for all procedures. At the time of the inspection the hospital had only formally approved facility DRLs for use in the Nuclear Medicine Department with draft DRLs for Cardiology awaiting approval. Inspectors noted that much work had been done in collecting data for the establishment of DRLs in other modalities with significant input provided by radiography staff to medical physics in this area. An example of good practice identified by inspectors was the initiation of an image quality review on the basis of low doses captured during the collection of data in each modality. This represented good local oversight and assurance relating to diagnostic image quality for the benefit of service users.

Overall, inspectors identified significant areas for improvement were required with respect of Regulations 11 and 14 which were attributed to deficiencies in medical physics staffing deficiencies. Management at UHL should prioritise these areas as a matter of urgency.

### Regulation 11: Diagnostic reference levels

The collection of data needed to establish DRLs was well underway at UHL which was evident in staff discussions and documentation reviewed by inspectors. Inspectors noted that the hospital had demonstrated oversight of the data collected to date and found that in some cases doses were much lower than nationally established DRLs which was a positive finding. As a consequence, an image quality review audit was initiated to provide diagnostic assurance on medical exposures undertaken at the hospital before finalising DRLs for the hospital.

However, DRLs had only been formally established for nuclear medicine at the time of the inspection. Cardiology DRLs were in the final stages of development and due to be signed off at the next RSC meeting. It was acknowledged by senior managers and staff who spoke with inspectors that more needed to be done with regard to DRLs to meet the requirements of this regulation.

Judgment: Not Compliant

## Regulation 14: Equipment

Inspectors were provided with an inventory of medical radiological equipment prior to the inspection demonstrating that medical radiological equipment was kept under close surveillance consistent with regulatory requirements. Inspectors were assured that there were processes in place to take equipment out of service where there were potential implications for patient safety with continued use. There was also evidence that an ongoing replacement programme was in place to upgrade equipment at the hospital which had exceeded the nominal replacement age.

Through discussions with staff and review of documentation provided, inspectors were not satisfied however that there was an appropriate ongoing QA programme in place at UHL. Annual QA at the hospital had to be outsourced in 2019 due to medical physics staffing levels. Furthermore, inspectors were informed that any follow up of any issues identified during the annual QA programme was the responsibility of the ULHG Medical Physics Department.

Inspectors were informed that annual QA testing of equipment at UHL had been completed for 2019, however associated QA reports were being finalised at the time of the inspection. This meant that the 2019 QA programme had not been formally closed off by either the Medical Physics Department or the hospital. In addition, inspectors were not assured that a formal QA programme for 2020 was in place. Communication provided to inspectors following the inspection indicated that negotiations for outsourcing 2020 QA had been initiated by the hospital but not finalised. Subsequent confirmation of outsourcing was provided to inspectors after the inspection.

Overall, inspectors identified that the hospital needs to adapt a more proactive approach to prioritise and future proof the maintenance and continuity of an appropriate quality assurance programme for medical radiological in line with regulatory requirements.

Judgment: Not 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 6: Undertaking	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 14: Equipment	Not Compliant

# Compliance Plan for University Hospital Limerick OSV-0007379

Inspection ID: MON-0029586

Date of inspection: 11/06/2020

## Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

## Section 1

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

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <p>Governance: The membership was reviewed following the Radiation Safety Committee (RSC) meeting on the 6th May. The terms of reference and membership of the RSC was updated by the RPA. The document was further revised by the CEO &amp; circulated to key staff on the 12th June 2020.</p> <p>The HSE sub-delegations orders are currently under review by the Head of Governance and Directorate Managers. In particular the roles and responsibilities of the Managers are under review.</p> <p>The content of the Radiation Safety Procedures (RSP) will be updated to reflect the requirements in SI 256 of 2018 by 30th Sept.</p> <p>The roles and responsibilities identified in the sub-delegation orders will be incorporated into the RSP and will be completed by the 29th August 2020.</p> <p>The RSP will be further updated as the Risk Assessments are revised in line with the schedule submitted to the EPA on the 26th June 2020</p>	
Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:</p> <p>Plan of Action</p> <ul style="list-style-type: none"> <li>• The Saolta Group Medical Physics Dept has agreed to revise a number of the Risk</li> </ul>	

Assessments for UHL to include the requirements of the new legislation and meet EPA requirements, this work is underway.

- The Saolta Group have agreed to provide contingency MPE services until the required MPE resources are available to the hospital group.
- Approval has been given to recruit 3 new staff at Principal, Senior and Basic grades. The job orders for the Senior Physicist was submitted to the HSE on the 9th June and orders for the Principal and basic Grade Physicists were submitted to the HSE for processing on the 7th July. We await the National Recruitment Service to commence the recruitment process.

These arrangements in the short to medium term should provide the necessary contingency.

December 2020

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:

There is scope to improve on the input and this will be addressed with the additional resources which are being progressed by the HSE.

All DRL work between 2018 and early 2020 in UHL has been lead and progressed by the Medical Physics Dept.

The input has been significant to date and this will continue as more resources are made available.

Radiography staff are providing significant assistance to progress the establishment of DRLs by collecting patient dose data across all sites at present.

Communication details and a copy of the presentations can be made available as evidence if required.

QA programme for 2019 is now closed out and a schedule for 2020 is agreed with ST James's Hospital

A level of optimisation is undertaken during commissioning and during the annual QC assessment and the evidence is available for review for systems tested in 2018 and 2019. If optimisation issues are noted they are detailed for action in the report. Details

on Medical Physics staff involvement in other areas of optimisation in Cardiology, Nuclear Medicine, General radiology and fluoroscopy.

In terms of providing training, Medical Physics staff delivered a number of lectures in 2018 and in 2019, and the priority was given to the High Risk Areas (e.g. Nuclear Medicine, Interventional Radiology, justification).

In addition Medical Physics staff have reviewed and provided feedback on draft policies and procedures and will continue to do so

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:

There is scope to improve on the input and this will be addressed with the additional resources which are being progressed by the HSE.

All DRL work between 2018 and early 2020 in UHL has been lead and progressed by the Medical Physics Dept.

The input has been significant to date and this will continue as more resources are made available.

Details were provided on the Feedback Form. Communication details and a copy of the presentations can be made available as evidence if required.

Radiography staff are providing significant assistance to progress the establishment of DRLs by collecting patient dose data across all sites at present.

A level of optimisation is undertaken during commissioning and during the annual QC assessment and the evidence is available for review for systems tested in 2018 and 2019. If optimisation issues are noted they are detailed for action in the report. Details on Medical Physics staff involvement in other areas of optimisation in Cardiology, Nuclear Medicine, General radiology and fluoroscopy, was provided on the Feedback Form.

In terms of providing training, Medical Physics staff delivered a number of lectures in 2018 and in 2019, and the priority was given to the High Risk Areas (e.g. Nuclear Medicine, Interventional Radiology, justification).

In addition Medical Physics staff have reviewed and provided feedback on draft policies and procedures and will continue to do so

ULHG Medical Physics staff has expertise in areas involving high patient doses and provide support to the clinical teams, although this is limited given the existing

resources, however the Saolta Group are providing MPE support and high risk areas will be prioritised.

Regulation 11: Diagnostic reference levels

Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

All Dose Reference Levels work has been lead and progressed by the Medical Physics staff since 2018. All Nuclear medicine, cardiology, general radiology, portable imaging, mammography and paediatric imaging in UHL has been collected by medical physics.

Nuclear Medicine, cardiology and general radiography data has been analysed by Medical Physics staff.

A number of presentations were delivered on the topic of establishing Dose Reference Levels to Radiography and Radiology by Medical Physics staff. The input has been significant to date.

Radiography staff are collecting doses for various examinations at present including CT (3 UHL systems), CT in Ennis Hospital, CT and General X-ray exams in Nenagh Hospital, neonatal imaging in the Maternity Hospital, fluoroscopy procedures in UHL and General Radiography exams in Croom Hospital.

Medical Physics staff will analyse the data to progress the establishment of the DRLs.

The UHL 2020 Nuclear Medicine, General and Cardiology Dose Reference Levels were approved at the RSC meeting on the 14th July 2020.

Mammography, paediatric imaging and CT will be considered at the next RSC meeting on October 14th 2020

As additional resources become available, the remaining Dose Reference Levels data collected by radiographers will be analysed by Medical Physics staff for submission to the RSC.

Regulation 14: Equipment

Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:

- The majority of the annual QA schedule has been outsourced to St. James's Hospital Medical Physics Dept.

- ULHG Medical Physics staff will commission the 5 new systems waiting testing and the remaining 2 systems not covered in the schedule confirmed by St. James's Hospital.
- The Saolta Group Medical Physics Dept has agreed to revise a number of the Risk Assessments for UHL to include the requirements of the new legislation and meet EPA requirements, this work is underway
- These Risk Assessments were last updated by the ULHG between December 2018 and March 2019. The ULHG Medical Physics staff will update the remaining High Risk Area and the Low Risk Area Risk Assessments.
- The outsourcing of some of this work will permit ULHG staff to revise the Radiation Safety Procedures.
- Approval has been given to recruit 3 new staff at Principal, Senior and Basic grades. The job orders for the Senior Physicist was submitted to the HSE on the 9th June and orders for the Principal and basic Grade Physicists were submitted to the HSE for processing on the 7th July. We await the National Recruitment Service to commence the recruitment process.
- These posts will bring the total staffing level in the Medical Physics Department in the ULHG to 6 (Chief, Principal, 2 X Senior and 2 X Basic grade physicists)
- The mammography QA schedule, including commissioning of the new Faxitron has been outsourced to Breast Check Medical Physics Dept date to be confirmed

QA reports were issued in 2019; approximately 70% of the reports had been issued by 31st Dec 2019.

There was a delay in issuing the remaining reports as Medical Physics staff were required to support the capital funded and COVID-19 related projects.

All reports for 2019 were issued for action by the 26th June 2020

All documents are accessible and available on site.



## 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 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	14/10/2020
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	31/12/2020
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing	Substantially Compliant	Yellow	27/07/2020

	compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.			
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.	Not Compliant	Orange	31/12/2020
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,	Substantially Compliant	Yellow	31/12/2020
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics	Substantially Compliant	Yellow	31/12/2020

	<p>expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none"> <li>(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;</li> <li>(ii) the definition and performance of quality assurance of the medical radiological equipment;</li> <li>(iii) acceptance testing of medical radiological equipment;</li> <li>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</li> <li>(v) the surveillance of the medical radiological installations;</li> <li>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</li> <li>(vii) the selection of equipment required to perform radiation</li> </ul>			
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	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	31/12/2020
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	31/12/2020
Regulation 21(2)(c)	In carrying out its obligation under paragraph (1), an undertaking shall,	Not Compliant	Orange	31/12/2020

	<p>in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.</p>			
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