



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Nenagh Regional Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Nenagh, Tipperary
Type of inspection:	Announced
Date of inspection:	12 February 2020
Medical Radiological Installation Service ID:	OSV-0007368
Fieldwork ID:	MON-0028241

## About the medical radiological installation:

Nenagh Hospital is part of UL Hospitals Group serving the County of North Tipperary and surrounding counties. Under the Acute Medicine Programme Nenagh's Local Emergency Centre has evolved into a Local Injuries Unit. The services provided at Nenagh Hospital are representative of a Model 2 Hospital and delivers non-complex care as close as possible to the patients' homes. Access for medical admissions is via the Medical Assessment Unit, Local Injuries Unit, direct GP admissions and transfer of patients from the University of Limerick Hospital's Group. Onsite Radiology Services available are general X-ray, CT scan and ultrasound. All other imaging modality services are available at the Level 4 Hospital, University Hospital Limerick.

## 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 12 February 2020	09:15hrs to 16:00hrs	Kay Sugrue	Lead
Wednesday 12 February 2020	09:15hrs to 16:00hrs	Noelle Neville	Support

## Governance and management arrangements for medical exposures

Inspectors found that governance arrangements for the radiation protection of service users at Nenagh Hospital was under the remit of University of Limerick Hospital Group (ULHG) Radiation Safety Committee (RSC). The Chief Executive Officer (CEO) had overall responsibility for radiation protection at the hospital. A recent review of the governance arrangements had been undertaken at group level and documentation was available to support this. Inspectors were satisfied that these proposed governance changes would further define the allocation of responsibilities for the radiation protection of services users at an appropriate level within the group and at Nenagh Hospital.

From discussions with management and staff and review of referrals, inspectors were assured that referrals were only accepted from appropriate professionals entitled to refer under the regulations. In addition, all medical radiological procedures conducted at the hospital took place under the clinical responsibility of a recognised practitioner. However, inspectors found that locally approved radiation safety procedures viewed did not identify radiographers as practitioners which was not consistent with the practices witnessed at the time of the inspection.

Nenagh Hospital had submitted a self-assessment questionnaire to HIQA demonstrating an awareness of its level of compliance with the requirements of the regulations. Compliance levels judged by the hospital were similar to those found by inspectors during the inspection and indicated that more work needed to be done to reach full compliance with the regulations. A quality improvement plan viewed by inspectors showed some improvements had been made but many remained in progress. An area of improvement identified by the hospital prior to this inspection related to limited Medical Physics Expert (MPE) resources available to the radiology service at the hospital.

Nenagh Hospital had access to services from the Medical Physics Department located at University Hospital Limerick with continuity of this service also provided by the same department. It was clear to inspectors from documentation reviewed and discussions with MPE staff and senior management that medical physics resources were less than optimal at Nenagh Hospital. This meant that while the hospital was meeting some regulatory requirements with respect of the MPE service, greater MPE input and involvement was needed to comply fully with the Regulations.

Inspectors found that ULHG had increased MPE resources at group level in recent years resulting in a doubling of resources. Despite these increases, MPE resources at Nenagh hospital had remained static. Minutes from the 2019 RSC meetings showed deficiencies in the MPE service was an ongoing concern which had been escalated appropriately through radiation protection governance structures to hospital group and HSE level and was recorded as a risk on the corporate risk register. Overall, inspectors found that this should be urgently addressed to provide an appropriate

level of MPE cover for the hospital. In the interim, the hospital needs to put arrangements in place to provide greater assurances on the optimisation of the radiation protection of service users undergoing medical exposures provided by its facility.

Inspectors identified that improvements were required in other areas. For example, more assurance was required to ensure that supporting documentation on radiation practices were relevant to the services provided at Nenagh Hospital, up-to-date and in line with regulatory requirements. Improvements were also required in local oversight of equipment quality control systems to ensure all quality control checks were completed in line with local policy.

#### Regulation 4: Referrers

Evidence seen at the time of the inspection demonstrated compliance with the requirements of this regulation. Documentation reviewed by inspectors showed that referrals were only accepted by identifiable referrers recognised by this regulation and staff who spoke with inspectors clearly understood the regulatory requirements of Regulation 4.

Judgment: Compliant

#### Regulation 5: Practitioners

Evidence seen at the time of the inspection demonstrated compliance with the requirements of this regulation. Inspectors found that only those entitled to act as practitioners such as radiologists and radiographers had taken clinical responsibility for individual medical exposures at the hospital as per the regulations.

Practitioners were identified as radiologists in local radiation safety procedures viewed by inspectors. These procedures were not aligned to current legislation and did not reflect day-to-day practices as described to and seen by inspectors. For example, radiographers carried out justification and pregnancy status assessment for all general radiography procedures at the hospital. To provide clarity on practitioner roles and responsibilities, local radiation safety procedures and supporting documentation should be reviewed and updated.

Judgment: Compliant

#### Regulation 6: Undertaking

Inspectors reviewed draft documentation outlining governance arrangements at Nenagh Hospital. Senior managers informed inspectors that radiation safety governance structures were centralised at University of Limerick Hospital Group (ULHG) level. The governance structures had been recently revised and updated to ensure oversight of all matters relating to radiation protection of service users.

The draft governance structures demonstrated that the Chief Executive Officer (CEO) of UHLG was delegated responsibility from the undertaking which was the Health Service Executive. In addition, the CEO sub-delegated to the Chief Operations Officer (COO) who in turn delegated to a member of senior management in each directorate. Inspectors were informed by the COO that approval of managers for each directorate had been agreed but had yet to be implemented. Following the inspection, inspectors received documentation providing clarity on the sub-delegation of responsibility to directorate managers within UHLG.

A Radiation Safety Committee (RSC) was in place at hospital group level with responsibility for recommending radiation protection measures. The RSC was incorporated into ULHG governance structures. Minutes of this committee reviewed by inspectors demonstrated standard agenda items covering a wide range of topics relevant to radiation safety and protection of service users. Issues arising that could not be addressed at this level were referred upwards to the Quality and Safety Executive Committee (locally known as the QUALSEC committee) which was evident in minutes reviewed. The CEO and the COO were members of this committee. Nenagh Hospital was appropriately represented on the RSC by the Radiation Safety Manager and the General Manager of the Diagnostics Directorate. Membership of this committee at the time of the inspection reflected current delegation of responsibilities for the radiation protection of service users which should be reviewed to ensure that there is appropriate representation on the committee in line with recent changes to the governance structures.

Inspectors reviewed radiation safety procedures also known as local rules which were developed and approved by the Radiation Safety Committee for application within each hospital within the ULHG. These procedures were issued in January 2018 and re-approved by the committee in June 2019. However, inspectors noted that the procedures were not revised and reviewed to ensure the document reflected current legislation and day-to-day practices.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

Inspectors found that all medical exposures took place under the clinical responsibility of a practitioner in line with regulations. The hospital was meeting regulatory requirements with respect of the involvement of practitioner and referrers in the justification process and practical aspects of medical radiological procedures. However, involvement of the medical physics expert (MPE) in the optimisation

process for medical exposures conducted at Nenagh Hospital was not strongly evident at the time of the inspection and should be reviewed.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that the hospital had access to off-site MPE services located at University Hospital Limerick. Continuity for the MPE service was provided from the ULHG Medical Physics Department. Staff working in the Radiology Department told inspectors that they had access to an MPE should the need arise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors were assured that the MPE's providing a service to Nenagh Hospital were registered by the appropriate registering body but up-to-date certification was not available for review on the day of inspection and should be maintained locally.

Inspectors spoke with medical physics staff who outlined that MPE input for the hospital was limited to quality assurance testing of medical radiological equipment. Inspectors were informed that MPEs contributed to the quality assurance testing, surveillance, acceptance testing and the technical specification and selection of new equipment. In addition, evidence of the analysis of radiation incidents by an MPE as appropriate was seen by inspectors. However, there was a lack of evidence of MPE involvement relating to training on relevant aspects of radiation protection, dose monitoring and the development of diagnostic reference levels (DRLs) at the hospital. Inspectors were informed that the deficiencies in relation to MPE involvement were as a result of resource constraints and competing challenges within the service. The outsourcing of quality assurance testing of medical radiological equipment was required by the hospital during 2019 as a result of resource deficiencies. As a result, inspectors were not assured that the requirements of this regulation were being fully met by the hospital.

A gap analysis of the medical physics service was conducted by medical physics staff. This gap analysis identified a deficit in resources estimating that the resourcing for Nenagh Hospital were insufficient. It was identified that resources needed to increase from 0.1 whole time equivalent (WTE) to 0.35 WTE to ensure compliance with the regulations.

The ULHG had sought to address these resource deficiencies, had escalated the issue to undertaking level and recorded the risk on the corporate risk register.

The COO told inspectors that medical physics resources had doubled from 1.5 to 3 WTE but acknowledged that current resources needed to be increased further to meet the needs of the service. It was accepted and acknowledged by senior managers that despite progress to date, further recruitment to boost the medical physics department resources would take time. Inspectors found that current MPE resources provided at the hospital were insufficient to meet regulatory requirements. Overall, inspectors were not satisfied that there was sufficient assurances relating to the optimisation of the radiation protection of service users undergoing medical exposures at Nenagh Hospital.

Judgment: Not Compliant

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

From discussion with staff and documentation reviewed, inspectors were assured that staff had access to the MPE service for advice on issues relating to the radiation protection of service users undergoing medical radiological procedures at the hospital. Staff informed inspectors that there had not been an issue contacting an MPE whenever issues arose. However, inspectors were not assured that the level of involvement of the MPE was commensurate to the radiological risk posed by medical exposures involving potential high doses in the Computed Tomography (CT) service.

MPE staff acknowledged that there was scope to improve involvement in relation the evaluation of the dose delivered to service users and the application and use of diagnostic reference levels (DRLs). Documentation and discussion with staff and senior management demonstrated that the hospital was working towards increasing MPE resourcing at the hospital which was expected to take some time before adequate resource levels were reached. In the meantime, the hospital should put systems in place to assure itself in relation to the oversight of records and doses delivered to service users locally to ensure that all medical exposures are optimised.

Judgment: Substantially Compliant

### Safe Delivery of Medical Exposures

Inspectors found that Nenagh hospital had an appropriate system for reporting radiation safety incidents through its electronic reporting system. Hard copy versions of incidents were also stored in a folder in general radiography viewed by inspectors. There was evidence demonstrating that near misses were also reported. Inspectors identified that there was scope to expand staff awareness through the learning gleaned from these records, through the tracking and trending of radiation

incidents and near misses and sharing of such events across the ULHG.

Documentation viewed by inspectors demonstrated that an appropriate quality assurance programme for all medical radiological equipment at the hospital was in place. An up-to-date inventory was provided and recent approval for replacing the CT scanner had been received by the hospital prior to the inspection. An area of improvement identified by inspectors related to the oversight and management of internal quality control checks for medical radiological equipment in use to ensure that all scheduled checks are completed in line with local policy.

Inspectors viewed a comprehensive log of all doses delivered to service users from CT procedures for 2018 and 2019. These records showed and staff acknowledged that sufficient data had been collected to enable the development of DRLs locally for the CT service. However, Nenagh hospital had not established local facility DRLs and therefore did not meet the regulatory requirements of Regulation 11(5) and 11(6).

Inspectors found that the hospital conducted a number of regular clinical audits relating to radiation protection of service users which included pregnancy status checks lists and compliance with service user identification protocols which was acknowledged by staff at the hospital as somewhat limited. A good example of audit practice was a retrospective review of computed tomography pulmonary angiograms (CTPA) conducted in 2019 which resulted in improvement in the overall percentage of optimal CTPA diagnostic studies. Inspectors identified that there was potential to expand clinical audit to provide greater assurances on adherence to local procedures, protocols and policies.

Other areas for improvement identified by inspectors were in relation to Regulation 8 and Regulation 13. Staff clearly and consistently described how each type of medical exposure was justified in practice. Documentation of justification for CT procedures was recorded on the radiology information system (RIS) and viewed by inspectors. However, inspectors were informed that a similar process for recording the justification for general radiography procedures was not evident which did not meet the requirements of Regulation 8(8) and 8(15). A consistent process for documenting justification for all medical exposures must be implemented following this inspection to fully meet regulatory requirements. Inspectors also noted a lack of patient information leaflets in radiology waiting areas which is an area for improvement.

Inspectors reviewed reports of medical procedures which showed that in the majority of the reports viewed, information relating to the patient exposure was not included in line with Regulation 13(2).

Overall, inspectors found that the hospital had met many aspects of the regulations inspected but improvements were required in a number of areas to ensure complete regulatory compliance. Areas requiring improvement mainly related to need for stronger local leadership, management and oversight arrangements for monitoring and ensuring the radiation protection of service users. In addition, more assurances were needed relating to document quality management systems for the

development, revision and ratification of policies, procedures, protocols and guidance of some supporting documentation including CT protocols.

## Regulation 8: Justification of medical exposures

In reviewing referrals, inspectors saw evidence which provided assurance that referrals received and viewed by inspectors were in writing, stated the reason for requesting the procedure and were accompanied by sufficient data. Staff also demonstrated systems in place to access previous diagnostic data if required to support the justification process.

In discussions with staff, inspectors found that staff clearly understood the justification process and consistently described a process followed to ensure that all requested procedures were justified by either a radiographer or radiologist in advance of conducting medical radiological procedures. Inspectors found in reviewing referrals for CT procedures that all were justified in advance by a duty radiologist, the records of which were recorded on the radiology information system. However similar documented records of justification were not evident in relation to general radiography. This meant that the hospital did not fully meet the regulatory requirements of Regulation 8(8) and Regulation 8(15). Inspectors also noted that the hospital draft justification policy did not reference the documentation of justification which should be reviewed following this inspection and updated to ensure all aspects of justification as required under Regulation 8 are considered for inclusion before final approval.

An area for improvement also identified by inspectors related to the proactive provision of information on the the benefits and risks associated with medical exposures. Posters in patient waiting areas and changing rooms were observed by inspectors but patient information leaflets relating to radiation protection were not available to service users at the time of the inspection. Inspectors were informed by radiography staff that further discussion on the risks and benefits relating to the procedures was generally provided when requested by the service user.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

Inspectors were shown systems in which radiation doses received by patients during medical exposures were recorded by the hospital radiology information system. In addition, inspectors saw log books with a record of patient doses for each CT procedure conducted at the facility from 2018 up to the day of the inspection in 2020. Nationally established DRLs were displayed in general radiography procedure rooms and the CT scanning room and staff informed inspectors that these

DRLs were referred to when monitoring patient doses associated with medical exposures conducted at the facility. However, inspectors found that Nenagh Hospital had not established facility DRLs in line with the requirements of Regulation 11(5). In addition, a formalised process of review for the optimisation of protection and safety for patients providing assurance of appropriate MPE oversight and to ensure that national DRLs were not exceeded was not evident at the time of the inspection. Deficiencies in medical physics resources were identified by staff who spoke with inspectors as one of the contributing reasons as to why facility DRLs were not established.

Judgment: Not Compliant

### Regulation 13: Procedures

Inspectors viewed protocols for each medical radiological procedure conducted at Nenagh Hospital which were readily accessible to staff in each clinical area. Radiology staff informed inspectors that these protocols were developed at University of Limerick Hospital Group (ULHG) level and used locally. Protocols viewed for the CT scanner were specific to a 64 slice CT scanner but not for the 6 slice CT scanner in use at the hospital which did not fully meet the requirements set out in Regulation 13(1). Additionally, inspectors found that the CT protocols viewed had not been formally reviewed and updated since 2009. Overall, inspectors were not satisfied that protocols viewed at the hospital were adapted for each type of equipment in use locally or assured that appropriate quality control, management and oversight of these written protocols was strongly evident.

Reports of medical radiological procedures viewed by inspectors found that the information relating to patient exposure was not consistently recorded with the exception of one CT scan report viewed on the day of inspection.

Referral guidelines for medical imaging were available to staff via desktop computers in general radiography and CT areas.

Inspectors found a good example of clinical audit practice. The hospital had carried out a retrospective audit of computed tomography pulmonary angiograms (CTPA) conducted in 2019 to determine the effectiveness of a quality improvement measure to optimise the diagnostic quality of CTPA studies. The audit found that providing a detailed instruction on the correct breathing technique to service users before the procedure to be applied during the scan led to an improvement in the overall percentage of optimal CTPA diagnostic studies performed in the CT Department. Overall, the potential to expand clinical audit at the facility was identified by inspectors to provided better assurance to the undertaking on compliance with processes such as justification and optimisation which are essential elements for the radiation protection of service users.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Inspectors found that Nenagh Hospital had an appropriate annual quality assurance programme in place which was performed by the ULHG Medical Physics Department and overseen by a MPE in line with regulations.

An up-to-date inventory of medical radiological equipment was provided for review. Inspectors were informed that the hospital had received recent approval for funding to upgrade the Computed Tomography (CT) scanner at Nenagh Hospital which had been installed in 2007. The replacement date for this piece of equipment was not available at the time of the inspection.

Inspectors found that there was a gap in the 2019 records viewed relating to in-house quality control equipment checks which were not completed in line with local policy. Inspectors identified that improvements were needed in the monitoring and oversight of these checks to ensure quality control measures on medical radiological equipment is completed within locally agreed schedules.

Judgment: Substantially Compliant

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

Regulatory aspects of this regulation assessed by inspectors were found to be compliant. For example, referrals viewed by inspectors demonstrated that where relevant, pregnancy status checks were completed appropriately by radiographers and uploaded onto the radiology information system. Inspectors were informed by practitioners that re-justification was carried out by a radiologist if required. This process was regularly audited compliance of which was high in audit records viewed by inspectors for 2019 and January 2020. An area for improvement identified by inspectors was the need to update the local protocol for managing female patient of child bearing age which had not been revised since November 2017 and therefore did not reflect current legislation.

Judgment: Compliant

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

Inspectors were satisfied that there was a system in place to record all radiation safety incidents and evidence of discussion at the Radiation Safety Committee. In

discussions with staff, the process for recording incidents in hard copy format and on the hospital electronic information system was clearly understood and consistently articulated. Inspectors viewed a folder in general radiography which was a record of all incidents to have occurred in the Radiology Department in 2018 and 2019. Incidents reviewed also included the record of near misses.

While a reporting culture in relation to radiation safety incidents was evident in documents reviewed by inspectors, trending and analysis of such incidents was not available as required by this regulation. Inspectors also identified that there was potential to share information gleaned from analysis and trending of radiation safety incidents and lessons learned from significant events within the radiology services at the hospital and within the ULHG.

Judgment: Substantially Compliant

## Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not 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	Substantially Compliant

# Compliance Plan for Nenagh Regional Hospital OSV-0007368

Inspection ID: MON-0028241

Date of inspection: 12/02/2020

## 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>1. 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. Timeline to achieve planned action: Complete</p> <p>2. The content of the Radiation Safety Procedures (RSP) will be updated to reflect the requirements of SI 256 of 2018 by 30th Sept. Timeline to achieve planned action 30th Sept 2020</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities:</p> <p>1. 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. Timeline to achieve planned action: December 2020</p> <p>Additional update to compliance plan received: In the interim, ULHG is on the process of employing an agency physicist on a temporary basis until the permanent filling of these approved posts has occurred. Significant work has been carried out by MPE on DRLs for Nenagh</p>	

Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:</p> <p>1. Certificates valid until 2021 were received by both MPEs just after the inspection and are maintained locally. Timeline to achieve planned action: Complete</p> <p>2. All DRL work between 2018 and early 2020 in UHL has been led and progressed by the Medical Physics Dept. The input has been significant to date and this will continue as more resources are made available. Communication details and a copy of the presentations can be made available as evidence if required.</p> <p>Radiography staff are providing significant assistance to progress the establishment of DRLs by collecting patient dose data across all sites at present.</p> <p>Medical Physics have drafted a template for assessing the quality of images; it is currently being used at UHL and proposed to roll out to all other hospitals in the group.</p> <p>Medical Physics staff delivered a number of lectures in 2018 and in 2019.</p> <p>In addition Medical Physics staff have reviewed and provided feedback on draft policies and procedures and will continue to do so.</p> <p>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 additional MPE support and high risk areas will be prioritised.</p> <p>Timeline to achieve planned action: 31 December 2020</p> <p>3. The ULHG Medical Physics Department staff performed all QA testing in Nenagh Hospital in 2019.</p> <p>4. 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. Timeline to achieve planned action: December 2020</p> <p>5. 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</p>	

2019. If optimisation issues are noted they are detailed for action in the report.

All DRL work between 2018 and early 2020 in UHL has been led 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 and radiology staff are providing significant assistance to progress the establishment of DRLs by collecting patient dose data across all sites at present and audit of the quality of the images.

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:

1. Medical Physics staff are very much involved in supporting areas at Nenagh Hospital however there is scope to improve this.

Details of presentations/ communications between Medical Physicist and radiography & clinical staff can be provided as evidence if required to confirm MP involvement.

It is acknowledged that additional MPE support is necessary; hence the three additional resources will assist to address this issue.

Timeline to achieve planned action: 31st December 2020

2. The template for auditing the quality of images has been established at UHL, it is planned to roll out across all other hospitals in the group.

Annual QA testing will be completed with the assistance of St James's Hospital.

Some risk Assessments have been outsourced to Saolta and this will assist in ensuring that we meet license requirements.

Timeline to achieve planned action: 31st December 2020

Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>1. As per current practice all radiographer appraise the clinical indications provided on each individual referral in advance of exposing the service user to ionising radiation bearing in mind legislative requirements and clinical evaluation criteria.</p> <p>1. Justification is a professional activity and must be performed by a suitably qualified practitioner.</p> <p>2. Justification must be performed in advance of exposing the service user to ionising radiation.</p> <p>3. Authorisation is the documentation that the professional activity of justification has taken place.</p> <p>Clinical indications deemed to be justified, the performing radiographer authorises the examination.</p> <p>Planned action: Evidenced by typing their - initials, time and date of when authorisation took place edited into the notes field of the National Integrated Medical Imaging System (NIMIS) Radiology information system (RIS).</p> <ul style="list-style-type: none"> <li>- All Radiographers CORU registration numbers are evidenced within NIMIS. (Current practice)</li> <li>- Every completed radiological examination must be completed and signed off by the performing radiographer. (Current practice)</li> </ul> <p>Timeline to achieve planned action: Complete</p> <p>Clinical Indications supplemented, by information gleaned from referrer or service user which may add to the clinical picture and may justify re-appraisal of the referral.</p> <p>QIP Action: A 'near miss form' will be completed to capture this process.</p> <p>This will be audited on a monthly basis to establish trends and to be used as learning experiences for both radiology and the referrer.</p> <p>Timeline to achieve planned action: Complete</p> <p>Clinical Indications deemed to be unjustified</p> <p>Action: The performing radiographer discusses this with the referrer &amp;/or the service user to explain rational. Referral will be rejected on NIMIS under the reject code of insufficient clinical information.</p> <p>This will be audited on a monthly basis to establish trends and to be used as learning experiences for both radiology and the referrer.</p> <p>Timeline to achieve planned action: Complete</p> <p>2. Action: Development of ULHG justification policy in collaboration with colleagues within our radiology group.</p> <p>Reference will be made to S.I. 44. of 2019 (section 27)</p> <p>'Responsibilities specific to Radiographers and Radiation Therapists.'</p>	

Reference will be made to S.I. 256. of 2018 Regulation 8(8) and Regulation 8(15).  
Reference will be made to ULHG Radiation Safety Procedures.

Timeline to achieve planned action: Complete

3. Action: Development of patient information leaflets relating to radiation protection is now complete

Timeline to achieve planned action: Complete

Regulation 11: Diagnostic reference levels	Not Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

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

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

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.

Medical Physics have drafted a template for assessing the quality of images , it is currently being used at UHL and propose to roll out to all other hospitals in the group

Medical Physics staff delivered a number of lectures in 2018 and in 2019.

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 additional MPE support and high risk areas will be prioritised.

Timeline to achieve planned action: 31 December 2020

2. Risk Assessments -currently in progress.

DRL compilation – currently in progress.  
 Once the necessary data has been collated the policy on optimisation will be completed.

Update to compliance plan received: Data has been collected for CT & General X-ray examinations in Nenagh by the MPEs. A meeting on 21st September is scheduled in UHL with all stakeholders to review and approve CT DRLs

Regulation 13: Procedures	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:  
 1. QIP currently underway in respect of the development of Siemens Emotion 6 slice dedicated protocols. These will be formally reviewed and signed off by local CT governance structure and the Radiation Safety Committee thus conforming to Regulation 13(1).

Timeline to achieve planned action: Complete

2. Action: Review of current written protocols for the general x-ray equipment for every type of patient.

Timeline to achieve planned action: Complete

3. Development of ULHG Dose Report Protocol to satisfy Regulation 13 (2) SI 256 bearing in mind the practical implications until a national solution is available.

1. The protocol will require radiologists to record CT dose on the report.
2. For general DR X-rays, the following statement will be included in the report:  
 'There is a statutory requirement to include patient exposure in the radiological report; this information is detailed in the image DICOM header

Timeline to achieve planned action: Q4 2020

4. An Audit Committee for ULHG was established in July 2020 and there is representation from Nenagh Hospital on the committee membership

Development of ULHG justification policy and ULHG optimisation policy in collaboration with colleagues within our radiology group is in process.

Justification Policy signed off at Radiation Safety Committee on the 14th of July 2020.

Timeline to achieve planned action: Q4 2020

Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:</p> <p>1. QIP: Developed back up plan in the event that the Radiation Safety Officer is unable to maintain current in house quality control equipment checks in line with local policy.</p> <p>Timeline to achieve planned action: Complete</p>	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:</p> <p>1. QIP: Develop stronger audit mechanisms to incorporate analysing and trending incidents and near misses incidents. This can be utilised as learning experiences for both radiology and the referrer.</p> <p>Timeline to achieve planned action: Complete</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 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/12/2020
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Not Compliant	Yellow	30/09/2020

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Substantially Compliant	Yellow	31/08/2020
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	31/08/2020
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Substantially Compliant	Yellow	31/12/2020
Regulation 11(5)	An undertaking shall ensure that diagnostic	Not Compliant	Yellow	31/12/2020

	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.			
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Yellow	31/12/2020
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for	Substantially Compliant	Yellow	31/08/2020

	relevant categories of patients.			
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	31/12/2020
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	21/05/2020
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	31/08/2020
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing	Substantially Compliant	Yellow	31/08/2020

	the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Orange	31/08/2020
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	Substantially Compliant	Yellow	31/12/2020

	<p>of quality assurance of the medical radiological equipment;</p> <p>(iii) acceptance testing of medical radiological equipment;</p> <p>(iv) the preparation of technical specifications for medical radiological 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</p>	Substantially Compliant	Yellow	31/08/2020

	involved, the level of involvement being commensurate with the radiological risk posed by the practice.			
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