



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Ennis Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Gort Road, Lifford, Ennis, Clare
Type of inspection:	Announced
Date of inspection:	14 June 2022
Medical Radiological Installation Service ID:	OSV-0007355
Fieldwork ID:	MON-0030681

## About the medical radiological installation:

Ennis radiology provides plain film radiography and computer tomography (CT) scanning services. The department has 2 general x-ray rooms and 1 CT scanner. The service is provided to the Medical Assessment Unit, the Local Injury Unit, the Outpatient Department, to general practitioners and the hospital's patients.

## 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
Tuesday 14 June 2022	08:58hrs to 14:45hrs	Kay Sugrue	Lead
Tuesday 14 June 2022	08:58hrs to 14:45hrs	Maeve McGarry	Support

## Governance and management arrangements for medical exposures

An announced inspection was carried out by HIQA at Ennis Hospital on 14 June 2022. The hospital is a Model 2 hospital and a member of the University of Limerick Hospitals Group (ULHG). Inspectors found that the Chief Executive Officer (CEO) of ULHG was the designated manager with overall responsibility for radiation protection of service users undergoing medical exposures at the hospital. A hospital group radiation safety committee (RSC) was in place. Inspectors reviewed minutes and were satisfied that there was appropriate representation of Ennis Hospital at this forum at the quarterly meetings held each year. Radiology governance arrangements included sub-delegation from the Chief Executive Officer to a general manager within each directorate. The charts outlining the governance structures viewed by inspectors demonstrated clear reporting lines via formal sub-delegation processes to the CEO and upwards to the Health Service Executive (HSE), the overall undertaking for this facility with ultimate responsibility for the service.

From the records reviewed and discussions with management and staff, inspectors were assured that systems and processes were in place to ensure that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and medical physics expert were involved in the optimisation process. Similarly, referrals were only accepted from those entitled to refer an individual for medical radiological procedures.

Inspectors were informed that the hospital had ensured that 24/7 consultant radiologist support was provided to this facility via a contracted external service and on-site presence of a consultant radiologist was provided from ULHG consultant radiologist resources one day a week. Staff informed inspectors that increased on-site radiologist support could be beneficial to radiography staff and the service, with the potential to increase clinical leadership within the radiology department and multi-disciplinary representation at local and hospital group level. Management informed inspectors that ULHG were working towards increasing on-site consultant radiologist support at the hospital once recruitment of additional resources had been concluded.

The role of the Radiation Safety Officer (RSO) assigned to Ennis hospital was not clearly identifiable to inspectors either in discussions with staff or documentation viewed by inspectors in advance of this inspection. Although local policy outlined that the pathway for reporting ionising radiation incidents was directly to the RSO, staff informed inspectors that significant events were reported to the Radiography Services Manager (RSM). Following on from this inspection, the hospital clarified that the RSM performs RSO duties in a shared capacity with other radiology staff and a plan to fill the RSO role was underway. These shared RSO roles were not clearly evident on the day of the inspection and the undertaking should ensure there is a clear allocation of responsibilities and that reporting of ionising radiation incidents is fully aligned with hospital policy.

Inspectors were satisfied from documentation reviewed and discussions with staff, that there were appropriate contingency arrangements in place to ensure the continuity of medical physics expert (MPE) access, input and involvement as per the regulations. While inspectors found that the hospital was compliant with Regulations 10, 19, 20 and 21, discussions with medical physics staff identified that there was potential to build on the level of involvement of an MPE in the future once current resources have been increased.

Inspectors were informed that Ennis Hospital, as part of the ULHG, had made a decision not to implement the HSE's interim measures to ensure compliance with Regulation 13(2) at the time of inspection. Management informed inspectors that a software update was the preferred option favoured by staff to resolve the issue. The undertaking must therefore address this deficit to ensure full compliance with the requirements of Regulation 13.

While noting the areas of improvement discussed within this report, inspectors were satisfied that overall, there were effective oversight and governance arrangements in place for the radiation protection of service users at Ennis Hospital.

#### Regulation 4: Referrers

Inspectors were satisfied that referrals reviewed were from referrers as defined in the regulations. Inspectors viewed referral records which routinely contained medical council registration numbers. Inspectors were informed that the hospital had a number of approved nurse referrers working within specific specialities and referring rights were restricted to those specialities in which they worked.

Judgment: Compliant

#### Regulation 5: Practitioners

Inspectors spoke with staff in the Radiology Department and reviewed a sample of records in relation to medical exposures on the day of inspection in computed tomography (CT) and general radiology and found that only persons entitled to act as a practitioner had taken clinical responsibility for individual medical radiological procedures.

Judgment: Compliant

#### Regulation 6: Undertaking

Inspectors reviewed several documents relating to the governance structures in place for radiation protection at Ennis Hospital and the overarching governance of the ULHG. These documents also included governance arrangements and reporting lines up to the HSE, as the undertaking, with overall responsibility for the radiation protection of service users. The CEO of University of ULHG was the designated manager and a member of the hospital's RSC. This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which reported upwards to the Executive Management Committee and from this committee to the Hospital Board. In addition, the hospital group had a Radiation Audit Committee and Radiation Protection Task Force which reported into the RSC. Although this structure was outlined in the radiation protection organogram and understood by staff, RSC terms of reference viewed did not incorporate these committees or their reporting lines.

Inspectors viewed minutes from radiation protection governance committees demonstrating multi-disciplinary membership and attendances at meetings and were satisfied that there were good reporting lines to the designated manager via the formal sub-delegation processes within each directorate of the ULHG.

From review of documentation and speaking with staff, inspectors were also satisfied that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and an MPE were involved in the optimisation process as per regulations. Inspectors were informed that the majority of consultant radiologist services at the hospital were provided by a contracted off-site external service. In addition, consultant radiologists from the ULHG vetted CT procedures and one consultant was on-site at the hospital one day a week. While these arrangements ensured that there was 24/7 radiologist support provided to radiographers, staff identified to inspectors that increased on-site access to consultant radiologist services had the potential to strengthen clinical leadership within the radiology service and improve multi-disciplinary representation of the service both locally and within the hospital group structure. Management informed inspectors that ULHG were currently in the process of increasing on-site consultant radiologist support at the hospital once recruitment of additional resources had been concluded.

Inspectors were assured that referrals were only accepted from those entitled to refer service users for medical exposures. However, *ULHG Radiation Safety Procedures* approved for use on 3 June 2022 stated that referrals for medical exposures could only be accepted from medical practitioners, dentists and nurses (with the appropriate education and training requirements). This guidance differed from the hospital group justification policy (2020) provided in advance of the inspection, in that, this policy also recognised the entitlement of the radiographer to refer as per the regulations. Greater assurance is required to ensure that any inconsistencies in policies are addressed.

Unlike other facilities within the ULHG, inspectors noted from reviewing documentation provided in advance of the inspection, that the designated RSO for Ennis Hospital was not identified. When describing the procedure for reporting radiation incidents to inspectors, staff said all radiation incidents were reported to

the RSM, whereas the reporting pathway outlined in local policy stated that events should be reported directly to the RSO. During these discussions, staff demonstrated a lack of awareness as to who the RSO was for the hospital. Following on from this inspection, the hospital clarified that the RSM performs RSO duties in a shared capacity with other radiology staff. This was neither evident in discussions with staff or in radiation protection related documents viewed by inspectors. To ensure clarity for all staff, a clear allocation of responsibilities, including the role of the RSO at Ennis Hospital, should be incorporated into local rules and radiation protection policy, procedures and guidelines.

Inspectors found that measures put in place by the HSE (who is the undertaking for Ennis Hospital and ULHG) to come into compliance with Regulation 13(2) were not enforced at the hospital. The hospital's position on this issue was clearly documented in ULHG Radiation Safety Procedures which were applied in this facility. Discussions with senior management indicated that a different solution was preferred by staff involving additional software. Therefore, inspectors found that further action must be taken to ensure oversight of regulatory compliance with respect to this regulation.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

Following review of documentation, medical exposure records and discussion with staff, inspectors were satisfied that the hospital met the requirement of Regulation 10. Inspectors found that all medical exposures took place under the clinical responsibility of persons entitled to act as practitioners. Medical exposure records reviewed by inspectors demonstrated that the undertaking had ensured that a practitioner and referrer was involved in the justification process in line with this regulation. Similarly, a practitioner and MPE were involved in the optimisation as per regulations.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The Medical Physics Department of ULHG provided MPE services at Ennis Hospital and also to the hospitals within the wider hospital group. On the day of the inspection, inspectors found that the undertaking had ensured the continuity of the MPE service at the hospital. Contingency arrangements were also in place which would be provided by a contracted external service if required. Inspectors were informed by staff and management that the ULHG continued to work closely to support the Medical Physics Department in increasing capacity and resources within



<p>the MPE services at the hospital and for the wider hospital group.</p>
<p>Judgment: Compliant</p>
<p><b>Regulation 20: Responsibilities of medical physics experts</b></p>
<p>Documentation viewed and discussions with staff demonstrated to inspectors that an MPE was available to give advice on medical radiological equipment, contributed to dose audits and the establishment and review of diagnostic reference levels (DRLs) at the hospital. MPEs contributed to the annual quality assurance (QA) programme. This included acceptance testing which was evident in records viewed for new equipment commissioned for use in 2020. MPEs also had responsibility for following up on any issues identified during annual QA performed by outsourced QA testing services and manufacturers' service engineers. Minutes from the RSC viewed by inspectors showed that an MPE attended each scheduled RSC meeting. MPEs advised on equipment if required and also provided advice in relation to the analysis of events involving or potentially involving accidental or unintended medical exposures. Training records viewed demonstrated that radiology staff at Ennis Hospital attended radiation protection training delivered by medical physics staff in February 2022.</p>
<p>Judgment: Compliant</p>
<p><b>Regulation 21: Involvement of medical physics experts in medical radiological practices</b></p>
<p>From discussion with staff and documentation reviewed, inspectors were assured that the level of involvement of the MPE was commensurate to the radiological risk posed by medical exposures provided by the service. While regulatory requirements were met, medical physics staff identified to inspectors that there was potential to increase the level of MPE involvement once allocated resources had improved. Particular areas of involvement identified included protocol development, training and optimisation of medical exposures.</p>
<p>Judgment: Compliant</p>
<p><b>Safe Delivery of Medical Exposures</b></p>
<p>Inspectors reviewed the systems and processes in place at Ennis Hospital to ensure the radiation protection of service users undergoing medical exposure to ionising</p>

radiation at the facility. Overall, inspectors found that the hospital was compliant with Regulations 8, 14, 16 and 17.

Inspectors identified an area of good practice in the evidence reviewed that all medical exposures were justified in advance and there was a system in place to record that justification had occurred. Furthermore, this process was audited with high levels of compliance achieved in audits conducted in 2021 and 2022.

An up-to-date inventory of equipment and quality assurance reports were provided to inspectors which showed that an appropriate QA programme was in place. Regular performance testing of medical radiological equipment was performed as scheduled and staff consistently articulated to inspectors the process for reporting any equipment faults. Inspectors noted that there was a programme in place for the replacement of ageing equipment with evidence of good oversight by senior management and progress made to replace equipment past its nominal date of replacement.

Inspectors were satisfied that there were systems and processes in place to track, trend and record radiation incidents. Staff consistently articulated to inspectors how radiation incidents and near misses were reported. While meeting requirement as set out under Regulation 17, inspectors identified potential scope to improve reporting of radiation incidents and near misses across all areas of the service to ensure that all events involving accidental or unintended medical exposures are captured as they occur and to inform quality improvement measures from trending and analysis of recorded events.

Inspectors found that improvements in regulatory compliance was required with respect of Regulation 11. Inspectors found that DRLs for Ennis Hospital had been established in 2020 and were the DRLs referenced by staff at the facility on the day of the inspection. Although some facility DRLs were available in draft format for 2022, the establishment of others had not yet commenced. To ensure compliance with Regulation 11, the hospital should ensure that DRLs are established, finalised and approved for use as an aid to the optimisation of patient radiation doses. In addition, the review of local DRLs found to consistently exceed national DRLs also needs to be reviewed in a timely manner and actions should be taken without undue delay for the radiation protection of patients.

The non-compliance identified in relation to Regulation 13(2) has been discussed under Regulation 6 and requires measures to be implemented by the undertaking that ensures that the information relating to patient exposure forms part of the report of the medical radiological procedure as per regulatory requirement.

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

## Regulation 8: Justification of medical exposures

Documentation and records reviewed demonstrated that medical exposures were appropriately referred and justified in advance in line with regulatory requirements. Staff explained the justification process to inspectors and demonstrated how justification in advance was recorded on the patient triple identification form, signed by the radiographer and professional registration details were also included. This completed form was uploaded onto the radiology information system, a sample of which were viewed by inspectors. In the case of CT examinations, justification was undertaken remotely by a consultant radiologist. To provide additional assurance in relation to the compliance with the requirements of this regulation, the hospital conducted justification audits in both general radiology and the CT service. Audit reports viewed by inspectors demonstrated consistently high compliance levels.

Information on the benefits and risks associated with radiation was available in a variety of formats in patient waiting areas and included posters on walls and information leaflets which were also visibly displayed and accessible to the service user.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

The establishment and review of hospital DRLs was underpinned by a ULHG wide DRL policy which was reviewed by inspectors prior to the inspection. The hospital had established facility DRLs in 2020 and these were the DRLs visibly displayed in the control rooms and viewed by inspectors. Staff also referenced the 2020 facility DRLs as those applied within the service on the day of the inspection. Inspectors found from speaking with staff, that staff awareness in relation to the use of DRLs in day-to-day practice was not strongly evident and therefore should be a focus of improvement following this inspection.

Draft facility DRLs for 2022 (based on 2021 data) for the examinations conducted on the CT and the digital radiology (DR) X-ray equipment were provided to inspectors but had yet to be approved for application within the service. Inspectors were informed that the collection of data for DRLs in the computed radiology (CR) room was in progress however, paediatric DRLs had yet to be commenced. Overall, from review of the evidence gathered prior to and during the inspection, inspectors were not satisfied that sufficient progress had been made to establish facility DRLs for 2022 at Ennis Hospital.

From the 2020 facility DRLs and 2022 draft DRLs, inspectors identified that a small number of facility DRLs both in CT and general radiology consistently exceeded the national DRLs. Inspectors noted that although these facility DRLs had decreased when compared with the 2020 DRLs, they still exceeded national DRLs. From

documentation reviewed in advance of the inspection, and from speaking with staff, inspectors found that a process to review DRLs was ongoing since 2020. This review was multi-disciplinary and included the input from an MPE. Inspectors noted that the approach taken involved a collective investigation of all DRLs exceeding national DRLs for comparable common procedures delivered by similar equipment across a number of facilities within the group; including Ennis Hospital. However, while inspectors were informed that a potential solution to the issue had been identified and implemented in one of the facilities, corrective actions had yet to be implemented at Ennis Hospital.

The hospital should ensure that facility DRLs are established for 2022 and applied as a reference point for staff to help optimise the radiation protection of patients who are subject to medical procedures at the hospital. In addition, corrective actions should be taken in a more timely way once the potential solution has been identified to enhance the radiation protection of the service user.

Judgment: Not Compliant

### Regulation 13: Procedures

Written protocols were available in electronic format for standard medical radiological procedures and accessible to staff in the clinical area. Not all staff who spoke with inspectors were familiar with these protocols and therefore inspectors found that awareness in relation to these protocols requires improvement following this inspection.

Documentation viewed demonstrated that referral guidelines for medical imaging were available and accessible on desktops in each clinical area.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. From a review of patient records, inspectors noted that information relating to the patient exposure did not form part of the report of the medical radiological procedure. Inspectors were informed that while measures had been put in place by the HSE to come into compliance with this regulation, these measures had not been implemented at Ennis Hospital. This decision to not implement these measures was documented in ULHG Radiation Safety Procedures which was updated and approved on 3 June 2022. Implementation of appropriate measures to ensure compliance with Regulation 13(2) is the responsibility of the undertaking and needs to be addressed in order to be compliant with Regulation 13.

Inspectors were satisfied from review of documentation that the hospital had a clinical audit programme in place. Audit reports demonstrated high compliance levels and where less than optimal compliance was achieved, corrective actions and follow-up audits were undertaken.

Judgment: Not Compliant

### Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection. From the documentation reviewed and discussions with staff, inspectors were satisfied that equipment was kept under strict surveillance. Records reviewed demonstrated that there were appropriate QA and quality control programmes in place which were maintained appropriately and kept up-to-date. Staff described the processes in place to inspectors for logging equipment faults with the RSM and service engineers.

It was noted that medical radiological equipment in the CT service and CR general radiology room were past nominal dates for replacement. However, inspectors were informed that there was an equipment replacement programme in place with funding approval received for replacement of the CT. Minutes viewed from the RSC demonstrated appropriate oversight of the replacement programme was in place, which was reliant on HSE funding and national procurement.

Judgment: Compliant

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

Measures were taken at Ennis Hospital to increase the awareness of people to whom this regulation applies. For example, inspectors observed posters on display in the waiting area, in a variety of languages alerting patients to inform staff of their pregnancy status. From the documents reviewed and speaking with staff, inspectors were informed of the process for inquiring about and recording pregnancy status. Inspectors viewed a sample of written records that demonstrated pregnancy status inquiries were made by staff and recorded where relevant. The record of pregnancy status was audited and demonstrated a high level of compliance in audit reports reviewed by inspectors.

Judgment: Compliant

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

Inspectors reviewed the ULHG *Procedure Regarding Ionising Radiation Incidents* which was the policy applied at the hospital and records of radiation incidents at the hospital in 2021 and 2022. Inspectors were satisfied from these documents and from speaking with staff, that there was a process in place to record radiation

incidents and near misses (where the intervention of a staff member had prevented an incident from occurring).

While regulatory requirements were met, inspectors identified scope to expand and improve what is reported across all modalities within the service. For example, given the levels of activity reported in each X-ray room and the CT service, inspectors noted from the records reviewed, that most of the recorded events were near misses reported from one X-ray room with very little reported from the other areas within the service. It was also unclear from the documentation viewed or from discussions with staff on the day, if quality improvement measures were implemented resulting from trends identified.

Judgment: Compliant

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

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

Regulation Title	Judgment
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Ennis Hospital OSV-0007355

Inspection ID: MON-0030681

Date of inspection: 14/06/2022

## Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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



## Section 1

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

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:            The Radiation Safety Committee (RSC) Terms of Reference:            The Radiation Safety Procedures (RSPs) were last approved on 03/06/22. The Terms of Reference of the RSC have since been amended in the Radiation Safety Procedures to include the Radiation Protection Task Group and the Radiology Audit Committee as requested during the HIQA inspection. The RSPs will be agreed at the relevant Task Group meeting and final approval for issue will be given by the Radiation Safety Committee.</p> <p>Appointment of Radiation Safety Officer (RSO):            The RSO post was approved by ULHG management staff in July 2022 and recruitment is progressing via the ULHG Recruitment Dept. In the interim, some of the RSO duties continue to be carried out by the radiography services manager and radiography staff in Ennis Hospital.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:            11(5) The Adult DRL data had been collated by radiography staff and analysed by medical physics staff including the MPE prior to the inspection. The radiologists are currently reviewing the image quality and it is expected that the local DRLs will be approved by the key stakeholders by the end of August.            Paediatric DRL data for the CR and DR systems has been collected by radiography and analysed by medical physics staff. An image quality review will be completed by the</p>	

radiologists.

11(6) The application specialist for the DR General X-ray Equipment has been contacted and requested to meet with radiography and medical physics staff to optimise the exam protocols where the DAP values exceed the NDRL.

The Lead CT Radiologist has been appointed since the HIQA inspection and the CT protocols requiring investigation and in particular the Abdomen/Pelvis protocol which exceeded the NDRL will be discussed and the protocol settings reviewed In conjunction with radiography and medical physics staff.

11(7) All documentation relating to the optimisation of the protocols will be retained for a period of 5 years from the date of the review.

Regulation 13: Procedures	Not Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:

It is envisaged that the issue will be addressed by the upgrade to the NIMIS system early next year.

## 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	31/12/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	31/08/2022

	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.	Substantially Compliant	Yellow	30/09/2022
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	30/09/2022
Regulation 13(2)	An undertaking shall ensure that	Not Compliant	Orange	31/07/2023

	information relating to patient exposure forms part of the report of the medical radiological procedure.			
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