

Health Information and Quality Authority

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

Name of Medical	University Hospital Limerick
Radiological	
Installation:	
Undertaking Name:	Health Service Executive
Address of Ionising	St Nessan's Road, Dooradoyle,
Radiation Installation:	Limerick
Type of inspection:	Announced
Date of inspection:	31 May 2023
Medical Radiological	OSV-0007379
Installation Service ID:	
Fieldwork ID:	MON-0035843

About the medical radiological installation:

University Hospital Limerick (UHL) is a level 4 hospital in the University Limerick Hospital Group (ULHG). The radiography governance incorporates Croom Orthopaedic Hospital and the Maternity Hospital. The imaging modalities using ionising radiation include:

- General X-ray including orthopantomograms (OPGs). There are 2 X-ray rooms in the Emergency Department (ED) with OPG in one room. In the main Radiology Department there are 2 digital X-ray systems, with an OPG in one room and a Fluoroscopy room which is also used for general X-ray imaging. There is an Acute Fracture Unit (AFU) which has 2 digital general X-ray rooms.
- Computerised Tomography (CT): There are 3 CT scanners in UHL, 1×128 slice CT in ED, 1×128 slice CT and 1×16 slice CT in the main x-ray department. The 16 slice scanner is currently being replaced with a 128 slice CT scanner. The project is scheduled to be completed in August and the new CT scanner will be put into clinical use. The activity in CT has consistently increased over the past five years. The demand is still growing.
- Mammography: There are 2 mammography installations in the Breast Unit, both include tomosynthesis capability.
- Nuclear Medicine: There is 1 SPECT/CT system.
- Interventional Radiology (IR): There is one IR room within the Radiology Department. There is a fixed hybrid installation in the theatre complex.
- Cardiac Cath Labs: There are 2 installations in the Cardiology Department. The service includes a 24/7 STEMI service. Replacement of the equipment is planned for end of 2023.
- Dual energy X-ray absorptiometry (DXA) scanning: There are 2 installations which are located in the Clinical Age Assessment Unit (CAAU) in the outpatient's department (OPD). The governance of this department is in the Medicine Directorate and the studies are carried out by the nursing staff there.
- Fluoroscopy: There are 2 installations both located within the Radiology Department.
- Fluoroscopy in Theatre: There are 2 C-arms in the Theatre complex and a fixed installation for complex vascular studies.

- Fluoroscopy in Endoscopy: There is a C-arm in Endoscopy for this service.
- Fluoroscopy in AFU: There is a C-arm in the unit but Fluoroscopy has not yet commenced.
- A Cone Beam CT (CBCT) system will be installed in the MaxFax Department later this year.

There are Clinical Specialist Radiographers in all of the modalities. These radiographers run the operational side of the 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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

² A medical radiological installation means a facility where medical radiological procedures are performed.

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

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 31 May 2023	09:30hrs to 15:25hrs	Noelle Neville	Lead
Wednesday 31 May 2023	09:30hrs to 15:25hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection was carried out at University Hospital Limerick on 31 May 2023 by inspectors to assess the hospital's compliance with the regulations. As part of this inspection, inspectors visited DXA, general X-ray and nuclear medicine, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking at University Hospital Limerick demonstrated compliance during this inspection with Regulations 4, 5, 6, 10, 14, 16, 17 and 19, substantial compliance with Regulations 8, 13, 20 and 21 and non-compliance with Regulation 11.

The undertaking at University Hospital Limerick had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Inspectors noted involvement in, and oversight of, radiation protection by the hospital's medical physics experts (MPEs) across a range of responsibilities. Inspectors were informed that Medical Physics Department resources had increased since the last inspection resulting in greater stability of on-site MPE resources and contingency arrangements were also in place to access external MPEs if required. Management confirmed that staff recruitment was continuing to ensure continuity of MPE resources to meet the demands of the growing radiology service at University Hospital Limerick.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at University Hospital Limerick and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff

that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at University Hospital Limerick.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms and spoke with staff and management in relation to governance arrangements in place at University Hospital Limerick.

The Health Service Executive (HSE) was the undertaking for University Hospital Limerick and the hospital was part of the University Limerick Hospitals Group (ULHG). The hospital had a radiation safety committee (RSC). Inspectors reviewed the most recent terms of reference for this committee, issued in March 2023, and noted that it had a multi-disciplinary membership including the chief executive officer (CEO) who was also the designated manager, the chief operating officer, a medical physics expert (MPE), clinical directors, general directorate managers, radiography services managers and radiation safety officers. The committee was incorporated into local governance structures, reporting to the hospital's quality and safety executive committee (QualSEC) and was accountable to the ULHG CEO.

A radiation protection task force (RPTF) was also in place at the University Hospital Limerick. Inspectors were informed that this committee supported the CEO and RSC to achieve compliance with the regulations relating to radiation protection and its membership included MPEs, radiography service managers, radiation safety officers, clinical specialists, the diagnostic directorate manager, radiation protection advisors (RPAs), the head of governance and a consultant radiologist. Inspectors reviewed the minutes of meetings from the RSC and RPTF and it was clear that there were effective communication lines in place in respect of issues relating to radiation protection.

Overall, inspectors were satisfied that the undertaking at University Hospital Limerick had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at University Hospital Limerick by individuals entitled to act as practitioners in the regulations. Practitioners and MPEs were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from discussions with staff and management and a review of documentation that the undertaking at University Hospital Limerick had arrangements in place to ensure access to and continuity of MPE services as required by Regulation 19. Inspectors were informed that Medical Physics Department resources had increased since the last inspection resulting in greater stability of on-site MPE resources and contingency arrangements were also in place to access external MPEs if required. Management confirmed that staff recruitment was continuing to ensure continuity of MPE resources to meet the demands of the growing radiology service at University Hospital Limerick.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1) at University Hospital Limerick. Inspectors noted that MPEs were involved across a range of responsibilities outlined in Regulation 20(2). MPEs gave advice on medical radiological equipment and records reviewed by inspectors demonstrated that MPEs had contributed to quality assurance and acceptance testing of medical radiological equipment. MPEs also provided advice and dose calculations for radiation incidents and attended RSC and RPTF meetings. MPEs at University Hospital Limerick liaised with radiation protection advisors (RPAs) assigned to the hospital, therefore satisfying the requirements of Regulation 20(3).

While inspectors found that MPEs were involved in dosimetry and optimisation, there was scope for improvement in relation to the regular review of local DRLs. Inspectors were informed that data collection was underway by radiology staff at the hospital and MPEs would then analyse this data to facilitate the regular review of local DRLs. The undertaking should ensure that data collection is progressed to

facilitate MPEs to contribute to optimisation as per Regulation 20(2)(c)(i). In addition, inspectors also noted that while MPEs had contributed to some training of staff, MPEs identified to inspectors that there was scope for further training of staff in relevant aspects of radiation protection.

Judgment: Substantially Compliant

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

From documentation reviewed and discussion with the MPEs and staff at the hospital, inspectors noted that there was some scope for improvement with the level of MPE involvement at University Hospital Limerick commensurate with the radiological risk posed by the facility as required by Regulation 21. For example, as outlined in Regulation 20, inspectors noted that there was scope for improvement in relation to the regular review of DRLs at the hospital and in contributing to the training of staff in relevant aspects of radiation protection.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors visited DXA, general X-ray and nuclear medicine, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at University Hospital Limerick. While regulations 14, 16 and 17 were compliant, inspectors noted that there was further work required to bring Regulations 8, 11 and 13 into compliance.

In relation to Regulation 8, since the previous inspection, inspectors found that some improvements had been made in relation to the recording of justification in advance in general X-ray, with evidence of same to be retained in the hospital's radiology information system (RIS). However, inspectors noted scope for further improvement in relation to meeting the requirements of Regulations 8(8) and 8(15) as not all records reviewed for general X-ray included a record of justification in advance in RIS.

In relation to Regulation 11, while inspectors found that DRLs had been established and used at the hospital, they had not been regularly reviewed as set out in the hospital's policy and as required by Regulation 11(5). The undertaking at University Hospital Limerick should ensure that local DRLs are based on contemporaneous data and regularly reviewed to achieve compliance with this regulation.

In relation to Regulation 13(2), inspectors found that while interim measures had been provided by the HSE through the National Integrated Medical Imaging System

(NIMIS) to facilitate compliance with this regulation, these measures had not been implemented by practitioners at the hospital. Inspectors reviewed a sample of records and noted that some records for certain modalities indicated the patient dose, some records indicated where the dose could be found if required and other records reviewed did not include any reference to the patient dose. A consistent approach to ensuring that information relating to exposure forms part of the report of each medical radiological procedure should be in place at University Hospital Limerick.

Overall, noting that improvements were required with Regulations 8, 11 and 13, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of information leaflets and posters in all waiting areas of the hospital.

There was a policy in place at University Hospital Limerick titled *ULHG Policy on Justification of Medical Exposures as per S.I. 256 of 2018*, the latest version of which was issued in April 2023. This policy outlined the justification process for each modality and who was responsible for carrying out this process at the hospital. Inspectors noted that staff spoken with demonstrated a clear understanding of this policy. From a sample of records reviewed for CT, nuclear medicine and DXA, inspectors were satisfied that justification in advance was recorded for each medical exposure.

Since the previous inspection, inspectors found that some improvements had been made in relation to the recording of justification in advance in general X-ray, with evidence of same to be retained in the hospital's radiology information system (RIS). Inspectors were informed that the process for recording justification in advance for general X-ray on RIS was relatively recent and staff at the hospital were regularly monitoring this process through audit to improve compliance. Recent audits of justification conducted in general X-ray at the hospital indicated compliance levels ranging from 55 percent to 75 percent. Inspectors noted that there was scope for further improvement in relation to meeting the requirements of Regulations 8(8) and 8(15) as not all records reviewed for general X-ray included a record of justification in advance in RIS.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The undertaking at University Hospital Limerick had a policy titled *Policy on the use* and establishment of Diagnostic Reference Levels, which was approved in September 2021. This policy set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using local DRLs. It stated that local DRLs should be reviewed annually or sooner after the introduction of new equipment, software, techniques, or changes in the protocols. While inspectors found that DRLs had been established and used at the hospital, they had not been regularly reviewed as set out in the hospital's policy and as required by Regulation 11(5). This meant that local DRLs in use at the hospital were based on data predominantly collected between 2019 and 2021. For example, some mammography DRL data was collected during 2019 and 2020, some fluoroscopy data was collected between 2020 and 2021 and some CT data was collected during 2021. Inspectors were informed that data collection was now in progress at the hospital to facilitate the review of local DRLs for 2023. Although inspectors were satisfied that DRLs had previously been established, the undertaking at University Hospital Limerick should ensure that local DRLs are based on contemporaneous data and regularly reviewed to achieve compliance with this regulation.

Judgment: Not Compliant

Regulation 13: Procedures

Inspectors noted that written protocols were available for each standard radiological procedure provided at University Hospital Limerick as required by Regulation 13(1). The hospital had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3). In addition, the hospital had completed a range of clinical audit including justification, image quality and optimisation. Inspectors noted that clinical audit was viewed as an important tool at the hospital and was used to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service users.

In relation to Regulation 13(2), inspectors found that while interim measures had been provided by the HSE through the National Integrated Medical Imaging System (NIMIS) to facilitate compliance with this regulation, these measures had not been implemented by practitioners at the hospital. Inspectors reviewed a sample of records and noted that some records for certain modalities indicated the patient dose, some records indicated where the dose could be found if required and other records reviewed did not include any reference to the patient dose. A consistent approach to ensuring that information relating to exposure forms part of the report of each medical radiological procedure should be in place at University Hospital Limerick.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at University Hospital Limerick as required by Regulation 14(1). The *Radiation Safety Procedures*, the latest version of which was issued in June 2022, outlined the quality assurance (QA) programme in place at the hospital. Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate QA programmes were in place for equipment as required by Regulation 14(2). Inspectors were informed that approximately 50 percent of the annual QA programme was outsourced at the time of the inspection due to medical physics capacity issues and competing priorities. Follow-up of any issues identified during the annual QA programme remained the responsibility of the ULHG Medical Physics Department. Inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3). In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at University Hospital Limerick had a document titled *Protocol for managing female patients of child bearing age undergoing examinations involving ionising radiation at the ULHG*, which was approved in June 2021. This protocol outlined specific staff responsibilities, for example, the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age.

From a sample of records reviewed, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of the hospital to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents, that the undertaking at University Hospital Limerick had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The hospital's incident management process was outlined in a procedure titled *ULHG Procedure Regarding Ionising Radiation Incidents*, issued in February 2022 and also included information on the requirement to notify HIQA of certain reportable incidents. Inspectors noted that staff and management demonstrated a clear understanding of the incident reporting process. In addition, incidents reported to HIQA since the commencement of the regulations in 2019 were within required timelines.

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially
	Compliant
Regulation 21: Involvement of medical physics experts in	Substantially
medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially
	Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Substantially
	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 University Hospital Limerick OSV-0007379

Inspection ID: MON-0035843

Date of inspection: 31/05/2023

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 20: Responsibilities of medical physics experts	Substantially Compliant

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

A weekly status report outlining the progress on data collection, analysis and approval of DRLs was initiated on the 9th June. This is prepared by the medical physics staff. A commitment has been given to have all DRLs approved by the 31/08/2023.

In the ULHG, the establishment of DRLs is a multidisciplinary task involving radiography, medical physics and radiology staff. Data collection is undertaken by radiography staff and data analysis by medical physics staff. Radiology and/or other relevant clinical staff are involved in the discussions with radiographers and medical physicists regarding approval or requirement for optimisation prior to sign off.

Training: Radiation protection training is due to be performed for non-consultant hospital doctors (NCHDs) (cardiology, vascular, orthopaedic, urology, radiology) by the end of July following the intake of new doctors. Practical radiation protection training will be delivered by the radiation safety officer and medical physics staff. The frequency of training is outlined in the ULHG Policy on Education and Training.

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

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

DRLs: Medical Physics staff analyse the DRL data as it is sent to them by radiography

staff. The data is discussed with the radiography and radiology staff prior to approval.

Training: Radiation protection training is due to be performed for NCHDs (cardiology, vascular, orthopaedic, urology, radiology) by the end of July following the intake of new doctors. Practical radiation protection training will be delivered by the radiation safety officer and medical physics staff. The frequency of training is outlined in the ULHG Policy on Education and Training.

Regulation 8: Justification of medical	Subs
exposures	

Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:

Monthly audits capturing compliance with this regulation as outlined in the ULHG Policy on Justification have been undertaken. Subsequent to the inspection, the QIP developed by stakeholders to come into compliance with this aspect of regulation was to increase the frequency of this audit process. This increased frequency of auditing now occurs with feedback of audit findings disseminated to radiographer practitioners as soon as audit results are available. Additionally, a radiographer staff meeting with the purpose of specifically discussing this radiographer practitioner responsibility was held by the UHL RSMs (subsequent to the HIQA inspection on 31/05/23).

Regulation 11:	Diagnostic reference
levels	

Not Compliant

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

The review of DRLs is currently in progress. A weekly status report outlining the progress on data collection, analysis and approval of DRLs was initiated on the 9th June. A commitment has been given to have all DRLs approved by the 31/08/2023.

In the ULHG, the establishment of DRLs is a multidisciplinary task involving radiography, medical physics and radiology staff. Data collection is undertaken by radiography staff and data analysis by medical physics staff. Radiology and/or other relevant clinical staff are involved in the discussions with radiographers and medical physicists regarding approval or requirement for optimisation prior to sign off.

Regulation 13: Procedures	Substantially Compliant
A permanent, automatic solution to this is	·

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	01/06/2023
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.	Substantially Compliant	Yellow	01/06/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and	Not Compliant	Orange	31/08/2023

	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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/08/2023
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical	Substantially Compliant	Yellow	31/08/2023

	radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or			
Regulation 21(1)	of the medical radiological installations; (vi) the analysis of events involving, or potentially involving,	Substantially Compliant	Yellow	31/08/2023
	being			

	commensurate with the radiological risk posed by the practice.			
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	Substantially Compliant	Yellow	31/08/2023