



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Letterkenny University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Kilmacrennan Road, Ballyboe, Glencar, Letterkenny, Donegal
Type of inspection:	Announced
Date of inspection:	18 April 2023
Medical Radiological Installation Service ID:	OSV-0007358
Fieldwork ID:	MON-0038777

## About the medical radiological installation:

Letterkenny University Hospital (LUH) is a model 3 hospital and part of the Saolta Hospital Group. The Hospital aims to deliver a patient-centred, quality-driven focused service and provides a wide range of diagnostic and support services. LUH is a teaching hospital with links to the National University of Ireland Galway, University College Dublin, the Royal College of Surgeons and the Letterkenny Atlantic Technological University.

The Radiology department in LUH provides imaging to patients within the hospital, the emergency department alongside outpatient services. The hospital is integrated with the National Integrated Medical Imaging System (NIMIS), and has a picture archiving and communication system (PACS) team on-site.

The Radiology department is operational Monday to Friday 9:00hrs-17:00hrs, and unscheduled care is provided 24 hours, seven days a week. LUH conducts approximately 104,000 diagnostic radiological procedures per year across a variety of modalities, both within and external to the Radiology department, including: general and dental Radiography, Fluoroscopy, Mammography, Dual-energy x-ray Absorptiometry (DXA), Computed Tomography, and Interventional Radiology & Cardiology. These alongside non-ionising modalities such as Magnetic Resonance Imaging and Ultrasound complete the Radiology department.

LUH utilises a Teleradiology company for CT emergencies each day from 20:00 until 9:00am.

## 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 18 April 2023	09:30hrs to 16:00hrs	Lee O'Hora	Lead
Tuesday 18 April 2023	09:30hrs to 16:00hrs	Kirsten O'Brien	Support

## Governance and management arrangements for medical exposures

As part of this inspection, the inspectors reviewed documentation and visited the DXA, computed tomography (CT) and interventional cardiology departments in Letterkenny University Hospital and spoke with staff and management.

Letterkenny University Hospital operated within the Health Service Executive (HSE) Saolta Hospital Group and the HSE was the undertaking with overall responsibility for the radiation protection of service users. Local responsibility for the radiation protection of service users lay with the Letterkenny University Hospital General Manager (GM) who communicated through the hospital group Chief Operations Officer (COO) to the HSE. Staff at Letterkenny University Hospital used a radiation safety committee (RSC) to oversee and ensure compliance with the statutory requirements regarding radiation protection and utilised many alternate platforms and communication pathways for the consideration and discussion of the radiation protection of service users. While the relevant responsibilities and lines of communication regarding the protection of service users was consistently articulated during the course of the inspection some work was required to ensure that day-to-day practice satisfied all requirements of the regulations and that all areas using ionising radiation were represented within the radiation safety platforms and communication pathways discussed. In particular the inspectors were not satisfied that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, the inspectors were not assured that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. While these non-compliances need to be addressed by the undertaking in a timely manner, inspectors did note that the associated medical radiological exposures represented a small proportion of medical radiological procedures carried out in an area delivering a very low service user dose.

The inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, the inspectors were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall the inspectors were satisfied that the allocation of responsibility for the protection of service users provided a satisfactory framework to ensure the safe conduct of medical exposures and that areas of non-compliance noted on the inspection were associated with a very small proportion of medical exposures provided in an area associated with negligible patient dose and associated risk.

## Regulation 4: Referrers

Inspectors reviewed referral documentation, a sample of referrals for medical radiological procedures from CT, general X-ray, theatre and DXA and spoke with staff in relation to medical radiological procedure referral.

In line with the regulations, radiographers and advanced nurse practitioners were considered referrers in this hospital. The specific circumstances in which radiographers could act as referrers were clearly outlined in local policies and articulated to inspectors by staff. Information identifying individual nurse referrers and their area of speciality was observed by the inspectors and this information was made available to the relevant staff. The hospital's advanced nurse practitioners, their area of speciality and scope of practice was well defined in documents reviewed and clearly and consistently articulated to inspectors by staff spoken with on the day.

In the majority of cases inspectors were satisfied that Letterkenny University Hospital only accepted referrals from appropriately recognised referrers. However, some imaging referrals reviewed for the DXA service demonstrated that individuals who did not meet the standards and requirements as set down by the relevant professional body had been accepted. This was brought to the attention of management on the day of inspection and must be addressed in a timely manner to ensure regulatory compliance.

Judgment: Not Compliant

## Regulation 5: Practitioners

Documentation submitted in advance of the inspection was reviewed by inspectors who also spoke with staff involved in the conduct of medical exposures in a range of clinical areas. While clinical responsibility for individual medical exposures was found to be taken by an individual entitled to act as a practitioner in most areas in the hospital, inspectors found that clinical responsibility for medical exposures in a subset of DXA procedures had been taken by individuals not recognised to act as a practitioner in the regulations. This was also brought to the attention of management on the day of inspection.

Judgment: Not Compliant

## Regulation 6: Undertaking

Letterkenny University Hospital operated as part of the wider HSE Saolta Hospital

Group. Inspectors were informed that the GM was the person with overall responsibility for the protection of service users at Letterkenny University Hospital and reported directly to the COO of the Saolta Group. Inspectors were informed that staff in Letterkenny University Hospital used a RSC and a Radiology Directorate Committee to consider all matters pertaining to radiation safety. Inspectors were assured that staff at Letterkenny University Hospital could convene the RSC for specific extraordinary purposes as required, and minutes of one such recent occurrence were reviewed by inspectors. The Radiology Directorate platform facilitated monthly consideration of relevant radiation safety matters and the hospital also used a medical exposure team, which had recently been established, to address practical issues as required. The GM was a member of both the RSC and the Radiology Directorate Committee. Inspectors were also informed that both the radiography services manager (RSM) and the Chair of the RSC had direct lines of communication with the GM as required.

Documentation reviewed by the inspectors outlined the allocation of responsibility for the protection of service users by the HSE operating at Letterkenny University Hospital. The relevant responsibilities and lines of communication regarding the effective protection of service users was articulated to the inspectors during the course of the inspection. However, while the inspectors were satisfied that Letterkenny University Hospital had the appropriate radiation safety platforms and lines of communication in place, some work was required in one service to ensure that only appropriately qualified persons acted as referrers and practitioners as discussed under Regulations 4, 5, 10 and 16. Additionally documentation defining the practitioner and the associated allocation of responsibility should be reviewed to ensure alignment with day-to-day practice and the regulations. Finally, formalising communication pathways to include the cardiac catheterisation suite would ensure radiation safety issues are considered in all areas conducting medical exposures.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

As discussed under Regulations 4 and 5, inspectors were not assured that all medical exposures took place under the clinical responsibility of a practitioner. While this non compliance related specifically to the justification and evaluation of the outcome for a small number of medical radiological exposures carried out in the DXA department, it still requires prompt action by the undertaking to ensure regulatory compliance for all medical exposures.

Practical aspects of medical radiological procedures were delegated in some instances by the undertaking and all professional registration, associated training records and formal documentation of delegation satisfied all aspects of the regulations in relation to regulation 10(4). Furthermore the inspectors were informed and noted from document review that staff at Letterkenny University Hospital retained the presence of a radiographer for all fluoroscopic radiological

procedures. In the absence of nationally defined training requirements on aspects of radiation protection for non-radiology physicians, this arrangement provided assurance of the radiation protection of service users undergoing interventional cardiology and theatre fluoroscopic medical radiological procedures at Letterkenny University Hospital.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to inspectors by staff and management and the details were formalised in documentation reviewed. Letterkenny University Hospital retained a MPE and arrangements for absence cover, as necessary, were consistently articulated to inspectors on the day. All supplied evidence satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Letterkenny University Hospital.



Judgment: Compliant

## Safe Delivery of Medical Exposures

The inspectors reviewed records of acceptance and performance testing and service engineer reports for all radiological equipment at the facility and were assured that the hospital had implemented and maintained an appropriate QA programme and kept its radiology equipment under strict surveillance.

Information for service users on radiation risks was available throughout the radiology department on the day of inspection in both pamphlet and poster format. However, inspectors were informed that a method to record practitioner justification for all radiological exposures, while developed, had not been implemented at the time of inspection. This was highlighted as an area that needed action by the undertaking to ensure regulatory compliance.

The inspectors were satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures.

While staff at Letterkenny University Hospital had established DRLs and inspectors observed evidence of good DRL related patient dose optimisation work in mammography, some work was required to enable meaningful comparison with national DRLs and subsequent patient dose optimisation for interventional radiology, fluoroscopy and paediatric radiography. Similarly, in order to ensure compliance with Regulation 16, work was required in relation to ensuring that only appropriately qualified persons take responsibility for the inquiry and recording of pregnancy status for the appropriate service users.

Although a number of areas required improvement to ensure regulatory compliance, inspectors were satisfied that these did not pose an immediate risk to the safety, health or welfare of service users.

## Regulation 8: Justification of medical exposures

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of these posters were also available to service users throughout the radiology department.

Records of justification in advance by a practitioner were reviewed by inspectors for a sample of CT procedures and DXA scans. However, records of justification in advance by a practitioner were not available for general X-ray procedures, fluoroscopy procedures or a number of DXA procedures as discussed further under Regulation 10. Inspectors were informed that a system to record practitioner justification in advance of all medical radiological procedures had been developed but it had not been implemented at the time of inspection. To ensure compliance with Regulation 8 the undertaking should prioritise the implementation of all systems to facilitate regulatory compliance.

Judgment: Not Compliant

### Regulation 11: Diagnostic reference levels

While DRLs were established in all areas providing medical radiological exposures, fluoroscopic and interventional radiology local facility DRLs had not been reviewed having regard to the national DRLs. Also the age categorisation of local facility paediatric DRLs did not align with the associated national age and weight categories making any national DRL comparisons of limited use for the optimisation of patient dose.

However, while the above areas of practice need to be addressed to ensure regulatory compliance good examples of dose review and audit were seen in the mammography department. In mammography, records of appropriate reviews detailed the undertaking's ability to monitor, review, consider and implement corrective actions as required.

Judgment: Substantially Compliant

### Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a quality assurance programme including appropriate acceptance and regular performance testing.

Evidence was also available to show that any issues identified as part of the equipment services had been followed up in a timely manner. Inspectors were provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed demonstrated that Letterkenny University Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status. However, in some circumstances discussed under Regulations 4 and 5, individuals not recognised as practitioners or referrers were asking patients about pregnancy status. As seen in other regulations some work was required in relation to ensuring that only appropriately qualified persons take responsibility for the requirements of Regulation 16.

Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Substantially Compliant

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

From reviewing documents, local incident records and speaking with staff inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Inspectors were satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Letterkenny University Hospital.

Evidence was available to show that incidents were discussed at the appropriate committee levels within the facility and as a result the undertaking had oversight of incidents in this facility.

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	Not Compliant
Regulation 5: Practitioners	Not 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	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	Not Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Letterkenny University Hospital OSV-0007358

Inspection ID: MON-0038777

Date of inspection: 18/04/2023

## 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 4: Referrers	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 4: Referrers:            Re referrers to Nurse led DXA service            LUH will not accept referrals from non-practitioners anymore, or from ANP's that have not completed the relevant NMBI approved referral training course.            Updates have been completed to the Standard Operating Procedures for performing DXA in the Radiology department in LUH, suspension of the nurse led service with Radiographer Practitioners justifying all examinations and taking clinical responsibility for the medical exposure of each DXA scan.            The DXA SOP was updated, presented at hospital PPPG committee by RSM on 04/06/23 and ratified with consultation trail.            Staff have been informed that only practitioners can take responsibility for medical exposures. Discussed at staff meeting on 01/06/23 and RSC meeting on 09/06/23</p>	
Regulation 5: Practitioners	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 5: Practitioners:            Clinical responsibility for medical exposures relating to DXA scans will be completed by the Radiographer practitioner, in compliance with departmental policy.            Updates have been completed to the Standard Operating Procedures for performing DXA in the Radiology department in LUH, suspension of the nurse led service with Radiographer Practitioners justifying all examinations and taking clinical responsibility for the medical exposure of each DXA scan.            The DXA SOP was updated, presented at hospital PPPG committee by RSM on 04/06/23 and ratified with consultation trail.            Staff have been informed that only practitioners can take responsibility for medical exposures. Discussed at staff meeting on 01/06/23 and RSC meeting on 09/06/23.</p>	

Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:  Updates have been completed to the Standard Operating Procedures for performing DXA in the Radiology department in LUH, suspension of the nurse led service with Radiographer Practitioners justifying all examinations and taking clinical responsibility for the medical exposure of each DXA scan.</p> <p>The policy was updated to ensure no referrals were accepted from non-referrers i.e non-practitioners or ANPs who have not completed the NMBI recommended training. The updated policy was ratified at the hospital PPPG committee meeting on the 04/05/23 and implemented. The policy was updated on the shared drive.</p> <p>A consultation trail ensured the policy was reviewed by all relevant stakeholders.</p> <p>Re Interventional Cardiology: A Radiographer practitioner in Interventional Radiology/Cardiology will become a member of LUH Radiation Safety Committee (RSC) and will bring any radiation safety issues to the agenda. The next meeting will take place on the 9/06/23.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities:  From this point on and for the foreseeable future this service will be managed under Radiology by a Radiographer Practitioner.</p> <p>Justification and evaluation of the outcome for all DXA scans conducted in LUH will be completed by a Radiographer practitioner in line the updated DXA SOP. The updated SOP was ratified at the hospital PPPG committee meeting on the 04/05/23 and implemented. The policy was also made available on the shared drive.</p> <p>Staff have been informed that only practitioners can take clinical responsibility for medical exposures. Discussed at staff meeting on 01/06/23 and RSC meeting on 09/06/23.</p>	
Regulation 8: Justification of medical	Not Compliant

exposures	
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>From Monday the 26/06/23 all Radiographer Practitioners must Justify in advance all medical exposures in the areas of general x-ray, theatre, mobile x-rays and Fluoroscopy procedures. This will be done by documenting the letters 'JIA' alongside the Radiographer practitioner's initials and the date within the notes section of the patient file on RIS.</p> <p>This has been communicated through the staff group Radiographer email on 19/06/23. Memos have been printed and attached to each x-ray unit reminding the Radiographer to ensure they have documented justification in advance for each medical exposure undertaken.</p> <p>The local LUH SOP entitled "Radiographer Roles and Responsibilities in Justification and Optimisation" was updated to include instructions on this JIA procedure. This procedure is currently operational will be formally ratified at the next PPPG meeting due on 6/07/2023.</p> <p>CPD information session for radiographers on justification of medical exposures and documenting same was completed on the 23/06/23 by the MPE.</p> <p>Re DXA service, the Radiographer Practitioner will record justification in advance of the procedure in the comments section in RIS, signed, dated and (JIA) noted on each examination as per departmental policy.</p> <p>Regular audits on justification in advance of exposures will be completed and reviewed in 3 months (August 2023) by the RPO and made available to all staff.</p> <p>Feedback on audit and radiation safety issues will be discussed at monthly staff meetings, the medical exposures team and radiology management meetings.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <p>The RPO and MPE have updated and reviewed all DRL's in fluoroscopy and Interventional Radiology.</p> <p>Paediatric DRL's have also been reviewed and updated to align with national age and weight categories.</p> <p>Paediatric DRLs are now in the age (Head) and weight (Body) categories as requested by H.I.Q.A. using the most recent national DRL's as per October 2022 document.</p> <p>The R.P. 185 'age to weight' conversion table has been used to categorise our Paediatric patients for DRL purposes.</p> <p>Data is currently based on small numbers due to low frequency of examinations, these will be reviewed by the RPO and MPE in September 2023. All of the posters are updated within the department to reflect the new national DRL, these were communicated to Radiographers at the staff meeting on 01/06/23.</p>	



Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <p>In order to ensure compliance with Regulation 16 in relation to DXA services, only a Radiographer practitioner will be able to enquire about pregnancy status of a service user, as noted in the updated departmental pregnancy policy.</p> <p>Updates have been completed to the Standard Operating Procedures for performing DXA in the Radiology department in LUH. This was presented at hospital PPPG committee by the RSM on 04/06/23 and ratified with consultation trail.</p> <p>The SOP was also discussed at staff meeting on 01/06/23 with minutes of the meeting available on the Radiographers shared drive, and also discussed at RSC meeting on 09/06/23.</p> <p>The updates to the Pregnancy policy state that only a Practitioner and Referrer have the Legal right to enquire about pregnancy status of a patient for all radiological procedures. This Policy is now operational and has been discussed at a staff meeting on 01/06/2023 informing staff of the update, discussed at the CPD event by MPE on 23/06/23 and forwarded to the PPPG committee in LUH for ratification. The next PPPG meeting is due to take place on 06/07/23, the RPO will present the updated policy for ratification.</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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Orange	09/06/2023
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person	Not Compliant	Orange	09/06/2023

	other than a referrer.			
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	09/06/2023
Regulation 5(c)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).	Not Compliant	Orange	09/06/2023
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters,	Substantially Compliant	Yellow	09/06/2023

	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.			
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.	Not Compliant	Orange	26/06/2023
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Not Compliant	Orange	26/06/2023
Regulation 8(15)	An undertaking shall retain records	Not Compliant	Orange	26/06/2023

	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.			
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	09/06/2023
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Orange	09/06/2023
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Orange	09/06/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic	Substantially Compliant	Yellow	01/06/2023

	reference levels established under paragraph (1) where available.			
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Not Compliant	Orange	01/08/2023
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Not Compliant	Orange	01/08/2023