



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Sligo University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	The Mall, Rathquarter, Sligo
Type of inspection:	Announced
Date of inspection:	06 December 2023
Medical Radiological Installation Service ID:	OSV-0007373
Fieldwork ID:	MON-0040124

## About the medical radiological installation:

Sligo University Hospital is an acute Level 3 teaching hospital with 360 beds and is part of the SAOLTA group. As well as providing local services it also provides regional services for neurology, ENT, rheumatology, ophthalmology, dermatology, urology and orthodontics for the northwest. The Radiology Department provides a comprehensive range of general and specialised imaging services to our patients in a digital environment. Both adult and paediatric imaging are provided across a wide range of specialities. It includes both scheduled and unscheduled care for outpatient, inpatients, emergency and GP services. The department comprises of 3 general X-ray rooms, 1 multipurpose fluoroscopy with 4 mobile x-ray, 2 theatre C-arms and 1 computed tomography (CT) scanner. Sligo University Hospital also provide regional Nuclear Medicine service for Sligo and Letterkenny University Hospitals' patients. A new dedicated Interventional suite opened in 2020, with a second IR radiologist appointed in 2023. A second CT scanner is expected to be installed in 2024. The service is delivered by radiographers, consultant radiologists and supported by medical physics experts and support staff. The service is operational from 08:45-16:45 with an x-ray, CT & US oncall service outside of these times. Radiology performs approximately 105000 examinations per annum (81000 involve medical exposure). There is a DXA service, located on Level 4, Sligo University Hospital which is operated by nursing staff.

## How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users<sup>4</sup> to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

## About the inspection report

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

### **1. Governance and management arrangements for medical exposures:**

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

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

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

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

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

**2. Safe delivery of medical exposures:**

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

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

**This inspection was carried out during the following times:**

Date	Times of Inspection	Inspector	Role
Wednesday 6 December 2023	09:30hrs to 16:00hrs	Lee O'Hora	Lead
Wednesday 6 December 2023	09:30hrs to 16:00hrs	Kirsten O'Brien	Support

## Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the general X-ray, CT and DXA departments and spoke with staff and management. Inspectors also discussed the compliance plan from the previous inspection carried out in January 2020 and noted that the majority of actions identified had been completed.

Sligo University Hospital operates within the larger Saolta Hospital Group and the Health Service Executive (HSE) is the undertaking with overall responsibility for the radiation protection of service users in this hospital. Local responsibility for the radiation protection of service users lay with the hospital General Manager (GM). Staff at Sligo University Hospital used a Radiation Safety Committee (RSC) to recommend radiation protection measures in order to comply with the statutory requirements regarding radiation protection.

On this inspection, inspectors found effective governance, leadership and management arrangements were in place. However, a radiation safety specific documentation update was required to ensure a clear and unambiguous allocation of responsibility for the protection of service users undergoing medical exposures at Sligo University Hospital.

Following a review of documents and records, and speaking with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

After speaking to staff and reviewing radiation safety related documentation and records, the inspectors were assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided and satisfied the requirements of the regulations.

Overall, although some work was required by the undertaking to meet full compliance, the inspectors were satisfied that the areas for improvement did not pose a risk in relation to the radiation protection of service users at Sligo University Hospital.

## Regulation 4: Referrers

Following a review of referral documentation and a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that

Sligo University Hospital only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

### Regulation 5: Practitioners

Following a review of radiation safety procedure documentation and a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

### Regulation 6: Undertaking

The HSE was identified to inspectors as the undertaking with overall responsibility for the radiation protection of service users at Sligo University Hospital. Sligo University Hospital operated within a the wider Saolta Hospital Group, inspectors were informed that the GM for the hospital was the individual responsible for the radiation protection of service users locally and reported to the undertaking via the hospital group. Staff at the hospital used a radiation safety committee (RSC) and inspectors were informed that this committee played a vital role in the governance of radiation protection issues locally. Inspectors reviewed the terms of reference for the RSC which met three times in 2023 and had a multi-disciplinary membership including the assistant GM, quality and safety representatives, radiologists, a radiation protection officer (RPO), MPEs and the radiography services manager (RSM). Inspectors also noted that areas outside the radiology department, but within the hospital, where radiological procedures also took place, for example, theatre and DXA were represented at this committee.

While inspectors were satisfied that multiple lines of communication existed between the RSC and the GM, documentation supplied did not provide a clear allocation of responsibility for the radiation protection of service users. For example, the document *Radiation Safety Procedures for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures Sligo University Hospital (SUH), OLHM, Ballyshannon PCC* stated that the RSC reports directly to the Sligo University Hospital Executive Management Team (EMT) but organograms supplied as part of the same document detail that the RSC feeds into the EMT via the Quality and Safety Executive Committee. Management staff noted the discrepancy and acknowledged the ambiguity.

Another area for improvement noted was the clear identification of professions considered referrers and practitioners by SUH. While documentation specific to the DXA service clearly identified the practitioner with overall responsibility, overarching radiation safety documents reviewed did not identify these professions. Staff spoken with consistently identified the professions considered referrers but ambiguity in relation to which professions were considered practitioners was articulated to inspectors on the day. Overarching radiation safety documentation for Sligo University Hospital must clearly allocate responsibility to all professions considered practitioners and, ideally, should delineate their involvement in every aspect of clinical responsibility and for each area where medical exposures to ionising radiation are conducted.

Also the documentation relating to special protection during pregnancy and breastfeeding noted the possibility of a non practitioner/non referrer 'operator' taking responsibility for asking and recording of pregnancy related questions. Documentation must be updated to align with the regulations and ensure that only practitioners and/or referrers are assigned responsibility, as appropriate, for asking and recording of pregnancy related questions. Ideally, documentation should also delineate each responsible individual's involvement in the asking and recording of pregnancy related questions for each area where medical exposures to ionising radiation are conducted.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

Following a review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner at Sligo University Hospital.

Inspectors were assured that the optimisation process involved the practitioner and the MPE in all aspects of optimisation. Similarly, inspectors were satisfied that the justification process for individual medical exposures involved the practitioner and the referrer at Sligo University Hospital.

As part of this inspection inspectors spoke to staff and management regarding the undertakings previously submitted compliance plan relating to the allocation of responsibility for the practical aspects of DXA scanning and were satisfied that the appropriate steps had been taken, as outlined by the undertaking in a previous compliance plan, to ensure compliance with Regulation 10 for the DXA service supplied within the hospital. For the DXA service located within Sligo University Hospital, practical aspects of medical radiological procedures were delegated to individuals registered with the Nursing and Midwifery Board of Ireland. The associated professional registration, radiation safety training records and record of

delegation was reviewed as part of the inspection process and was found to satisfy the requirements of Regulation 10(4) and 10(5).

Judgment: 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 all evidence supplied satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at Sligo University Hospital.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, the 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 and the training of practitioners.

The inspectors were assured that the involvement and contribution of MPEs at Sligo University Hospital was in line with the requirements of Regulation 20.

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, the inspectors established that the involvement of the MPE was now both appropriate for the service and commensurate with the risk associated with the service provided.

Inspectors also spoke to staff and management in relation to the undertakings previously submitted compliance plan and were assured that the necessary steps had been taken, since the last inspection, to secure additional medical physics resources to ensure compliance with Regulation 21.



Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safe delivery of medical exposures to service users at this hospital.

Following a review of a sample of referrals the inspectors were satisfied that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Compliance issues in relation to the record of justification raised in the previous inspection had been addressed and appropriate systems had been implemented as outlined in the undertakings 2020 compliance plan.

Although improvements were noted in the establishment, review and use of DRLs some work was still required to ensure full compliance with Regulation 11. Similarly, while some improvements were noted with the undertakings progress in ensuring that information relating to patient exposure forms part of the report, more work was required to become compliant with Regulation 13(2).

Records of acceptance and performance testing for all radiological equipment at the hospital satisfied the inspectors that the undertaking had kept all medical radiological equipment under strict surveillance and had implemented and maintained a QA programme.

Inspectors were satisfied that the undertaking employed a systematic approach to ensure the special protection during pregnancy and breastfeeding of the relevant service users. However, improvements were required to ensure that the appropriate staff were consistently involved in this process and that regulatory requirements were consistently reflected in the associated radiation safety documentation.

Finally, while the undertaking employed a system for the record keeping of accidental and unintended exposures and significant events, near miss event identification and recording as well the appropriate use of all quality and safety resources in the investigation of reportable events were highlighted as necessary improvements required to ensure compliance with Regulation 17.

Overall, although a number of areas required further work by the undertaking to meet compliance, the inspectors were satisfied that the areas for improvement did not pose a risk in relation to the safe delivery of medical exposures at Sligo University Hospital.

## Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referrals from a number of clinical areas on the day of inspection. The evidence reviewed on the day of inspection verified the information supplied in Sligo University Hospital's previous compliance plan and demonstrated that staff at the hospital had implemented the required changes to ensure regulatory compliance in relation to Regulation 8. For example, evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. Similarly, in line with Regulation 8, all referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

Inspectors reviewed documentation and records pertaining to DRLs and spoke with staff. Sligo University Hospital had established DRLs across all imaging modalities and had compared these local facility DRLs to national DRLs as required by the regulations.

Where local facility DRLs exceeded national DRLs inspectors saw evidence of investigations and corrective actions in some instances, however such records were not available for all instances where local facility DRLs exceeded national DRLs. In addition, for the investigation reports and corrective actions that were available, inspectors noted that the records were lacking detail, including the investigation team members involved, persons responsible for implementation of corrective actions, specific corrective actions planned or taken and associated time lines.

Although these areas were highlighted as needing consideration to achieve compliance with Regulation 11, inspectors were informed that a comprehensive DRL document was currently under development which will clearly outline the routine approach to the investigation and implementation of corrective actions and which would address the above shortcomings. Inspectors were also informed that improved protected time for key radiation safety personnel involved in the DRL process, recently secured by Sligo University Hospital, would help ensure compliance with Regulation 11 in the near future.

While inspectors did see some improvements in the record keeping of DRL related information, as detailed in the previous inspections compliance plan, more work was required by the undertaking to be complaint with the entirety of Regulation 11.

Judgment: Substantially Compliant

## Regulation 13: Procedures

Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. Since the previous inspection in 2020, inspectors noted that some improvements had been made in relation to meeting the requirements of Regulation 13(2). Inspectors reviewed a sample of reports for general X-ray, theatre, DXA and CT medical radiological exposures and found that information relating to the patient exposure formed part of the report for 10 of 17 records reviewed. Inspectors noted when information relating to patient exposure was included on the report it was in the format of a template supplied by the undertaking. Furthermore, in some cases this information was modified by the staff member responsible for the clinical evaluation of the outcome to more specifically reflect the individual procedure types. Where information relating to patient exposure was supplied it satisfied the requirements of Regulation 13(2). However, information relating to patient exposure was not seen on all records reviewed and the undertaking, the Health Service Executive, must ensure that patient exposure information forms part of all reports to ensure compliance with Regulation 13(2).

Judgment: Not 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. All records reviewed detailed that all testing was up to date and appropriately followed up or closed off as required. Inspectors were provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

Following documentation and imaging record review and after speaking with staff, inspectors were satisfied that Sligo University Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status and the answer recorded. However, for a small subset of patients presenting to the DXA department this questioning and recording of the answer, at the point of imaging,

was not done by individuals recognised as practitioners.

Also, as mentioned under Regulation 6, the documentation relating to special protection during pregnancy and breastfeeding must be updated to align with the regulations and ensure that only practitioners and/or referrers take responsibility, as appropriate, for asking and recording of pregnancy related questions.

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

On the day of inspection, inspectors were satisfied that Sligo University Hospital took some measures to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposures, however, some areas for improvement were identified to ensure compliance with the entirety of Regulation 17. For example, inspectors were informed that the hospital had recently changed the software platform used to record both incidents and near-miss incidents. While inspectors were assured that externally reportable incidents were identified, recorded and reported, the RSC minutes noted the need for improvement in the recording of near miss events. Inspectors were informed that measures were being taken by the hospital to address this through routine education from the hospital Quality and Safety team.

Also radiation investigation reports supplied to HIQA as part of the external reporting process were generally brief and the undertaking was asked to provide further information on a number of occasions. Investigation reports supplied to HIQA, while satisfying the associated time line requirements established by the Authority in guidelines issued for this purpose, frequently did not contain the required details as outlined in the same guidance document, namely; the findings of the investigation including causation and contributing factors if known, corrective actions taken immediately following identification of the significant event and those due to be taken, any recommendations (which should be specific and time bound) made or implemented as a result of the investigation conducted and confirmation that those affected by the significant event and relevant stakeholders were informed.

While inspectors were satisfied that incidents were discussed at RSC meetings and that a member of the hospital's Quality and Safety department attended these meetings, the investigation reports supplied could be improved, for example by further utilisation of Quality and Safety resources thus ensuring a corporate approach to the investigation and subsequent mitigation of radiation safety incidents. This was brought to the attention of staff on the day.

Judgment: Substantially Compliant

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

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

Regulation Title	Judgment
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

# Compliance Plan for Sligo University Hospital OSV-0007373

Inspection ID: MON-0040124

Date of inspection: 06/12/2023

## 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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: RPO has amended pregnancy policy to reduce ambiguity regarding professional roles and responsibilities. This document is to be ratified at next RSC meeting 7th March 2024</p> <p>The RSC will report to Executive Management Team via Quality &amp; safety Committee (QUALSEC). The RSC minutes will be forwarded to the QUALSEC.</p> <p>The Assistant General Manager (AGM) is a member of both committees. The AGM will update both committees in relation to radiation safety issues. The QUALSEC met in Jan 2024 and have agreed to add radiation incidents as a standing agenda item. Other members of the RSC will also attend the QUALSEC meetings on request to advise/discuss radiation safety issues.</p> <p>RSP's &amp; TOR's will be updated to include this information.</p> <p>These documents to be reviewed and approved at the next RSC 7th March 2024.</p> <p>They will then be circulated to the relevant staff. Completed by 08/03/24.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: A new more detailed draft DRL policy has been compiled. It outlines the roles and</p>	



responsibilities of the image optimisation team involved in the collation, analysis & approval of DRLs. We have developed a comprehensive DRL Review Report document for the timely investigation and actions of image optimisation team.

This will be reviewed and ratified at the next RSC Meeting 7th March 2024.

RPO will arrange sessions during March & April 2024 to update relevant staff on these changes.

This will be completed by 30th April 2024.

Regulation 13: Procedures

Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: Consultant Radiologist/RSC Chair presently rolling out a single revised modified 'footer' for radiological reports in conjunction with PACs manager, agreed by all consultant radiologists.

This will be completed by 01/03/2024.

Regulation 16: Special protection during pregnancy and breastfeeding

Substantially Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:  
RPO has revised the Pregnancy policy to align all SUH departments/facilities where ionising radiation is used. A new refined policy reduces ambiguity regarding professional roles and responsibilities, clearly defining their functions.

This document is to be ratified at next RSC meeting 7th March 2024. Once ratified it will be circulated to relevant staff.

RPO will then arrange sessions during March & April to update relevant staff on these changes.

This will be completed by 30th April 2024.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:</p> <p>A new SOP for Incident Reporting is currently being drafted to provide more detail especially with respect to recording near misses. The RPO and MPE have commenced a review of the radiation incident investigation report forms in order to provide adequate detail to the regulator.</p> <p>Q&amp;S dept ran an education session 11/12/23 for radiology staff on the reporting of incidents/near misses on NIMS.</p> <p>The RSC representative (AGM) on the QUALSEC team has added radiation incidents as a standing agenda item for their meetings &amp; will amend that committees TOR to reflect this change. This was agreed at QUALSEC Meeting Jan-24. The AGM will update both committees in relation to radiation safety issues and actions discussed. Other members of the RSC will also attend the QUALSEC meetings on request to advise/discuss radiation safety issues.</p> <p>All items for ratification at next RSC March 7th 2024. Once ratified it will be circulated with all relevant staff.</p> <p>The RPO will arrange sessions during March &amp; April to update relevant staff on these changes.</p> <p>The Chair of the RSC will arrange a patient radiation safety presentation to the clinical specialty teams. These will be completed by 30th April 2024.</p>	

## Section 2:

### Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	08/03/2024
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	30/04/2024

	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.			
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.	Substantially Compliant	Yellow	30/04/2024
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	Red	01/03/2024
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,	Not Compliant	Orange	30/04/2024

	unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and			
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	30/04/2024
Regulation 17(1)(a)	An undertaking shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,	Substantially Compliant	Yellow	30/04/2024
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended	Substantially Compliant	Yellow	30/04/2024

	medical exposures, commensurate with the radiological risk posed by the practice,			
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