

## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Our Lady of Lourdes Hospital, Drogheda
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Windmill Road, Moneymore, Drogheda, Louth
Type of inspection:	Announced
Date of inspection:	14 November 2024
Medical Radiological Installation Service ID:	OSV-0007369
Fieldwork ID:	MON-0039935

## About the medical radiological installation (the following information was provided by the undertaking):

Our Lady of Lourdes Hospital, Drogheda is a statutory hospital owned and managed by the Health Service Executive (HSE). It forms the Louth Hospitals with Louth County Hospital, Dundalk and the Cottage Community Hub. Our Lady of Lourdes Hospital is a level three acute hospital within the Dublin North East Regional Health Area. The hospital is a 485 bed acute general hospital delivering medical, surgical, maternity, neonatal intensive care and paediatric services.

The Radiology Department in Our Lady of Lourdes provides a Diagnostic Imaging service to patients from all across the North East, both as inpatients and outpatients. It also provides full emergency and acute high dependency services. The Radiology Department accepts general practitioner (GP), paediatric, neonatal and oncology referrals. It also provides general X-ray, fluoroscopy, mobile X-ray, computed tomography (CT), ultrasound, vascular ultrasound and interventional radiology services to medical and surgical specialities and is part of the HSE National Integrated Medical Imaging System (NIMIS) Radiology Information System/Picture Archiving and Communication System (RIS/PACS) programme.

An on-site MRI service is provided by a third party undertaking. Our Lady of Lourdes Hospital, Drogheda has an on-site Medical Physics Expert and a Radiation Protection Advisor as well as a team of thirty eight dedicated radiographers and twelve Radiologists. Our Lady of Lourdes radiology department also provide a 24 hour emergency service with a dedicated Emergency Department (ED) x-ray room and a resus/trauma imaging system. There is also a 24 hour CT on-call service for inpatients, trauma and CT stroke service as well as an on-call theatre imaging 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, as amended. 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:

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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.

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

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
Thursday 14 November 2024	09:30hrs to 16:15hrs	Kirsten O'Brien	Lead
Thursday 14 November 2024	09:30hrs to 16:15hrs	Margaret Keaveney	Support

## Governance and management arrangements for medical exposures

An inspection of the Health Service Executive (HSE) at Our Lady of Lourdes Hospital, Drogheda was carried out on the 14 November 2024. As part of this inspection, inspectors reviewed documentation and records and spoke with staff and management at the facility.

Overall, inspectors were assured that governance and management arrangements for medical exposures were clearly allocated and understood at the hospital. The designated manager for the service was the general manager who had responsibility for the day-to-day operation of the hospital. A consultant radiologist was the chair of the radiation safety committee (RSC), which included representation from the designated manager and different areas and professions using medical exposures at the hospital.

Inspectors also reviewed documentation and policies relating to the allocation of responsibility for different aspects of radiation protection at the facility. A sample of referrals were reviewed and inspectors spoke with staff and members of the management team at the hospital on the day of inspection. From the evidence reviewed inspectors were satisfied that only referrals for medical radiological procedures from those who were entitled to refer had been carried out. Similarly, only those entitled to act as a practitioner had taken clinical responsibility for medical exposures. The facility was also found to have appropriate medical physics involvement in line with the level of radiological risk.

Overall, inspectors were satisfied that there was a clear allocation of responsibility for the radiation protection of service users in place at the hospital.

### Regulation 4: Referrers

Inspectors reviewed a sample of referrals for medical exposures that had been carried out and spoke with staff working at the hospital. On the day of inspection, referrals were only accepted at the hospital from those entitled to refer in line with Regulation 4.

Judgment: Compliant

### Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation were reviewed. Inspectors also spoke with staff working at the hospital and found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

### Regulation 6: Undertaking

The inspectors spoke with staff and management working at Our Lady of Lourdes Hospital, and reviewed documentation and other records to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures. The designated manager for the service was the general manager who had responsibility for the day-to-day operation of the hospital.

An RSC was in place across the Louth Hospitals which included the designated manager and staff representing different areas and professions using medical exposures at the hospital. A radiation protection task force was also in place which reported into the RSC. The RSC reported into the radiology clinical governance committee over which the general manager had accountability. A line management reporting structure was also in place.

Inspectors were also satisfied that there was a clear allocation of responsibility for radiation protection to individuals, as defined in the regulations. For example, where responsibility for justification was allocated to different professional groups for different modalities, such as radiographers for general X-ray procedures, this was documented in policies and communicated to inspectors by staff. Similarly, the roles and responsibilities of the medical physics expert (MPE) were also documented in the *Radiation Safety Procedures*.

Inspectors were also informed about the mechanisms to share information in the radiology department. These included a notice board, a *Radiology Radiation Safety Newsletter* and staff huddles to highlight and update staff on policies, procedures and regulatory updates relevant to radiation protection.

Overall inspectors were satisfied that governance and management arrangements for medical radiological procedures were in place at Our Lady of Lourdes Hospital on the day of inspection.

Judgment: Compliant

### Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and an MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. Inspectors were also satisfied that the referrer and practitioners were involved in the justification process for individual medical exposures. In particular, inspectors noted the use of the *OLOL Radiation Safety Checklist in a Fluoroscopic-guided procedure* as an area of good practice. This checklist was completed by a radiographer for each patient to ensure the principles of justification and optimisation were implemented, and that appropriate patient pathways for follow-up were activated, when required, depending on the dose received.

Additionally, the practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations. As an additional assurance Our Lady of Lourdes Hospital had also retained the presence of radiographers and or radiologists for all medical radiological procedures carried out at the hospital. In the absence of training requirements prescribed by a training body approved by the Medical Council, as per Regulation 22, this was viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from communication with staff and a review of relevant policies and other records, including a service level agreement, that adequate processes were in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users at Our Lady of Lourdes Hospital. On the day of inspection, an MPE was found to take responsibility for dosimetry and contributed to quality assurance and acceptance testing at the hospital. An MPE was also involved in optimising medical exposures at the hospital and in the analysis of events involving, or potentially involving, accidental or unintended medical exposures.

Judgment: Compliant

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

On the day of inspection, inspectors were satisfied from the evidence reviewed that an MPE was appropriately involved at the hospital in line with the radiological risk.

Judgment: Compliant

## Safe Delivery of Medical Exposures

The inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Our Lady of Lourdes Hospital.

Diagnostic reference levels (DRLs) were found to be established for medical radiological procedures and were available for use by radiographers. Inspectors found evidence that DRLs were used annually to ensure that all medical radiological procedures were optimised. Inspectors noted that the recording of these reviews, findings and corrective actions were clearly recorded and this was noted as an example of good practice.

Signage in the form of posters containing information about the benefits and risks associated with medical exposure to ionising radiation and to raise awareness of pregnancy were observed in the waiting areas. However, inspectors reviewed a sample of referral records and found that a written record of an inquiry regarding the pregnancy status of patients was not available for all procedures reviewed on the day of inspection.

Information relating to patient exposure was included on reports of medical radiological procedures reviewed on the day of inspection. Written protocols were available in all areas, however the protocols for fluoroscopy procedures in theatre did not include the standard medical radiological procedures and must be updated for full compliance with the regulations.

All referrals reviewed as part of the inspection were in writing and accompanied by sufficient information. Staff working at the hospital informed the inspectors that a practitioner justified all medical exposures in advance. However, a record of justification in advance by a practitioner, in line with the hospital's *Justification in Advance Policy*, was not available for all interventional radiology records reviewed on the day of inspection.



As part of the inspection, the implementation status of a clinical audit strategy and other requirements as specified in the *National Procedures for Clinical Audit of Radiological Procedures Involving Medical Exposure to Ionising Radiation*, were discussed. Staff and members of the management team communicated the steps taken to date, including the establishment of a clinical audit steering group. However, minutes from the most recent meeting of the clinical audit steering group noted that a lack of resources was contributing to the clinical audit strategy not being fully implemented in line with the requirements of Regulation 13(4).

The inspectors reviewed documentation and records relating to the medical radiological equipment at the facility. An up-to-date inventory was provided in advance of the inspection. A quality assurance (QA) programme, which included performance testing had been established. However gaps in the conduct of regular performance testing were found on the day of inspection as discussed in Regulation 14: Equipment. Inspectors were assured however that an appropriate programme of assessment of dose was in place at the hospital.

Overall, while areas for improvement to come fully into compliance with the requirements of the regulations were identified on the day of inspection, inspectors were satisfied arrangements were in place to ensure the safe delivery of medical radiological procedures at Our Lady of Lourdes Hospital.

## Regulation 8: Justification of medical exposures

Inspectors observed information about the benefits and risks associated with the radiation dose from medical exposures available to patients in the form of posters and information leaflets in waiting areas in the department. The inspectors also found that the CT Checklist was audited to ensure that the check box about patient awareness to radiation dose was completed.

A sample of referrals were reviewed by the inspectors who found that these 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.

On the day of inspection, inspectors spoke with practitioners who explained how medical exposures were justified in advance and how this justification was recorded. The *Justification in Advance Policy* was also reviewed as part of the inspection. However, a record of justification in advance by a practitioner was not recorded in line with the hospital's policy and allocation of responsibility for all interventional radiology procedures. In order to ensure full compliance with the regulations, a record of justification in advance by a practitioner must be available for each individual medical radiological procedure. This record of justification should reflect the allocation of responsibility for justification as per the hospital's policies and procedures.

Judgment: Substantially Compliant

### Regulation 11: Diagnostic reference levels

Inspectors reviewed documentation submitted in advance of the inspection and also spoke with staff and management, to determine how DRLs were established, used and reviewed at Our Lady of Lourdes Hospital. Local facility DRLs were reviewed to ensure they were in line with relevant national DRLs, where available. This review was clearly recorded and available for review on the day of inspection.

Inspectors found that the hospital had implemented corrective actions, up to and including replacing equipment, following one such review. This comprehensive approach to optimisation was noted as an example of good practice to ensure compliance with the regulations and the safe delivery of medical exposures.

Judgment: Compliant

### Regulation 13: Procedures

The inspectors reviewed a sample of medical radiological procedures and found that information relating to patient exposure formed part of the report of medical radiological procedures as required by Regulation 13(2).

Inspectors reviewed documentation provided to assess if written protocols were established for standard medical radiological procedures at the hospital. On the day of inspection, the documentation in place for the fluoroscopy-guided theatre procedures did not include written protocols for the standard medical radiological procedures conducted in theatre, and this should be addressed to ensure full compliance with Regulation 13(1).

As part of the inspection, the implementation status of a clinical audit strategy and other requirements as specified in the *National Procedures for Clinical Audit of Radiological Procedures Involving Medical Exposure to Ionising Radiation*, were reviewed. The management team and staff at the hospital communicated the steps that had been taken to implement these requirements. Documentation submitted in advance also provided evidence that implementing a strategy was in progress. Inspectors also saw evidence of clinical audits which had been completed to date and the actions which had been implemented as a result to improve the quality and safety of patients. Inspectors also noted that the results of these clinical audits were circulated to staff in the radiology department as part of a newsletter which was noted as a positive mechanism to share learning and promote improvements in the radiology department. However, while acknowledging the work undertaken to date by staff in the radiology department, some areas for improvement were identified to come into full compliance with the *Procedures for Clinical Audit of Radiological*

*Procedures Involving Medical Exposure to Ionising Radiation* as required under Regulation 13(4). Inspectors found that not all the principles and essential criteria had been fully implemented. For example, while oversight and assurance mechanisms, including a clinical audit steering group, had been put in place, the clinical audit strategy was limited to radiography and radiology staff working in the radiology department only and did not incorporate all areas where medical exposures take place across the entire hospital service. In addition, from a review of the documentation, including minutes from the Louth Hospitals Radiology Clinical Audit Steering Committee meetings, inspectors found that the requirement for the undertaking, to provide resources to implement the clinical audit strategy at Our Lady of Lourdes Hospital had not been put in place.

Judgment: Substantially Compliant

## Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was provided in advance of the inspection. Inspectors were also satisfied that a QA programme had been established which included an annual QA assessment by an MPE and regular maintenance by the equipments' manufacturers. Inspectors were also assured that a programme of the assessment of dose was in place as further detailed under Regulation 11. Records of acceptance testing before first clinical use were also available.

However records reviewed on the day of inspection demonstrated that there were gaps in the conduct of routine performance testing by a radiographer in line with the frequency requirements as specified in the undertaking's QA programme. Inspectors found that lack of availability of testing equipment due to calibration was a contributing factor which had resulted in routine performance testing not being carried out in line with the hospital's QA schedule. In addition, recent records of routine performance testing were not available on the day of inspection due to a technical issue with the electronic storage and back-up of these records.

As a result, the QA programme should be reviewed to ensure that contingency arrangements are put in place to prevent gaps in the conduct of routine performance testing at Our Lady of Lourdes Hospital. The arrangements in place to store records evidencing compliance should also be strengthened, to ensure that evidence of strict surveillance of medical radiological equipment with regards radiation protection at the hospital is available in line with the requirements of this regulation.

Judgment: Substantially Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the waiting area in the radiology department. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations.

Inspectors were satisfied that a practitioner carried out an inquiry as to the pregnancy status of service users in the general X-ray and computed tomography (CT) areas, where appropriate, and this inquiry was recorded in writing. However, from a review of records for medical radiological procedures using fluoroscopy, a record of an inquiry regarding patients' pregnancy statuses were not available for review for all applicable patient records reviewed on the day of inspection.

Judgment: Substantially Compliant

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

The hospital was found to be compliant with the requirements of Regulation 17 assessed as part of the inspection. Inspectors found that a system to record and analysis of accidental and unintended medical exposures was in place. Inspectors also noted that the *Radiology Radiation Safety Newsletter* included information about accidental and unintended exposures and the importance of reporting near misses and this was noted as a positive action to encourage reporting in the department which should be maintained.

However, while inspectors were assured that appropriate measures were taken to minimise the probability of accidental or unintended exposures, an area for improvement was identified to increase the level of detail provided when reporting significant events and the corrective actions to HIQA as part of the hospital's statutory obligation.

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, as amended. 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	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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Our Lady of Lourdes Hospital, Drogheda OSV-0007369

Inspection ID: MON-0039935

Date of inspection: 14/11/2024

## 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, as amended.

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 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:                      The following actions have been implemented in response to this finding following the inspection</p> <p>The implementation of regulation 8 for all Interventional Radiology Examinations will be carried out by ensuring all examinations are justified in advance in line with departmental policy. This will be actioned in that no examinations will be scheduled until they are justified in advance by either a radiographer or radiologist. The IR radiographers will have oversight of all referrals prior to scheduling to ensure that all examinations have been justified in advance in line with departmental policy. All interventional radiology staff and radiology admin staff have been informed of this via staff huddles and written correspondence. This process will be audited monthly by RSO to confirm compliance. Results of these audit will be fed into Radiation Protection Task Force meetings.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:                      Regulation 13(1) – The Theatre Standard Operating Procedures are currently being updated in line with recommendations advised during the inspection. The process will be completed by 31 January 2025.</p> <p>Regulation 13(4) – Clinical Audit Strategy –                      The Radiology Clinical Audit Steering Group will formally meet with the Louth Hospitals Clinical Audit Committee on an annual basis to share information pertaining to audits of</p>	

medical exposures across the entire hospital once the group has restarted. Going forward Radiology audits will include areas outside radiology such as Theatre, SCBU and collaboration from these areas will be sought at this time. All this is dependent on additional resources being made available and current staffing deficits being addressed. A business case will be submitted in January 2025 to General Manager for an additional RSM I (Quality & Audit Manager) similar to other hospitals as well as seeking permission to fill existing radiographer and radiologist vacancies.

The shortfall in Clinical Audit has been risk assessed and is included in the Radiology Risk Register for ongoing discussion/follow up at Radiology Governance.

Regulation 14: Equipment	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 14: Equipment:  
The following actions have been implemented in response to this finding following the inspection

Protected time has been assigned to the RPO & QA Radiographer by the RSM I to ensure that QA will be completed consistently.

Oversight of QA – To ensure that QA is completed the RSM1/RSM3 are updated on QA progress on a bi-monthly basis. Compliance with QA program is discussed at Louth Hospitals Radiation Protection Task Force and Radiation Safety Committee.

Record management – Records of QA status and test results are backed up monthly to the Radiology share drive maintained on HSE network.

An agreement has been made with Louth County Hospital to use their dosimeter during the annual calibration of the OLOL dosimeter.

Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:  
The following actions will be implemented in response to this finding following the inspection on (31/01/2025).

All relevant staff were reminded of their responsibilities as per the Pregnancy Status



Declaration Policy and awareness of this responsibility was reinforced during staff information sessions.

Theatre management have been contacted to provide assurances that radiographers are present before an operation starts to complete the pregnancy declaration form with the patient where relevant.

Adherence to the Pregnancy Status Declaration Policy is being audited in theatre monthly by the Radiation Safety Officer.

## 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	25/11/2024
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.	Substantially Compliant	Yellow	25/11/2024
Regulation 8(15)	An undertaking shall retain records	Substantially Compliant	Yellow	25/11/2024

	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 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/01/2025
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	30/06/2025
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	25/11/2024
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a	Substantially Compliant	Yellow	25/11/2024

	regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.	Not Compliant	Orange	25/11/2024
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, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	31/01/2025
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under	Not Compliant	Orange	31/01/2025

	subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.			
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