



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Radiology Department Our Lady's Campus Cashel
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	The Green, Cashel, Tipperary
Type of inspection:	Announced
Date of inspection:	02 October 2024
Medical Radiological Installation Service ID:	OSV-0008539
Fieldwork ID:	MON-0042273

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

The Department of Radiology in Tipperary University Hospital (TippUH) has succeeded in delivering a highly efficient and effective service within the hospital, primary care and community services. We support the community by providing access to X-ray, DXA and Ultrasound services at our satellite Radiology unit in Our Lady's Campus, Cashel. This satellite unit is part of the Radiology Department in TippUH and follows the same governance structure and Undertaking and all radiation safety documentation referring to TippUH, is applicable to the workflow and practices in Cashel. The same radiology team in TippUH supports the services that are provided in Cashel and rotates there when the skill mix and staff availability facilitates this.

The Radiology Department staff complement includes consultant radiologists, radiography services managers, clinical specialist radiographers, senior radiographers, staff grade radiographers, radiology nurse and clerical and administration support. The service in Cashel are operational from 09:00hours to 17:00hours, Monday to Friday on average 2 days per week. Primarily the examination referrals accommodated in the unit in Cashel are received from the Injury Unit and the local general practitioners. As the sole DXA scanner is located in Cashel for TippUH referrals, this service supports the TippUH consultants, the Fracture Liaison Outpatient Clinics as well as general practitioner referrals. This workflow environment is well received by the TippUH Radiology team as the patients are usually scheduled and can be managed in a structured and supported way through their examination process, with minimum complexity. This can be a welcome change from the demands of a busy and unpredictable emergency department and the acute hospital in-patient referrals in Clonmel. In 2023 there were 8, 921 X-ray examinations completed and 2,277 DXA examinations completed in Cashel Radiology Department. This accounts for 10% of the total workload of the radiology team in TippUH. The TippUH Radiology Department is partnered with UCC for radiography education and facilitates clinical placements for graduate entry radiography programmes.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

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

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

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

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

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
Wednesday 2 October 2024	09:25hrs to 13:55hrs	Noelle Neville	Lead

Governance and management arrangements for medical exposures

An inspection of Radiology Department Our Lady's Campus Cashel was carried out on 2 October 2024 by an inspector to assess compliance with the regulations at the facility. As part of this inspection, the inspector visited the general X-ray and dual-energy X-ray absorptiometry (DXA) units, spoke with staff and management and reviewed documentation. The inspector noted that the undertaking, Health Service Executive (HSE), demonstrated compliance during this inspection with Regulations 4, 5, 8, 11, 14, 16, 17, 19, 20 and 21 and substantial compliance with Regulations 6, 10 and 13.

The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. The inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer. While a practitioner took responsibility for general X-ray medical exposures at the facility, the inspector was not satisfied that a practitioner took clinical responsibility for DXA medical exposures at Radiology Department Our Lady's Campus Cashel.

Overall, despite areas for improvement in relation to DXA medical exposures, the inspector was satisfied that a culture of radiation protection was embedded at Radiology Department Our Lady's Campus Cashel and clear and effective structures were in place for medical exposures to ensure the radiation protection of service users.

Regulation 4: Referrers

The inspector was satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4 at Radiology Department Our Lady's Campus Cashel.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical

responsibility for medical exposures at Radiology Department Our Lady's Campus Cashel.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed documentation including governance structure organograms (organisational chart that shows the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Radiology Department Our Lady's Campus Cashel. The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. The inspector found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3) for general X-ray medical exposures carried out at the facility. However, the inspector noted that further work was required with regard to the clear allocation of responsibilities for DXA medical exposures.

There was a radiation safety committee (RSC) in place at the facility and this committee met twice a year. The inspector reviewed the terms of reference for this committee, which were issued in March 2023, and noted that it had a multi-disciplinary membership. This membership included the general manager who was also the designated manager of the facility, a radiologist, radiation protection officer (RPO), radiographic services manager (RSM), medical physics expert (MPE), radiation protection adviser (RPA), risk manager and quality manager. The inspector noted that the committee had a standing agenda and items such as training, incidents and clinical audit were discussed. The committee was incorporated into local governance structures, reporting to the radiology governance committee and the undertaking, demonstrating good communication and oversight structures in place for the radiation protection of service users. The inspector was also informed that a radiation protection unit had been recently formed at the facility. This unit was a sub-group of the RSC and was responsible for operational issues relating to radiation protection. Its membership included an RPO, MPE, RPA and RSM.

Overall, despite areas for improvement in relation to the allocation of responsibilities for DXA medical exposures, the inspector was satisfied that the undertaking, Health Service Executive, had clear and effective management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at Radiology Department Our Lady's Campus Cashel.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector noted that all general X-ray medical exposures took place under the clinical responsibility of a practitioner as defined in the regulations. However, DXA medical exposures did not take place under the clinical responsibility of a practitioner. For example, from discussions with staff and review of records, the inspector found that the clinical evaluation of the outcome, which is an aspect of clinical responsibility, was not carried out by a practitioner as defined in Regulation 5 for DXA procedures.

The practical aspects of medical radiological procedures were only carried out at Radiology Department Our Lady's Campus Cashel by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, the inspector was satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure continuity of medical physics expertise at Radiology Department Our Lady's Campus Cashel.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE at Radiology Department Our Lady's Campus Cashel and was satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at the facility. The MPE was a member of the radiation safety committee and radiation protection unit in place at the facility. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE was available to carry out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relevant aspects of radiation protection. The inspector also noted that the MPE liaised with

the radiation protection adviser in place at the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, the inspector was satisfied that the level of MPE involvement at the facility was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector visited the general X-ray and DXA units at Radiology Department Our Lady's Campus Cashel, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the facility. The inspector noted compliance with each regulation reviewed with the exception of Regulation 13.

For example, there was evidence showing that each medical exposure was justified in advance as required by Regulation 8. Facility DRLs were established, regularly reviewed and used for each modality at the facility. Staff at the facility ensured that medical radiological equipment was kept under strict surveillance as required by Regulation 14. In relation to Regulation 16, records of pregnancy inquiries for relevant service users were seen by the inspector. In addition, there was a process for identification, management, reporting, analysis and trending of radiation incidents and potential incidents as required by Regulation 17.

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. The inspector noted that a technical solution had been implemented at Radiology Department Our Lady's Campus Cashel to meet compliance with Regulation 13(2). However, the inspector reviewed a sample of reports for general X-ray and DXA and found inconsistencies relating to information regarding patient exposure on reports reviewed. A consistent approach to meeting the requirements of Regulation 13(2) should be implemented at Radiology Department Our Lady's Campus Cashel.

Overall, noting that improvements were required to bring Regulation 13 into compliance, the inspector was satisfied that systems and processes were in place at

the facility to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

The inspector was satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with radiation dose from medical exposures was available to service users in leaflets and displayed on posters throughout the facility. The undertaking at Radiology Department Our Lady's Campus Cashel had a document titled *Radiation Safety Procedures Medical Radiography & Fluoroscopy (inc. Bone Densitometry)*, the most recent version of which was issued in January 2023. This document included information about the justification process in place at the facility and staff responsibilities in relation to same. The inspector reviewed a sample of records for general X-ray and DXA and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The undertaking at Radiology Department Our Lady's Campus Cashel had a document titled *Standard Operating Procedure Medical Physics Radiology Dose Audit*, the most recent version of which was issued in May 2022. This document set out the responsibilities in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. The inspector found that facility DRLs had been established, regularly reviewed and used for general X-ray and DXA having regard to national DRLs and were displayed prominently in the facility as a reference for staff. The inspector was informed that a review was carried out of a facility DRL which was found to be higher than the national DRL for a particular general X-ray exam as required by Regulation 11(6). A quality improvement plan had been put in place at the facility and included adjusting the exam exposure parameters and progressing the re-audit of the DRL in place for the exam. This was noted as an example of good practice by the inspector.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Radiology Department Our Lady's Campus Cashel for standard radiological procedures as required by Regulation 13(1). Referral guidelines were adopted at the facility and were available to staff as required by Regulation 13(3). Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's national procedures document, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). The inspector found that the undertaking at Radiology Department Our Lady's Campus Cashel had sought to align clinical audit practices with the national procedures and had a document titled *Standard Operating Procedures Clinical Audit Policy*, the most recent version of which was approved in September 2024. This document outlined the process for radiation clinical audits at the facility including audit identification, approval, methodology, scoring, results and quality improvement plan, action and re-audit. The inspector reviewed a sample of audits carried out at the facility including audits of justification, patient identification and last menstrual period (LMP).

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. The inspector noted that a technical solution had been implemented at Radiology Department Our Lady's Campus Cashel to meet compliance with Regulation 13(2). However, the inspector reviewed a sample of reports for general X-ray and DXA and found inconsistencies relating to information regarding patient exposure on reports reviewed. A consistent approach to meeting the requirements of Regulation 13(2) should be implemented at Radiology Department Our Lady's Campus Cashel.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Radiology Department Our Lady's Campus Cashel as required by Regulation 14(1). The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The undertaking at Radiology Department Our Lady's Campus Cashel had documents titled *Procedures for QA & Acceptance Testing of X-Ray Equipment*, the most recent version of which was issued in December 2022 and *Standard Operating Procedure Radiography Quality Assurance Checks*, the most recent version of which was issued in December 2022. These documents outlined staff responsibilities and frequency of testing for each modality at the facility. The inspector reviewed records of regular performance testing and was satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, the inspector was satisfied that acceptance

testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at Radiology Department Our Lady's Campus Cashel had a document titled *Radiation Safety Procedures Medical Radiography & Fluoroscopy (inc. Bone Densitometry)*, the most recent version of which was issued in January 2023. This document included information on the pregnancy procedures in place at the facility including the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed, the inspector was satisfied that a referrer or practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, the inspector noted multiple notices in the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector was satisfied from discussions with staff and management and a review of documents that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended exposures was implemented at Radiology Department Our Lady's Campus Cashel. The incident management process in place at the facility was outlined in a document titled *Radiation Safety Procedures Medical Radiography & Fluoroscopy (inc. Bone Densitometry)*, the most recent version of which was issued in January 2023. This document included information on the requirement to notify HIQA of certain notifiable incidents. The inspector noted that no incidents were reported to HIQA since the commencement of the regulations in 2019.

While the undertaking, Health Service Executive, demonstrated compliance with this regulation, the inspector determined that there was potential scope for improvement in relation to the identification and reporting of potential incidents, analysis and learning in the context of the number of procedures taking place at the facility each year and the low level of incidents and near misses being reported.

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Radiology Department Our Lady's Campus Cashel OSV-0008539

Inspection ID: MON-0042273

Date of inspection: 02/10/2024

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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Standard Operating Procedures for Dual Energy X-ray Absorptiometry (DXA) Department in TippUH have been updated in October 2024 to reflect the Consultant Radiologist’s role in this Service delivery.</p> <p>The Undertaking has delegated responsibility in October 2024 to a Consultant Radiologist to be the lead Consultant for all DXA procedures and in particular with regard to radiation safety during these examinations.</p> <p>Please note the Allocation of Responsibilities for DXA Medical Exposures.</p> <p>All DXA exposures are performed under the clinical responsibility of a Consultant Radiologist.</p> <p>The practical aspects of all DXA medical exposures are only delegated by a Consultant Radiologist to Radiographers with a post graduate training in DXA who are members of the CORU Radiographers Registration Board.</p> <p>A Consultant Radiologist and the Radiography Services Manager in conjunction with the lead DXA Senior Radiographer will review the standard of training, level of post graduate qualification annually and competencies annually to ensure that the delegation of the practical aspects is of the highest radiation safety level for service users.</p> <p>In the Standard Operating Procedures for Dual Energy X-ray Absorptiometry Department in TippUH it is clearly documented that the DXA Radiographers role and actions in radiation safety are clearly delegated by the authority of a practitioner. The DXA examination analysis and the evaluation of the outcome/analysis of the medical exposure is ultimately the responsibility of a Consultant Radiologist. A Consultant Radiologist's name and Medical Council number will be visible at the end of each DXA report as the Lead Responsible Clinician.</p> <p>The DXA Procedures and the radiation safety will also be reviewed biannually at our</p>	

Radiation Safety Committee Meetings and will be added to the standing agenda. All above actions scheduled for and completed in October 2024.

Regulation 10: Responsibilities

Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities: The Standard Operating Procedures for Dual Energy X-ray Absorptiometry (DXA) Department in TippUH have been updated in October 2024 to reflect a Consultant Radiologist's role in this Service delivery.

Please note the Allocation of Responsibilities for DXA Medical Exposures.

All DXA exposures are performed under the clinical responsibility of a Consultant Radiologist.

The practical aspects of all DXA medical exposures are only delegated by a Consultant Radiologist to Radiographers with a post graduate training in DXA who are members of the CORU Radiographers Registration Board.

A Consultant Radiologist and the Radiography Services Manager in conjunction with the lead DXA Senior Radiographer will review the standard of training, level of post graduate qualification and competencies annually to ensure that the delegation of the practical aspects is of the highest radiation safety level for service users at our local Radiation Protection Unit meetings.

DXA Radiation Safety will be added to our audit list for 2025.

In the Standard Operating Procedures for Dual Energy X-ray Absorptiometry Department in TippUH it is documented that the DXA Radiographers role and actions in radiation safety are clearly delegated by the authority of a practitioner in TippUH, namely a Consultant Radiologist. The DXA examination analysis and the evaluation of the outcome/analysis of the medical exposure is ultimately the responsibility of a Consultant Radiologist. A Consultant Radiologist's name and Medical Council number will be visible at the end of each DXA report as the Lead Responsible Clinician.

The complete DXA Analysis is sent to all our Referrers including Consultant colleagues and our General Practitioners – Hip/Spine and plus or minus Forearm. Information is included for all Referrers on the Report/Analysis outlining the procedure for contacting the Lead Practitioner if they have any questions regarding the analysis. The above actions scheduled for and completed in October 2024.

The DXA Procedures and the radiation safety will also be reviewed biannually at our Radiation Safety Committee Meetings and will be added to the standing agenda Quarter 4 2024.

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: The TippUH local RIS / PACS radiology information system has been modified in October 2024 to automatically incorporate specific text as a footnote in all ionising radiation medical reports. This footnote only is displayed for diagnostic imaging examinations involving ionising radiation. This information has been standardised for all Consultant Radiologist reporting of ionising radiation in TippUH.</p> <p>TippUH Radiology Department ensures that there is a communication pathway in operation locally to manage potential queries about the specific dose of radiation a patient may have received during a radiological procedure. All queries are responded to by our Radiation Safety Officer and Medical Physicist Expert and are co-ordinated through the RSM Office. This new measure from October 2024 supports practitioners, in addition to the previously introduced interim solution on the NIMIS platform, to facilitate compliance to Regulation 13.</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	31/10/2024
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	31/12/2024

Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	31/10/2024
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