Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Monaghan General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Mullaghmonaghan, Monaghan
Type of inspection:	Announced
Date of inspection:	15 November 2022
Medical Radiological Installation Service ID:	OSV-0007366
Fieldwork ID:	MON-0037517

About the medical radiological installation:

Monaghan General Hospital has 17 day beds and a total of 52 in-patient beds comprising of 26 step-down and 26 rehabilitation. The hospital is affiliated to the Royal College of Surgeons in Ireland (RCSI) for medical education, to Dundalk Institute of Technology for nursing education and to University College Dublin (UCD), Trinity College Dublin (TCD) and the Institute of Technology for health and social care professional education. Cavan Monaghan Hospital's Radiology Department exists over two sites, Cavan and Monaghan inclusive. The Radiology Department of Monaghan General Hospital services the population of both Cavan and Monaghan Counties. It provides outpatient diagnostic imaging services with reference to X-ray absorptiometry (DXA), General X-ray (including OPG dental examinations) and ultrasound. The Department also provides X-ray services to Monaghan General Hospital Injury Unit, Monday to Friday 8 a.m. to 8 p.m. The Department currently has a single general X-ray room, also housing an OPG unit on the ground floor of the Hospital. A second general X-ray facility is currently being installed following the removal of the CT services from the Department. A DXA suit is installed on the hospitals first floor where a single scanner is used for this service. The department has a total of 3 ultrasound rooms where both general and obstetric scans are performed. The staffing compliment for the Radiology Department is 12 radiographers who are based in this location and another 4 radiographers who rotate between the Monaghan and Cavan Departments. The main Radiology department is located on the ground floor of the hospital opposite the Minor Injuries Unit. The DXA Suite is located at the top of the main stair well on the first floor. The Cavan Monaghan Hospital radiology department is supported by a cross site Consultant Radiologist team.

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[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 15 November 2022	09:30hrs to 16:00hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation and visited the general X-ray and dual-energy X-ray absorptiometry (DXA) departments in Monaghan General Hospital and spoke with staff and management. On this inspection, the inspector found effective governance, leadership and management arrangements for the protection of service users undergoing medical exposures**.**

Monaghan General Hospital operated within the Health Service Executive (HSE) Royal College of Surgeons Ireland (RCSI) North East Hospital Group and the HSE was the undertaking with overall responsibility for the radiation protection of service users. Local responsibility for the radiation protection of service users lay with the Cavan Monaghan Hospital General Manager (GM) who communicated both upwards through the hospital group to the HSE and also directly to the HSE.

Monaghan General Hospital was part of the HSE RCSI North East Hospitals Group radiation safety committee (RSC), which covers Our Lady of Lourdes Hospital, Louth County Hospital, Cavan General Hospital and Monaghan General Hospital. The Committee had responsibility for recommending radiation protection measures to comply with the requirements of Irish radiation protection legislation for all sites involved. Locally a Cavan Monaghan radiation protection task force was used for consideration of radiation safety issues and this task force reported directly into the RSC. While the inspector was satisfied that the allocation of responsibility was clear as articulated by staff and management and observed throughout the inspection, documentation in relation to the allocation of clinical responsibility for the protection of service users must be reviewed and updated to align with the current regulations and reflect day-to-day practice at Monaghan General Hospital.

Following a review of documents and records, and speaking with staff, the inspector was 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, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

The inspector reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, the inspector was assured that MPEs took responsibility for dosimetry and gave advice on medical radiological equipment, however, the HSE must ensure that MPE contribution to the application and use of diagnostic reference levels (DRLs) is enhanced to ensure regulatory compliance.

Overall, although some areas require improvement, the inspector was satisfied that the allocation of responsibility for the protection of service users ensured the safe

conduct of medical exposures at Monaghan General Hospital.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Monaghan General Hospital only accepted referrals from appropriately recognised referrers.

In line with the regulations, radiographers and advanced nurse practitioners were also considered referrers in this facility and the specific circumstances in which both professions could act as referrers were clearly outlined in local policies and articulated to the inspector by staff.

Judgment: Compliant

Regulation 5: Practitioners

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

Judgment: Compliant

Regulation 6: Undertaking

Monaghan General Hospital operated as part of a wider hospital group, namely the HSE RCSI North East Hospital Group. The HSE was the undertaking with overall responsibility for the protection of service users from medical exposure to ionising radiation for the hospital group and the General Manager (GM) for Cavan Monaghan Hospital was the person with responsibility for the protection of service users from medical exposure to ionising radiation at Monaghan General Hospital.

Monaghan General Hospital utilised the Cavan Monaghan Radiation Protection Task Force which reported directly to the RCSI North East Hospital Group RSC. The RSC reported to the Cavan Monaghan Hospital Radiology Governance Committee and a Quality and Safety Executive Committee, the GM was represented at all three of these committees. The GM reported externally through monthly RCSI meetings and

had a direct line of communication with the Deputy Director General of the HSE.

The inspector was also supplied with a *Radiology Radiation Safety Newsletter* employed by Cavan Monaghan Hospital radiology department which clearly defined MPE staff members and contact details, identified key radiation safety roles within the governance structure and communicated radiation safety audit results for each site. This was considered a positive initiative, making practical radiation safety related information and the associated allocation of responsibility clear and available to staff.

Generally, the overarching allocation of responsibility and associated communication and escalation pathways for the protection of service users from medical exposure to ionising radiation was well defined in documents reviewed and clearly articulated to the inspector on the day. However, the inspector found that terminology and definitions, in particular relating to clinical responsibility, in the document *Radiation Safety Procedures* did not align with the regulations or day-to-day practice and must be updated.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner as defined in the Regulations.

The inspector was assured that the optimisation process involved the practitioner and the medical physics expert. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer.

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 the inspector by staff and management and the details were available in a service level agreement (SLA) reviewed as part of this inspection. All evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. From reviewing the documentation and speaking with staff at the hospital, the inspector was satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. However, the contribution of the MPEs in relation to the application and use of DRLs needs to be reviewed and enhanced by the undertaking to ensure complete regulatory compliance. This is further discussed under Regulation 11.

Judgment: Substantially Compliant

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

After document review and communication with staff, the inspector noted that the involvement of the MPE must be further developed, relating specifically to the contributions of the MPE as outlined in Regulation 20 and detailed under Regulation 11, to ensure that the MPE involvement is commensurate with the radiological risk.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

The inspector found that radiation protection processes implemented by Monaghan General Hospital ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals from a range of departments, the inspector was assured that the hospital had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Service user information on radiation risks was available throughout the radiology department on the day of inspection.

The inspector reviewed records of acceptance and performance testing for all radiological equipment at the facility and was assured that the hospital had

implemented a QA programme and kept its radiology equipment under strict surveillance. The inspector was also satisfied that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded, however the associated policy documentation must be reviewed and updated to align with current regulations and day-to-day practice. Another area of improvement, noted by the inspector, related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of patients' reports as required by the regulations.

The inspector was satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures. Records reviewed highlighted a comprehensive approach by the hospital to the analysis and mitigation of accidental and unintended exposures and significant events. Trends highlighted by a multidisciplinary team analysis of near miss events had also been used to implement corrective actions thus reducing the possibility of re-occurrence and mitigating the associated risks**.**

While DRLs were established in all areas, evidence of a systematic review having regard to the national DRLs and records of timely corrective actions were not available on the day of inspection. This non compliance as detailed further under Regulation 11, 20 and 21 must be addressed by the undertaking.

Overall, the inspector was assured that Monaghan General Hospital had effective systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose immediate risks to the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. 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. Additionally, records of practitioner justification routinely included professional registration numbers as well as practitioner signatures, this was seen as a positive measure enhancing the undertakings ability to identify practitioners with clinical responsibility for the justification of individual medical exposures.

In line with Regulation 8, all referrals reviewed by the inspector 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.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the

benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was supplied with DRL information for DXA, adult radiography, paediatric radiography and dental orthopantomography. Evidence reviewed detailed that all facility DRLs were completed in February of 2022 and reviewed by a MPE in June 2022.

Adult radiography DRL records supplied satisfied the inspector that adult radiography DRLs had been established and compared to the national DRLs and all were below that of the national levels. However, the facility's DRL for the orthopantomogram had been compared to and found to exceed the national DRL. On speaking with staff it was established that no investigation or subsequent corrective actions had been initiated by the undertaking at the time of the inspection. Also, while the facility's paediatric radiography DRLs were established, no evidence of a review having regard to or comparison with the national DRLs was available at the time of inspection.

During the course of the inspection it was brought to the attention of the inspector that the facility's DRLs established for routine DXA procedures were produced using an incorrect dose quantity which meant that comparisons with national levels were not fit for purpose. The inspector was informed that this error had been noticed recently and an investigation had been commenced. However, the time lines associated with the investigation did not assure the inspector that corrective actions were taken without undue delay.

The undertaking must ensure that all DRLs are established in a format that makes national DRL comparison meaningful, all DRLs established are compared to national DRLs and if local facility DRLs exceed the national DRLs reviews and corrective actions are recorded and completed without undue delay.

Judgment: Not Compliant

Regulation 13: Procedures

The inspector found that written protocols were established for standard medical radiological procedures. A sample of these were reviewed by the inspector.

On the day of inspection, information relating to patient exposure did not form part of the reports of medical radiological procedures reviewed by the inspector. The

inspector spoke with staff and management and was informed that although measures had been put in place by the HSE to come into compliance with Regulation 13(2), these measures had not been implemented in this hospital. The inspector was also informed that management at Monaghan General Hospital had recently escalated this matter to the HSE. The HSE, as the undertaking, is responsible for ensuring compliance with this requirement of the regulations and must ensure compliance measures are implemented.

Judgment: Not Compliant

Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. Documentation and records reviewed established that Monaghan General Hospital had implemented and maintained a QA programme including appropriate acceptance and regular performance testing.

The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Processes observed and records reviewed on site satisfied the inspector that the undertaking had systems in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to the inspector on the day of inspection and sample referrals reviewed by the inspector verified the consistent recording of the relevant information in line with regulatory requirements.

Multilingual posters were observed throughout the department. The inspector was assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Although, the inspector was satisfied that only recognised practitioners inquired and recorded pregnancy status at Monaghan General Hospital, the document *Policy for the Protection of the Unborn Child Arising From Ionising Radiation Received During Medical Diagnostic or Therapeutic Procedures* included the provision for a person other than a practitioner to inquire and record the answer to whether an individual subject to the medical exposure is pregnant or breastfeeding. As the Regulations specify that the inquiry and recording of pregnancy and breastfeeding status can only be done by appropriately recognised referrers and practitioners the undertaking

must update the relevant documentation to ensure it reflects both the regulatory requirements and day-to-day practice.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility. The inspector was satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Monaghan General Hospital. Evidence was available to show that incidents were discussed at the appropriate committee levels by Monaghan General Hospital and the wider Hospital Group.

Records of incident near miss trending as well as corrective actions undertaken by the facility were supplied to the inspector. Staff spoken with and referral records reviewed demonstrated that Monaghan General Hospital had expanded a routine patient check list to include procedure matching after a number of similar near miss events. The procedure matching component added a question where the practitioner would check with the service user that the procedure that had been ordered was appropriate given that service user's clinical history. The inspector was informed that this extra procedural step had reduced the possibility of associated incidents occurring at Monaghan General Hospital and this was seen as a positive use of near miss data to mitigate the risks associated with similar referral errors.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

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

Compliance Plan for Monaghan General Hospital OSV-0007366

Inspection ID: MON-0037517

Date of inspection: 15/11/2022

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: SMART Objective: The terminology and definitions, in particular relating to 'clinical responsibility' in the Radiation Safety Procedures policy document will be revised and implemented to ensure practice is in line with regulations by Q1 2023. The Undertaking Representative is satisfied that this action has begun, the document and terminology therein is currently being considered and changed to align with Regulation 6. Following this review, the document will be submitted to the Radiology Clinical Governance meeting for approval as well as the Regional Radiation Safety Committee.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: C&MH will request a review of the roles and responsibilities of the services provided to C&MH by the MPE by Q1 2023. The review will include responsibilities in relation to the application and use of DRLs. This action will include a review and consideration of the current Service Level Agreement with the current Medical Physics service provider with the aim of ensuring compliance with Regulation 20.	
Regulation 21: Involvement of medical	Substantially Compliant

physics experts in medical radiological practices	

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
SMART Objective:
The undertaking will request a review of the roles and responsibilities of the services provided to C&MH by the MPE by Q1 2023. This action will include a review and consideration of the current Service Level Agreement with the current Medical Physics service provider with the aim of ensuring compliance with Regulation 21. We have begun to liaise and meet with the Medical Physics Support Team in this regard. With specific reference to DRL activity and support, action has already commenced to align our practices with Regulation 11(please see below).

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
SMART Objective:
C&MH will establish a system of early collection of DRL data, timely submission to MPE services for review including comparison with the national DRL's. Where the local DRL data set exceeds that of the national DRL, the systematic review will ensure that timely corrective actions are undertaken that will be further monitored both locally in the department and by MPE support.

The process described above will be added to the local DRL SOP and followed thereafter.

These action has commenced and will be complete by Q1 2023 thereby aligning local practice with Regulation's 11, 20, and 21.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
SMART Objective:
C&MH will take the following measures towards achieving compliance with regulation 13(2):
1. Possibilities will be explored in relation to utilising a new or existing software package to support the recording of exposure dose on x-ray reports on the Carestream x-ray

machines by Q1 2023
2. Letter to be sent to the PACS National Team highlighting the concern that the automatic recording of patient dose is an ongoing issue. This communication will ask if consideration has been given to a national solution and if so when will this be operational. This action will be complete by the first week of February 2023.

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:
SMART Objective:
The "Policy for the Protection of the Unborn Child Arising From Ionising Radiation Received During Medical Diagnostic or Therapeutic Procedures" will be revised, approved and implemented to ensure that the Regulations specify that the inquiry and recording of pregnancy and breastfeeding status can only be done by appropriately recognised referrers and practitioners by Q1 2023.

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	31/03/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	31/03/2023

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and 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.	Not Compliant	Orange	31/03/2023
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.	Not Compliant	Orange	31/03/2023
Regulation 13(2)	An undertaking shall ensure that	Not Compliant	Orange	31/03/2023

	information relating to patient exposure forms part of the report of the medical radiological procedure.			
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	31/03/2023
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	31/03/2023
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics	Substantially Compliant	Yellow	31/03/2023

	expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation			

	protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	31/03/2023