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:	Mater Private Hospital Cork
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Building 3000, Citygate, Mahon, Cork
Type of inspection:	Announced
Date of inspection:	09 August 2023
Medical Radiological Installation Service ID:	OSV-0005998
Fieldwork ID:	MON-0040478

About the medical radiological installation:

Alliance Medical Diagnostic Imaging (AMDI) at Mater Private Hospital, Cork, is located in level B2 in the Mater Private Hospital with an extended service located in the Orthopedic and Spinal centre in Building 2000, City Gate, Mahon. AMDI is contracted for the provision of Radiology Services within the Mater Private Hospital to include MRI, CT, general X-ray, DXA and Ultrasound to both outpatient cohorts, privately insured and self-paying, alongside in-patients as required. HSE initiatives are facilitated in conjunction with the Mater Private, Cork as part of outsourcing waiting list initiatives, in addition to ad hoc outsourcing of both inpatients and outpatients from HSE sources. AMDI in the Mater participates in the HSE GP access to diagnostics scheme (CHO) thus providing diagnostic imaging services to the wider public. The service is managed and operated by Alliance Medical Diagnostic Imaging to include management of radiation processes within the Cardiac Cath Lab(s). Radiology reporting is supported on the Alliance Medical Diagnostic Imaging network. All of the policies are strategically linked with existing Alliance Medical Policies and fully integrate with Mater Private Hospital, Cork operations.

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
Wednesday 9 August 2023	09:00hrs to 15:00hrs	Noelle Neville	Lead
Wednesday 9 August 2023	09:00hrs to 15:00hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the undertaking Alliance Medical Diagnostic Imaging (AMDI) Ltd at the Mater Private Hospital Cork was carried out on 9 August 2023 by inspectors to assess the facility's compliance with the regulations. As part of this inspection, inspectors visited the dual-energy X-ray absorptiometry (DXA) and computed tomography (CT) units, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking, Alliance Medical Diagnostic Imaging Ltd, demonstrated compliance during this inspection with Regulations 4, 5, 6, 10, 14, 16, 17, 19, 20 and 21, substantial compliance with Regulations 11 and 13 and were not compliant with Regulation 8.

Inspectors were informed that there were two co-located undertakings providing radiological services within the Mater Private Hospital Cork.The majority of on-site radiology services were provided by Alliance Medical Diagnostic Imaging Ltd, with interventional cardiology services provided by a separate undertaking. The undertaking, Alliance Medical Diagnostic Imaging Ltd, had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. Inspectors noted involvement in, and oversight of, radiation protection by the facility's medical physics experts (MPEs) across a range of responsibilities. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at AMDI, Mater Private Hospital Cork and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

Inspectors were 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.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were 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 AMDI, Mater Private Hospital Cork.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors 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). Inspectors reviewed documentation including governance structure organograms (organisational charts that show the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at AMDI, Mater Private Hospital Cork.

Inspectors were informed that there were two co-located undertakings providing radiological services within the Mater Private Hospital Cork; the majority of on-site radiology services were provided by Alliance Medical Diagnostic Imaging Ltd, with interventional cardiology services provided by a separate undertaking.

The facility had a radiation protection committee (RPC). Inspectors reviewed the terms of reference for this committee, with an approval date of July 2023, and noted that it had a multi-disciplinary membership including the unit manager who was also the designated manager of the facility, a radiologist, an MPE, members of senior management and the quality department, clinical specialist radiographers, and representatives of the Mater Private Hospital Cork including the hospital's quality and risk manager, operations manager and chief executive officer. The committee was incorporated into local governance structures, reporting to the undertaking's quality and governance committee and senior management team. The committee also reported to the host site, Mater Private Hospital Cork's, QUEST (Quality using Safe and Effective Treatments) committee and senior management team demonstrating good communication and oversight structures in place for the radiation protection of service users.

Overall, inspectors were satisfied that the undertaking, Alliance Medical Diagnostic Imaging Ltd, had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the facility.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at AMDI, Mater Private Hospital Cork by individuals entitled to act as practitioners in the regulations. Practitioners and MPEs were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at AMDI, Mater Private Hospital Cork.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of MPEs at AMDI, Mater Private Hospital Cork and were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors noted MPE involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at AMDI, Mater Private Hospital Cork. MPEs were members of the facility's radiation protection committee. MPEs gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. MPEs were involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, MPEs carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection.

Inspectors noted that MPEs also acted as radiation protection advisers for 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, inspectors were satisfied that the level of MPE involvement at AMDI, Mater Private Hospital Cork was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the facility's DXA and CT units**,** spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at AMDI, Mater Private Hospital Cork. While Regulations 14, 16 and 17 were compliant, inspectors noted that there was further work required to bring Regulations 8, 11 and 13 into compliance.

In relation to Regulation 8, inspectors noted that justification in advance as required by Regulation 8(8) was not recorded as required by Regulation 8(15) for all medical exposures. The undertaking, Alliance Medical Diagnostic Imaging Ltd, should ensure that all individual medical exposures carried out on its behalf are justified in advance and that records evidencing same are retained to ensure compliance with Regulations 8(8) and 8(15).

In relation to Regulation 11, while inspectors found that facility DRLs had been established, regularly reviewed and used, having regard to national DRLs for the majority of modalities at the facility, inspectors noted that there were no facility DRLs available for the DXA service. In addition, inspectors noted that the facility DRL for a small number of CT procedures exceeded the national DRL. While inspectors were informed that some reviews were carried out and corrective actions taken, there was no record of these reviews and corrective actions retained as required by Regulation 11(7).

In relation to Regulation 13(2), inspectors found that while information relating to the patient exposure formed part of the report for DXA, it was not available for all CT reports reviewed. The undertaking, Alliance Medical Diagnostic Imaging Ltd, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Overall, noting that improvements were required to bring Regulations 8, 11 and 13 into compliance, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to

service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed 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 the radiation dose from medical exposures was available to service users displayed on posters throughout the facility. Staff also carried an information card to assist in providing meaningful information to service users in relation to the benefits and risks associated with the radiation doses from particular medical exposures.

The *Radiation Safety Policy* in place at the facility, dated October 2021, outlined the justification procedure in place at AMDI, Mater Private Hospital Cork. This policy outlined that the practitioner must justify the requested medical exposure at both the vetting stage and just before initiating the exposure. While inspectors noted that justification was carried out at the vetting stage, inspectors were informed that the practice of documenting justification just before initiating the exposure was only recently introduced at the facility. Inspectors reviewed a sample of records in DXA and CT and noted that justification in advance as required by Regulation 8(8) was not recorded as required by Regulation 8(15). The undertaking, Alliance Medical Diagnostic Imaging Ltd, should ensure that all individual medical exposures carried out on its behalf are justified in advance and that records evidencing same are retained to ensure compliance with Regulations 8(8) and 8(15).

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

The undertaking at AMDI, Mater Private Hospital Cork had a document titled *Management of Dose Reference Levels*, which was issued in January 2022. This document set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. It stated that DRLs should be calculated annually or after the introduction of new software, equipment, or techniques. While inspectors found that facility DRLs had been established, regularly reviewed and used, having regard to national DRLs for the majority of modalities at the facility, inspectors noted that there were no facility DRLs available for the DXA service. In addition, inspectors noted that the facility DRL for a small number of CT procedures exceeded the national DRL. While inspectors were informed that some reviews were carried out and corrective actions taken, there was no record of these reviews and corrective actions retained as required by Regulation 11(7). The undertaking, Alliance Medical Diagnostic Imaging Ltd, should

ensure that facility DRLs are established for DXA procedures and that records are retained of reviews and corrective actions taken for procedures where the facility DRL consistently exceeds the national DRL.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols were in place at AMDI, Mater Private Hospital Cork for standard radiological procedures as required by Regulation 13(1). The facility had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3). In addition, inspectors noted a range of clinical audits which were ongoing and complete at AMDI, Mater Private Hospital Cork. These audits included an annual facility-wide radiation safety audit, DRL audits and last menstrual period audit.

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. Inspectors reviewed a sample of reports for DXA and CT medical radiological exposures and found that while information relating to the patient exposure formed part of the report for DXA, it was not available for all CT reports reviewed. Management informed inspectors that this was due to a technical issue with the system used to transfer information relating to the patient exposure to the report. The undertaking, Alliance Medical Diagnostic Imaging Ltd, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at AMDI, Mater Private Hospital Cork as required by Regulation 14(1). Inspectors 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 AMDI, Mater Private Hospital Cork had a document titled *QA performed in the Radiology Department*, issued in January 2023, which outlined staff responsibilities and the frequency of testing for each modality. In addition, detailed quality assurance procedure documents were available to staff for each modality and set out the different tests to be carried out as part of quality assurance checks. Inspectors reviewed records of

regular performance testing and were 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, inspectors were 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 AMDI, Mater Private Hospital Cork had a document titled *Radiation Safety Policy*, the most recent version of which was issued in October 2021. This policy included information on the pregnancy procedures in place at AMDI, Mater Private Hospital Cork 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, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of 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

Inspectors were satisfied from discussions with staff and management and a review of documents, that AMDI, Mater Private Hospital Cork had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The facility's incident management process was outlined in two procedure documents titled *Internal Incident Reporting Procedure*, the most recent version of which was issued in March 2023 and *External Incident Reporting Procedure*, the most recent version of which was issued in January 2023. The latter document included information on the requirement to notify HIQA of certain reportable incidents. Inspectors noted that two incidents had been reported to HIQA within required timelines since the commencement of the regulations in 2019.

While the undertaking, Alliance Medical Diagnostic Imaging Ltd, demonstrated compliance with this regulation, inspectors 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 relatively high number of

procedures taking place at the facility each year and the low levels 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 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	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 11: Diagnostic reference levels	Substantially 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 Mater Private Hospital Cork OSV-0005998

Inspection ID: MON-0040478

Date of inspection: 09/08/2023

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: The manual process of recording justification had been recently introduced to this site prior to the inspection, however radiographers are aware of the need to record justification on radiology information system (RIS) until an information technology (IT) solution has been implemented. Processes on site are now compliant with Regulation 8. However, we wish to automate this process further and have further set an objective. S The IT department are to implement a tick box field within the examination record on RIS which will not allow the exam status to change from "arrived" to "exam ongoing". Once selected, this will be associated with the radiographer user who has clinically justified the examination. M This will create a permanent record, which is auditable, within the RIS, as to who clinically justified the examination, along with a time and date stamp. A This solution is currently implemented on other hospital sites using the same RIS/ picture archiving and communication system (PACS) system. R This solution is currently implemented on other hospital sites using the same RIS/PACS system. T This IT solution will be implemented by 30/11/2023.	

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
S
The annual DRL process is currently underway, the compilation and review of DRLS will be undertaken by senior staff on site in conjunction with the Quality Manager. Specific recommendations will be made based on DRLS produced and will form an action plan for improvement and also DRLs for the DXA service.
M
DRLs will be on display within clinical areas and stored locally for reference.
A
DRL generation forms part of the annual radiation safety audit which will be given as a priority action for completion to the clinical specialist radiographer in each area, supported by the quality lead.
R
The lead and specialist staff member will be given dedicated, protected, time to complete this.
T
These DRLS and any subsequent recommendation for review will be issued by 30/11/2023

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
The new dose monitoring system became live on the Alliance Medical radiology information system in late 2022. Doses now appear at the bottom of patient examination reports in compatible modalities.
DXA is not compatible for routing to this dose monitoring system, as such, Alliance Medical has implemented a process whereby the clinical evaluation page, displaying the patient dose, is posted to the referrer in hard copy.
S
DXA clinical evaluation page, displaying the patient dose, is posted to the referrer in hard copy.
M
Will be distributed to the referrer in hard copy & available for redistribution in future.
A
This is now in place.
R
This is a realistic objective and does not involve any new processes/workflows.
T
This is complete and in effect at present.

CT, whilst compatible with the dose management system, requires the cooperation of reporting radiologists to ensure that the examination has the required fields available prior to completion of report. This has been addressed by re-education delivered by the unit manager to the staff involved.
S
Re-education of reporting radiologist to understand compliance with regulation 13 (2).
M
Will be evident on re-audit to assess dose information on CT reports.
A
This will be implemented by the unit manager with the support of AMDI clinical director.
R
This is an achievable solution as it does not require any technical implementation.
T
This is complete and in effect at present.

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.	Not Compliant	Orange	08/09/2023
Regulation 8(15)	An undertaking shall retain records 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.	Not Compliant	Orange	08/09/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and	Substantially Compliant	Yellow	30/11/2023

	where appropriate for interventional 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.	Substantially Compliant	Yellow	30/11/2023
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	30/11/2023

Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	08/09/2023