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:	Affidea Naas
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Vista Primary Care Centre, Ballymore Eustace Road,, Naas, Kildare
Type of inspection:	Announced
Date of inspection:	15 February 2024
Medical Radiological Installation Service ID:	OSV-0005986
Fieldwork ID:	MON-0039457

About the medical radiological installation:

We provide General Radiography at Affidea Naas. Services are for medical radiological procedures only. We accept referrals for medical exposures to ionising radiation from general practitioners and consultant specialists.

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
Thursday 15 February 2024	09:30hrs to 14:35hrs	Margaret Keaveney	Lead

Governance and management arrangements for medical exposures

On 15 January 2024, the inspector completed an inspection of the radiological service at the Affidea Naas. During this inspection, the inspector met with the management team, and spoke with staff involved in completing the radiological examinations and with the medical physics expert (MPE) for the service.

Affidea Diagnostics Ireland Ltd. is the undertaking for the service, and the inspector saw that, overall, there were appropriate governance and management arrangements in place to ensure good oversight of the radiation protection of service users. However, some action is required by the management of Affidea Naas in order to achieve compliance with Regulation 6. This is discussed further in the report.

The radiology department consists of a general X-ray unit that provides medical exposures of ionising radiation to out-patients referred by general practitioners, and by medical practitioners working in local hospitals. The service is led by the undertaking's Clinical Services Manager who is also the Designated Manager of the service, while day-to-day operations are overseen by a lead radiographer, who also oversees a team of radiographers. There is also a contracted MPE team involved in the service.

During the inspection, a sample of patient radiological records were reviewed by the inspector who noted that only appropriate persons as per the regulations were involved in referring and justifying medical exposures completed at the service. The inspector noted that the management team completed a monthly audit of Irish Medical Council numbers on referrals received, to ensure that the undertaking's referral system only accepted referrals from appropriate persons. This monitoring system was identified as an area of good practice within the service.

The inspector was also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

On the day of the inspection, the inspector spoke with one of the MPEs involved in the service, and determined that their involvement in the service was now proportionate to the radiological risk posed by the service. For example, the inspector noted in meeting records that the undertaking held an annual radiation protection study day for staff, and that the MPE provided training at this event. The inspector also noted that the undertaking had arrangements in place to assure the continuity of this expertise. However, the inspector observed that a lapse in availing of this expertise, for the review of DRL information, had occurred in June 2022.

A service level agreement between the undertaking and MPE was viewed by the inspector, and showed that appropriate responsibilities had been allocated to the MPE, including an annual review of diagnostic reference levels (DRLs). Although the

most recently established DRL information had been reviewed by the MPE, the inspector was informed that the MPE had not contributed to the review of previous DRL information gathered by staff in the service. This is further discussed under Regulation 20 below.

Nothwithstanding the non compliance with the regulations highlighted above, the inspector was assured that service users were receiving a safe radiological service at Affidea Naas.

Regulation 4: Referrers

The inspector was satisfied that referrals for medical radiological procedures to the service Affidea Naas were made only from persons defined in Regulation 4. The *Local Rules and Radiation Safety Procedures* stated that this role had been allocated to medical practitioners and to dentists, while radiographers could adapt referrals in the interests of justification and optimisation.

The inspector was informed that when an external referral was received, there was a system in place to ensure the referrer was clearly identifiable and that their professional registration was up-to-date.

Judgment: Compliant

Regulation 5: Practitioners

From the review of a sample of medical exposure records and from speaking with staff, the inspector was satisfied that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in the service.

Judgment: Compliant

Regulation 6: Undertaking

Although some improvement was required, overall, the inspector was satisfied that the management team had allocated roles and responsibilities for the radiation protection of services users in Affidea Naas. Documentation reviewed by the inspector prior to and during the inspection demonstrated that there were clear lines of communication within the corporate and clinical governance and management structures. These documented arrangements aligned with those described by staff to the inspector.

The radiation safety committee (RSC) provided oversight for radiation protection arrangements in the service, and met every 6 months to discuss items such as radiation safety incidents, clinical audit and the radiological equipment quality assurance programme. The inspector saw that this group was attended by the country manager, who was the undertaking representative, the clinical services manager, the medical director, the quality manager, an MPE and the lead radiographer in Affidea Naas. This committee subsequently reported up to the Quality and Safety Committee, which in turn reported to the Executive Board of Affidea Diagnostic Ireland Ltd. The undertaking representative for Affidea Naas also attended each of these committee meetings. A sample of minutes from the Quality and Safey Committee was viewed on the day of the inspection and showed that actions and minutes from the biannual RSC meeting were an agenda item for this committee.

Despite these governance and management structures, the inspector noted that improvements were required in the allocation of roles and responsibilities in some areas of radiation protection within the service. For example;

- although the inspector was assured that staff were aware of the professional group entitled to act as a practitioner in Affidea Naas and that only these personnel carried out the responsibilities of a practitioner in the service, the role of practitioner was not clearly allocated in documentation. This area for improvement had been identified to the undertaking's management team during inspections of other Affidea services by HIQA, and should be actioned to ensure that staff, acting as practitioners, are fully aware of their responsibilities under the role of practitioner.
- improvements in the document quality management arrangements were also required, to ensure that the procedures and protocols, available to staff in the department, were regularly reviewed and, when required, updated by the appropriate personnel. For example,
    - the inspector observed that the procedure *Radiology In-House Checks* had not been reviewed and updated to outline the recommended QA checks to be completed on the radiological equipment installed in March 2023. Although there was evidence that these checks were being completed, the checks must be documented to ensure that staff are clearly aware of their roles and responsibilities in implementing an effective quality assurance programme in the service
    - the inspector also noted that the oversight of DRL reviews required action, as although this oversight responsibility had been allocated to the RSC, such reviews were not discussed at RSC meetings
    - the *Local Rules and Radiation Safety Procedures* stated that a referral for a radiological procedure must contain the last menstrual period date, where relevant. However, this did not align with the safe and appropriate inquiry practice being completed by practitioners in the service
    - the inspector noted that a number of other procedures and protocols required updating to ensure that they referenced the most recently published guidance available from HIQA. This is a key element to

ensuring that service users continue to receive a safe and appropriate service.

Nothwithstanding these findings identified on the day of inspection, the inspector was satisfied that service users were receiving a safe service in Affidea Naas.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector was satisfied that there were systems in place to ensure that all medical exposures, carried out in this service, took place under the clinical responsibility of a practitioner.

Documentation viewed and discussions with staff during the inspection demonstrated that Affidea Diagnostics Ireland Ltd. had processes and procedures in place to ensure that the referrer and the practitioner were appropriately involved in the justification of individual medical radiological procedures. Similarly, a practitioner and MPE were involved in optimisation of medical exposures as required by this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From discussions with staff and a review of documentation, including a service level agreement, the inspector was satisfied that the undertaking had arrangements in place to ensure access to and continuity of MPE services.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Evidence of the MPE's professional registration was reviewed by the inspector on the day of inspection, and a MPE had been assigned the role of radiation protection advisor (RPA) in the service, which satisfied the inspector that the MPE and the RPA liaised, as appropriate.

From a review of procedures and records, the inspector noted that the MPE assumed and completed a range of responsibilities across the service. For example, they were involved in the quality assurance of medical radiological equipment,

patient dosimetry and were also available to provide advice and dose calculation for radiation incidents when required. The MPE also attended the RSC meetings, at which they provided and received updates on their responsibilities.

There was evidence that the MPE had contributed to the application and use of the most recent DRLs established in the service, and as discussed under Regulation 11: Diagnostic Reference Levels, the inspector was assured that the DRLs in use on the day of the inspection were appropriately reviewed and contributed to the optimisation of medical exposures carried out in the service. However, the inspector was informed that the MPE had not contributed to the application and use of previous DRL information gathered in the service. Due to this lapse in contribution by the MPE, to the review of DRL information, the inspector was not assured that the undertaking was compliant with Regulation 20(2).

Judgment: Substantially Compliant

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

From documentation reviewed and discussions with the MPE and management staff, the inspector was satisfied that the level of MPE involvement in medical radiological practices was commensurate with the radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, the inspector noted that the management team in Affidea Naas had good radiation protection measures in place for service users, for example, the use of DRLs recently established for the new equipment. However, some action was required to ensure that DRLs were reviewed in line with the undertaking's allocation of this responsibility, and that review records were available in line with Regulation 11.

During the inspection, the inspector reviewed a number of referrals, received from external medical practitioners, and saw that each was in writing, stated the reason for the request and was accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. There was evidence that justification in advance was recorded for each medical radiological procedure reviewed by the inspector, and staff who spoke with the inspector detailed this process.

From a review of documentation, the inspector was satisfied that local DRLs had recently been established and reviewed by the MPE for the radiological equipment in

the service. These DRLs had been compared with national DRLs and were on display in the console area for use by practitioners.

Although some updates were required to the *Radiology In-House Checks* procedure, on the day of inspection, the inspector was assured that the equipment in use in the service was clinically fit for use and provided a safe and reliable service to service users. From a review of records and discussions with staff, the inspector was informed that staff were completing quality assurance checks on the equipment in line with manufacturer guidance. The inspector also reviewed records that showed that equipment manufacturer and the MPE were involved in testing of the equipment before its first clinical use.

From a review of patient records and clinical audits, the inspector was assured that there was a process in place to determine the pregnancy status of service users, where relevant, and that this process was monitored and adhered to by staff.

The management of Affidea Naas had arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. These arrangements included ensuring that the undertaking had oversight of an actual or potential incidents that occurred in the service, and that HIQA was notified of any reportable events.

Nothwithstanding the findings discussed above, the inspector was satisfied that, overall, Affidea Naas had systems and processes in place that ensured the safe delivery of medical radiological exposures to service users on the day of the inspection.

Regulation 8: Justification of medical exposures

A sample of written referrals were reviewed by the inspector on the day of the inspection. All referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was also displayed in poster format in the waiting area and changing room, however repositioning of these posters should be considered to ensure the information is more easily viewed by service users.

There was a documented justification procedure in place which stated that justification in advance was completed at the protocolling stage, and there was evidence in the service user records reviewed, that this had been completed. Therefore the inspector was satisfied that the undertaking was compliant with Regulation 8(8).

The inspector was also informed that, on the day of the medical exposure examination, supplementary checks on justification were completed by practitioners. However, the undertaking should document and clearly allocate roles and responsibilities for these supplementary steps if they are to provide further assurances to the undertaking of the justification process.

Judgment: Compliant

Regulation 9: Optimisation

The inspector reviewed documentation and spoke with staff about the measures in place to ensure that the medical radiological procedures in the service were optimised. The *Local Rules and Radiation Safety Procedures* outlined a number of optimisation considerations for service users undergoing a general X-ray examination, such as tailoring exposure parameters when required, collimation and limiting number of views per examination. The document also clarified the responsibilities of those involved in the optimisation of service users' doses.

Optimisation systems in Affidea Naas also included the use of DRLs in the service, the implementation of regular quality assurance testing on the medial radiological equipment, the use of written protocols by staff and the conduct of clinical audits in the service.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector observed that DRLs had been established for common radiological procedures completed at Affidea Naas, and were comparable to national DRLs. These DRLs had been established with exposure data gathered over the nine months from the installation of the new radiological equipment in March 2023. This recent proactive approach to the establishment of relevant DRL data was identified as an area of good practice in the service. This DRL information was displayed in console areas and staff who spoke with the inspector demonstrated an awareness of how to use the data when completing medical exposures of ionising radiation.

The undertaking's management team had also developed a document *Radiology Dose Audit*, which was in line with the regulations and stated that DRLs should be calculated and reviewed annually by the MPE. However, from a review of documentation and discussions with staff, the inspector noted that the service's DRLs were not regularly reviewed. Although the inspector was provided with a

comprehensive record of exposure data, gathered on procedures completed in the service from July 2021 to June 2022, the records evidencing that this information had been reviewed were not available to the inspector.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, the inspector reviewed the written protocols available for standard medical radiological procedures and noted that staff were familiar with the protocols and that they were accessible to staff in the clinical area and guided them on the optimised patient preparation and positioning, and exposure parameters for different medical exposures. The inspector also noted that appropriate referral guidelines were available to staff, for reference.

The inspector also reviewed a sample of reports on medical exposures carried out in the service, and found that information relating to patient exposure formed part of the report as required by Regulation 13(2).

A number of clinical audits had been completed in the service, such as audits on the assessment of dose, adherence to checking pregnancy status and that the clinical justification of medical exposures was completed by staff. Affidea Naas's management team informed the inspector that plans were being developed to align the services' clinical audit programme with the national procedures, recently published by HIQA. The team also demonstrated an understanding that clinical audit is an important tool in identifying areas for improvement and of good practice in the service, which would assist in the safe delivery of medical exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory of medical radiological equipment. The undertaking's management team demonstrated good awareness of ensuring that medical radiological equipment in Affidea Naas continued to meet the criteria of acceptability, with a new general X-ray unit installed in Mach 2023.

The QA records reviewed by the inspector showed that the medical radiological equipment in the service was kept under strict surveillance regarding radiation protection, and that regular performance testing as advised by the equipment manufacturer was completed on the equipment. The inspector was also provided with records of acceptance testing on the equipment before its first clinical use.

There was also a system in place for reporting and recording equipment faults, which included an identifiable responsible person, and staff in the service communicated this system to the inspector.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

In Affidea Naas, there were appropriate measures in place to minimise the risks, associated with potential foetal irradiation, during medical exposures of female patients of childbearing age. The *Local Rules and Radiation Procedures* stated that practitioners were responsible for inquiring on and recording in writing the service user's pregnancy status, where relevant. From discussions with practitioners, the inspector was satisfied that they were aware of their specific responsibilities in this area. During the inspection, the inspector and management team reviewed the inquiry form used by practitioners and acknowledged that it required a minor review to ensure that it fully aligned with the local practice. This was identified as an area for improvement within the service, but did not impact on the undertaking's compliance with Regulation 16.

The inspector also observed that the management team had placed notices to raise awareness of the special protection required during pregnancy in advance of medical exposures, in service user waiting areas and in changing rooms.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The local *Incident Management Policy* outlined the process for the management of accidental and unintended exposures and significant events, and staff who spoke with the inspector were able to describe this process. This process included information on the requirement to notify HIQA of certain reportable incidents, if required.

Incidents and potential incidents were recorded and analysed and the inspector was informed that they were then discussed at a weekly group incident meeting where actions and investigations were agreed on. Records showed that they were subsequently discussed at a bimonthly radiation protection officer meeting, and at the biannual RSC meeting which was attended by the Affidea group's undertaking representative and Quality and Risk Manager.

On the day of the inspection, the inspector noted that there was a good culture of reporting near misses in the service, and that the trending and analysis of this

incident data contributed to the safety of the service. For example, a review of this near miss data demonstrated that a number of duplicate referrals had been submitted, noted during a protocolling process and subsequently rejected before an unnecessary repeat medical radiological examination was completed on the service user. This analysis had been used to remind protocolling staff on the importance of the thorough review of referrals received for medical exposures in the service.
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	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	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 Affidea Naas OSV-0005986

Inspection ID: MON-0039457

Date of inspection: 15/02/2024

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 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: • The role and responsibilities of practitioners has been clearly outlined in the relevant documentation to ensure staff acting as practitioners are aware of their responsibilities. • The Radiology In-House checks SOP has been revised and staff educated on the requirement to document all QA checks. • DRL reviews is now a standing Agenda item for every RSC meeting. • The Local Rules and Radiation Safety Procedures have been revised to include a number of key changes. Expanded roles and responsibilities. Deletion of LMP required from referrer. Updating of Related documents and references • Update of all related documents-procedures and protocols to include most recently published HIQA guidance.	
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: The Local Rules and Radiation Safety Procedures have been revised to include a more detailed explanation of the role and responsibilities of the MPE	

Compliance plan as per Regulation 11.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Yearly reminder documented in the calendar for DRL's to be signed off by the MPE. The reminder notification entered in the calendar by the head of the RSO.
The date will be the end of each calendar year and a reminder notification the end of the first month for the previous year's DRL's to be signed off by the MPE.
A compliance audit to be carried out yearly on the 28th of February by the head of the RSO. Action to be taken for non-compliance.
DRL's that is not available will be documented with a valid explanation for example: insufficient data due to low X-ray activities (pandemic)

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	31/03/2024
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	31/03/2024

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	31/03/2024
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics 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	Substantially Compliant	Yellow	31/03/2024

	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.			