

# Health Information and Quality Authority

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

| Name of Medical          | Bon Secours Diagnostic                  |
|--------------------------|---|
| Radiological             |   |
| Installation:            |   |
| Undertaking Name:        | Alliance Medical Diagnostic Imaging Ltd |
| Address of Ionising      | Bon Secours Health System,              |
| Radiation Installation:  | Barringtons, George's Quay,             |
|                          | Limerick                                |
|                          |   |
| Type of inspection:      | Announced                               |
| Date of inspection:      | 22 August 2023                          |
| Medical Radiological     | OSV-0005992                             |
| Installation Service ID: |   |
| Fieldwork ID:            | MON-0039913                             |

# About the medical radiological installation:

Bon Secours Diagnostic (BSD ) imaging is contracted for the provision of all radiology services within the Radiology Department of the Bon Secours Hospital Limerick at Barringtons including MRI, CT, General X-ray, Ultrasound, and DEXA. Additionally, BSDI provide a radiographer to undertake theatre screening and the provision of a radiographer for the Pain Service. This is a wholly private service for inpatients of the Bon Secours Hospital, Limerick at Barringtons, with the addition of privately insured individuals and a self-paying outpatient service as required.

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

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users<sup>4</sup> to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

# About the inspection report

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

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

<sup>&</sup>lt;sup>1</sup> Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

<sup>&</sup>lt;sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>&</sup>lt;sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>&</sup>lt;sup>4</sup> 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 22 August 2023 | 10:00hrs to<br>15:20hrs | Kay Sugrue     | Lead    |
| Tuesday 22 August 2023 | 10:00hrs to<br>15:20hrs | Noelle Neville | Support |

# Governance and management arrangements for medical exposures

Alliance Medical Diagnostic Imaging Ltd (AMDI) is the undertaking contracted to provide the radiology service at Bon Secours Diagnostic, Barrington's Limerick. Inspectors carried out an inspection of this medical radiological facility on 22 August 2023 to assess compliance with the regulations. Inspectors also assessed the measures implemented to address the non-compliances identified during the previous inspection at this facility in February 2020. Inspectors spoke with staff and management, reviewed documentation and also visited the general radiography, dual-energy X-ray absorptiometry (DXA) and computed tomography (CT) services as part of this inspection. Improvements in compliance were found with respect to Regulations 10(4), 13(1) and 11(5) since the previous inspection. However, inspectors noted that despite measures implemented to improve compliance with Regulations 13(2) and Regulation 8, more needs to be done to achieve compliance with these regulations. This will be discussed further under each of these regulations.

Inspectors were satisfied through the review of documentation and discussions with staff, that all medical exposures took place under the clinical responsibility of a practitioner. Radiation safety procedures had been updated since the last inspection to provide greater clarity regarding the role of the radiographer as a practitioner. Inspectors were informed that a radiographer was present for each medical exposure conducted at this facility. There was a process in place to ensure that referrals for medical radiological exposures were only accepted from individuals entitled to refer. Medical physics expert (MPE) involvement in medical radiological practices was evident, with the level of involvement commensurate with the radiological risk posed by the practice. Staff were clear in discussions with inspectors as to their individual roles in each area visited, therefore satisfying inspectors that the allocation of responsibilities was clearly defined in line with the regulations.

Overall, inspectors were satisfied from the evidence gathered that staff and management were committed to ensuring the radiation protection of service users and work was in progress to address gaps in regulatory compliance found during this inspection.

# 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 that medical exposures only took place under the clinical responsibility of a practitioner as recognised under this regulation.

Judgment: Compliant

## Regulation 6: Undertaking

Radiology governance and management structures were described by staff at Bon Secours Diagnostic and were consistent with documented structures viewed by inspectors. A radiation safety committee (RSC) was in place and met twice a year. The RSC had representation both from AMDI senior management and a senior management representative from the host hospital. The designated manager of Bon Secours Diagnostic also attended quality and risk committee meetings at the host hospital which provided assurance that there was a direct communication pathway between the host hospital and the undertaking. Additionally, minutes reviewed from the RSC, the Clinical Governance Committee, the Bon Secours Group Radiology Forum and reports to the international chief medical officer of the parent company showed that there was effective oversight of matters relating to the radiation protection of service users. Staff described the Bon Secours Group Radiology Forum, which was attended by designated managers from other facilities within the group and under this undertaking, as an effective means to share information in relation to notifiable radiation incidents and regulatory compliance issues. Management also informed inspectors that learning from HIQA inspections carried out at other medical radiological facilities was shared at this forum with the aim of improving compliance with regulations.

Staff demonstrated awareness regarding the allocation of responsibilities for medical exposures to inspectors. Radiation protection training was provided to staff working directly with ionising radiation. An online presentation on radiation protection was available with further plans in place to provide face-to-face education sessions to staff working in the facility. While meeting the requirements under this regulation, inspectors noted from the training records reviewed that monitoring and oversight of ongoing radiation protection training to staff by the undertaking should be formalised to ensure that staff undertake continued training as relevant in radiation protection.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that progress had been made by staff at Bon Secours Diagnostic to clarify the role of the radiographer as a practitioner in this facility since the inspection in 2020. For example, radiation safety procedures were revised to ensure that the role of the practitioner for all medical exposures was clear to all staff.

Radiologists and radiographers were recognised as practitioners at this facility and only persons entitled to act as a practitioner carried out the practical aspects of medical radiological procedures conducted there. Inspectors were satisfied that a practitioner and MPE were involved in the optimisation process for medical exposure to ionising radiation. Similarly, evidence showed that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

From discussions with management, staff and the MPE, it was clear to inspectors that staff had appropriate access to the MPE if and when required. Inspectors were informed that the undertaking had access to other MPEs for consultation and advice as necessary, should the MPE with responsibility for the unit be unavailable, thereby, ensuring the continuity of medical physics expertise for this service.

Judgment: Compliant

# Regulation 20: Responsibilities of medical physics experts

MPE responsibilities for this facility which met regulatory requirements were described to inspectors. Current professional certification was also viewed. Inspectors noted that the MPE was involved across a range of responsibilities outlined in Regulation 20(2). The MPE was responsible for dosimetry and gave advice on medical radiological equipment. Records reviewed by inspectors demonstrated that the MPE had contributed to quality assurance and acceptance testing of medical radiological equipment and was involved in optimisation including review and sign-off of the facility's DRLs. The MPE also provided advice and dose calculations for radiation incidents and attended the RSC meeting. The MPE also acted as the RPA for this facility fulfilling the requirements under Regulation 20(3).

Judgment: Compliant

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

The level of involvement by the MPE was described by staff to inspectors and aligned with responsibilities detailed by staff working in the facility. Overall, inspectors found that the level of contribution and involvement was proportionate to the radiological risk posed by the service provided at Bon Secours Diagnostic.

Judgment: Compliant

## **Safe Delivery of Medical Exposures**

Inspectors viewed the systems and processes in place to assess the safe delivery of medical exposures at Bon Secours Diagnostic. Since the 2020 inspection, improvements in compliance were found with respect to Regulation 13(1) and 11(5). For example, protocols for medical radiological procedures had been updated in February 2023 and were viewed by the inspectors in each of the services visited. Diagnostic reference levels (DRLs) were established in all modalities and applied in practice. Good practice was evident where dose audits carried out in 2022 and 2023 in the pain clinic identified a need to further optimise doses delivered by different practitioners for a standard procedure. A number of recommendations were implemented in consultation with pain management consultants, where radiographers further collimated and reduced the pulse rate of each examination. These measures resulted in significant reductions in median doses and screening times which were evident in the follow-up audit completed in 2023 and viewed by inspectors. Inspectors found this to be a good example of the application of DRLs for the optimisation of the radiation dose to the service user.

Inspectors noted that actions were taken by the undertaking to improve compliance with Regulation 13(2) which included the installation of a system that facilitated the automated transfer of information relating to the patient exposure to the report of the examination. However, while information relating to the medical exposure was evident in reports issued to referrers which were viewed in the general radiology, CT and DXA services, reports to demonstrate compliance with this regulation were not available to view in the fluoroscopy service at the time of the inspection.

While actions had been taken by the undertaking to improve compliance with Regulation 8, the measures outlined in the compliance plan and implemented did not sufficiently address the non-compliances with this regulation. Inspectors found that there was disparity between the process for documenting justification in advance detailed in the radiation procedures and day-to-day practices. In addition, improvements were also required with respect of Regulations 8(10) and 8(11) where the rationale, clinical details and professional registration number of the referrer were not evident in a sample of written referrals viewed from the fluoroscopy

service.

In relation to Regulation 14, inspectors found that a quality assurance (QA) programme was in place and maintained. However, inspectors found that the QA programme should be documented, regularly reviewed and updated to ensure the continuity of this programme and that the strict surveillance of all medical radiological equipment in use is maintained in line with Regulation 14(1).

Overall, notwithstanding that improvements were required with Regulations 8, 13 and 14, 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

In assessing compliance with this regulation inspectors reviewed a sample of referrals and records relating to the justification of procedures carried out. Inspectors also spoke with staff and reviewed the information about the benefits and risks associated with the radiation dose from medical exposures available to service users at the facility. Posters detailing the risks and benefits associated with medical exposures were displayed on the walls in service user waiting areas. These posters were developed by staff working in this facility and were modality specific, comprehensive and the risks compared to naturally occurring background radiation.

Since the inspection of this facility in 2020, inspectors found that the undertaking had implemented measures to address the findings of the inspection with respect to this regulation and had updated the process for justifying medical radiological procedures in practice and in local policy as per the compliance plan submitted after the previous inspection. However, despite the measures taken to date, further gaps were identified during this inspection which continued to impact compliance levels with respect to this regulation.

Inspectors viewed the *Radiation Safety Policy* in place at this facility prior to the inspection. This document had been updated and implemented in October 2021 following the last inspection. The policy stated that "the practitioner, or designate, must justify the requested medical exposure at both the vetting stage and just before initiating the exposure" outlining that there was a two-step approach involved in the justification process for each medical radiological procedure. While inspectors saw evidence that step one of the justification process was completed by a practitioner at the vetting stage on each record viewed, the second step of justifying the examination prior to the procedure was not documented in all records viewed and therefore did not follow local policy. The undertaking should ensure that the process of justification in practice aligns with local procedure and policy to achieve compliance with Regulation 8(8) and 8(15).

In the fluoroscopy service, inspectors viewed a sample of referrals and found that the rationale or relevant clinical data for the prescribed procedure was not evident in these referrals as required by Regulation 8(10). This meant that there was little

assurance to satisfy inspectors that the practitioner carrying out the procedure had taken into account relevant medical data when justifying the medical exposure in advance as per Regulation 8(11). Additionally, although inspectors were informed that the internal referrer was recognisable to staff, the referrer's professional registration number was not included by the referrer in the referrals viewed in this setting and was therefore not in line with local policy. The referral and justification requirements are specified under Regulation 8 for each medical radiological procedure, therefore, gaps in the referral and justification processes identified by inspectors must be addressed by the undertaking to ensure compliance with this regulation.

Judgment: Not Compliant

#### Regulation 11: Diagnostic reference levels

Since the inspection in 2020, staff at the hospital had established DRLs in the DXA service. Facility DRLs for all modalities were displayed in the control rooms of each area visited and were compared with national DRLs.

Discussion with staff demonstrated to inspectors how DRLs are used when carrying out medical exposures to ionising radiation. Inspectors viewed evidence of good practice in the review of doses for fluoroscopic guided medical exposures carried out as part of common procedures provided in the pain clinic service in an audit undertaken in 2022. The audit found that although doses were below national and local DRLs, there was potential to further optimise and standardise the doses delivered by different practitioners for a specific procedure. A change in practice followed which included lowering the pulse rate, further collimating each exam and allowing radiographers to conduct the practical aspects of the medical exposure. A follow up audit in 2023 found that median doses and screening times had significantly reduced for the same procedure following the implementation of these measures.

Judgment: Compliant

#### Regulation 13: Procedures

Inspectors viewed protocols in place for each modality which were last reviewed in February 2023. Each of the records of medical exposures reviewed by the inspectors during the inspection had an appropriate protocol for the procedure. Inspectors were satisfied that the undertaking had taken sufficient action to come into compliance with Regulation 13(1).

To improve compliance with Regulation 13(2), the undertaking had installed a

system that facilitated the automated transfer of information relating to the patient exposure to the report of the examination for most of the X-ray equipment which was compatible with this system. This meant that information relation to the exposure was available to view on reports originating from general X-ray and CT services. Inspectors were informed that the DXA unit and C-arm units in the fluorosopy service were not compatible with this system, however, the dose from procedures conducted in the DXA service was available on the image which was included with the report issued to the referrer. In the fluoroscopy service, inspectors were informed that the dose was also on the image from the procedure, however, the report of the procedure was not available to view on the day of the inspection to verify compliance with the requirement of this regulation. While noting the actions taken by staff to improve compliance since the previous inspection, more assurance was needed to ensure that reports from every modality contained information relating to the medical exposure as per Regulation 13(2).

Referral guidelines were available to staff and referrers as required by Regulation 13(3). A clinical audit programme was in place that included but was not limited to an annual radiation safety audit, DRL audits for each modality and pregnancy status audits. Audits that were focused on optimisation were evident in CT and the pain clinic services.

**Judgment: Substantially Compliant** 

#### Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was provided in advance of the inspection and verified by inspectors on site. Inspectors reviewed records of acceptance testing of equipment before the first clinical use and regular performance testing which demonstrated compliance with Regulation 14(3). Records also showed that any issues or equipment faults were promptly addressed as needed.

Inspectors found that an appropriate quality assurance programme for medical radiological equipment as required by Regulation 14(2) was implemented and maintained. Inspectors were informed that implementation and oversight of the QA programme was reliant on one member of staff and that the QA programme as described, was not documented in any of the documentation provided. To ensure the continuity of the QA programme and that the strict surveillance of all medical radiological equipment in use is maintained as per Regulation 14(1), the QA programme should be documented and regularly reviewed and updated as required.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The procedure for establishing the pregnancy status of women of child-bearing age was reviewed in the *Radiation Safety Policy* document and verified by inspectors in discussions with staff. A sample of referrals and completed pregnancy declarations of relevant service users performed in advance of conducting a medical exposure were viewed. Posters were observed throughout the diagnostic imaging department to help increase the awareness of the special protection required during pregnancy prior to undergoing a medical exposure.

From the records reviewed, inspectors were satisfied that pregnancy inquiries involving the referrer and or practitioner were appropriately documented, ensuring that all reasonable measures were taken to prevent the unnecessary exposure of a foetus during a medical exposure of a pregnant individual.

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 the undertaking at Bon Secours Diagnostic had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. Inspectors found that learning from incidents was shared within the facility and externally to other facilities under the remit of the undertaking through the group radiology forum previously mentioned.

Inspectors noted that statutory notifications of significant events which have occurred in this facility have been submitted within the required time frames along with any additional information requested. While meeting the requirements of this regulation, inspectors found that given the level of procedures performed in this facility, and the corresponding levels of radiation incidents and near misses reported annually, there was scope to further improve the level of awareness of reporting to ensure the early identification of radiation incidents and to help identify trends and quality improvement measures where needed.

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                  | Compliant     |
| medical radiological practices  |               |
| Safe Delivery of Medical Exposures  |               |
| Regulation 8: Justification of medical exposures                          | Not Compliant |
| Regulation 11: Diagnostic reference levels                                | Compliant     |
| Regulation 13: Procedures   | Substantially |
|   | Compliant     |
| Regulation 14: Equipment  | Substantially |
|   | Compliant     |
| Regulation 16: Special protection during pregnancy and breastfeeding      | Compliant     |
| Regulation 17: Accidental and unintended exposures and significant events | Compliant     |

# Compliance Plan for Bon Secours Diagnostic OSV-0005992

**Inspection ID: MON-0039913** 

Date of inspection: 22/08/2023

#### **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 the radiology information system (RIS) until an information technology (IT) solution has been implemented. The site audit program has been expanded to include specific checks for clinical justification immediately prior to exposure. Processes on site are now compliant with Regulation 8.

However, we wish to automate this process further and have further set an objective. 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.

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.

This solution is currently implemented on other hospital sites using the same RIS/PACS system. This IT solution will be implemented by 30/11/2023.

Medical Council Number (MCN) and clinical details on referral

A fluoroscopy service is provided for pain clinic and theatres, referrals are completed immediately prior to the examination commencement. Re-education has been provided to staff involved in referring with respect to the details that are required to form a complete and justified examination referral. The existing clinical justification audit has been expanded to include this. This is a simple solution to the non-compliance, without involving any additional technical measures which is now in place and will be continuously assessed through audit.

**Substantially Compliant** 

Outline how you are going to come into compliance with Regulation 13: Procedures: Alliance Medical utilises an automated dose management system which transfers the dose from the modality across to the patient report on picture archive communication system (PACS). The image intensifiers in use, whilst still providing a safe and appropriate clinical service, do not have the ability to transfer in this manner, therefore their inclusion in the automated dose management system will not be achieved prior to equipment upgrade. Alliance Medical have committed to ensuring that all new equipment purchased will be compatible with the dose management system. On this site, equipment is expected to be replaced in early 2025. In the interim, text will be included on the examination report which includes information on the medical exposure. This process will be in place by 30/11/2023.

#### Regulation 14: Equipment

**Substantially Compliant** 

Outline how you are going to come into compliance with Regulation 14: Equipment: A QA procedure will be written to reflect the process on site for each modality and will be available to all staff on site. The master document framework will be written centrally with local modality clinical specialists completing the document locally. This will be completed by 30th November 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<br>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         | 30/11/2023               |
| Regulation<br>8(10)(b) | A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and  | Substantially<br>Compliant | Yellow         | 30/11/2023               |
| Regulation<br>8(10)(c) | A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by   | Substantially<br>Compliant | Yellow         | 30/11/2023               |

|                  |                        |               | ı      | 1          |
|------------------|------------------------|---------------|--------|------------|
|                  | sufficient medical     |               |        |            |
|                  | data to enable the     |               |        |            |
|                  | practitioner to        |               |        |            |
|                  | carry out a            |               |        |            |
|                  | justification          |               |        |            |
|                  | assessment in          |               |        |            |
|                  | accordance with        |               |        |            |
|                  | paragraph (1).         |               |        |            |
| Dogulation 0/11) |                        | Cubatantially | Yellow | 26/00/2022 |
| Regulation 8(11) | A practitioner         | Substantially | Yellow | 26/09/2023 |
|                  | carrying out a         | Compliant     |        |            |
|                  | medical                |               |        |            |
|                  | radiological           |               |        |            |
|                  | procedure on foot      |               |        |            |
|                  | of a referral shall,   |               |        |            |
|                  | having taken into      |               |        |            |
|                  | account any            |               |        |            |
|                  | medical data           |               |        |            |
|                  | provided by the        |               |        |            |
|                  | referrer under         |               |        |            |
|                  | paragraph (10)(c),     |               |        |            |
|                  |                        |               |        |            |
|                  | satisfy himself or     |               |        |            |
|                  | herself that the       |               |        |            |
|                  | procedure as           |               |        |            |
|                  | prescribed in the      |               |        |            |
|                  | referral is justified. |               |        |            |
| Regulation 8(15) | An undertaking         | Not Compliant |        | 30/11/2023 |
|                  | shall retain records   |               | Orange |            |
|                  | evidencing             |               |        |            |
|                  | compliance with        |               |        |            |
|                  | this Regulation for    |               |        |            |
|                  | a period of five       |               |        |            |
|                  | years from the         |               |        |            |
|                  | date of the medical    |               |        |            |
|                  |                        |               |        |            |
|                  | exposure, and          |               |        |            |
|                  | shall provide such     |               |        |            |
|                  | records to the         |               |        |            |
|                  | Authority on           |               |        |            |
|                  | request.               |               |        |            |
| Regulation 13(2) | An undertaking         | Not Compliant |        | 30/11/2023 |
|                  | shall ensure that      |               | Orange |            |
|                  | information            |               |        |            |
|                  | relating to patient    |               |        |            |
|                  | exposure forms         |               |        |            |
|                  | part of the report     |               |        |            |
|                  | of the medical         |               |        |            |
|                  | radiological           |               |        |            |
|                  | procedure.             |               |        |            |
| Dogulation 14(1) | •                      | Cubetantially | Vollou | 20/11/2022 |
| Regulation 14(1) | An undertaking         | Substantially | Yellow | 30/11/2023 |
| 1                | shall ensure that      | Compliant     |        |            |

| all medical         |  |  |
|---------------------|--|--|
| radiological        |  |  |
| equipment in use    |  |  |
| by it is kept under |  |  |
| strict surveillance |  |  |
| regarding radiation |  |  |
| protection.         |  |  |