



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Merlin Park Imaging Centre
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Merlin Park University Hospital, Galway
Type of inspection:	Announced
Date of inspection:	08 January 2020
Medical Radiological Installation Service ID:	OSV-0005999
Fieldwork ID:	MON-0028256

## About the medical radiological installation:

Merlin Park Imaging Centre is a computed tomography (CT) service based at Merlin Park University Hospital, Galway, and is operated by Alliance Medical Diagnostic Imaging Ltd. The service is provided in a stand alone building, which caters for both CT as well as Magnetic Resonance Imaging (MRI). The CT service provides clinical services to HSE and private patients. The CT service operates Monday- Friday, typically from 0800-1700. The CT system is a Siemens Perspective 128 slice, installed in Dec 2015. Alliance Medical Diagnostic Imaging Ltd. engage services of an independent Medical Physics expert to commission the system, and annually commission medical physics testing on the system.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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:**

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

<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>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
Wednesday 8 January 2020	09:00hrs to 17:00hrs	Lee O'Hora	Lead
Wednesday 8 January 2020	09:00hrs to 17:00hrs	Agnella Craig	Support

## Governance and management arrangements for medical exposures

Inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposure at Merlin Park Imaging Centre. Overall responsibility for the radiation protection of services users was held by Alliance Medical Diagnostic Imaging Ltd.

The managing director of Alliance Medical Diagnostic Imaging Ltd. oversaw radiation safety issues across the company via senior management and quality department, local radiation safety committee and local unit manager. Merlin Park Imaging Centre is a facility within the larger governance structure of Alliance Medical Diagnostic Imaging Ltd. with its own radiation safety committee. The radiation safety committee is formed of the quality manager, regional manager, lead practitioner, site manager and radiation protection officer. The quality manager chairs the radiation safety committee and reports to the head of patient quality and safety. The head of quality and safety is part of the senior management team providing comprehensive reporting and communication of radiation safety concerns and issues throughout Alliance Medical Diagnostic Imaging Ltd. Facility staff meetings also provided a further assurance that radiation safety issues were appropriately communicated throughout the undertaking.

Some potential areas for improvement were identified by inspectors. Merlin Park Imaging Centre documentation does not clearly allocate practitioner status by profession. The identification of recognised practitioners by profession would provide clarity and improve transparency in the allocation of clinical responsibility for all medical exposures. Similarly, the requesting of professional registration details from all referrers would give Merlin Park Imaging Centre further assurances that only appropriately qualified staff refer patients for CT imaging ensuring the radiation protection of service users. Furthermore, minutes reviewed suggested that facility radiation safety committee meetings and staff meetings occurred less frequently than documented in terms of reference and local rules. This was acknowledged as an area for potential improvement at Merlin Park Imaging Centre.

Overall, inspectors were satisfied that Alliance Medical Diagnostic Imaging Ltd. provided clear processes, guidance and appropriate allocation of responsibility for the safe referral and conduct of medical radiological procedures at Merlin Park Imaging Centre.

## Regulation 4: Referrers

Inspectors reviewed documentation that clearly defined accepted referrers in line with the regulations. Documents reviewed by inspectors required the name and

signature of referring doctors on all CT referrals. It was noted that, although available for many referrals reviewed, evidence of professional registration, such as a medical council number is not documented as a requirement by Merlin Park Imaging Centre.

Inspectors were informed that digital referring systems had inbuilt mechanisms to ensure that only appropriately qualified staff could make referrals, but written referrals relied on the familiarity of staff with the referrer and in some cases merited further information requests. All referrals reviewed by inspectors during a document review and clinical area visit included the name and signature of the referring doctor as outlined in Merlin Park Imaging Centre documentation.

Throughout the course of the inspection, senior management and staff in the clinical area consistently articulated to inspectors who were considered accepted referrers by Merlin Park Imaging Centre.

Judgment: Compliant

### Regulation 5: Practitioners

Inspectors spoke to senior management and clinical staff and were informed that consultant radiologists only are considered practitioners at Merlin Park Imaging Centre. Records reviewed by inspectors clearly defined recognised individual consultant radiologists and included their professional registration numbers. This categorisation of practitioners as consultant radiologists only was not clearly defined by any documentation reviewed by inspectors, a point acknowledged by senior management as a potential area for improvement.

Judgment: Compliant

### Regulation 6: Undertaking

Inspectors reviewed documentation and were satisfied that Alliance Medical Diagnostic Imaging Ltd. provided clear allocation of responsibility for radiation safety of service users. Radiation safety procedures and local rules reviewed by inspectors outlined the responsibilities of the managing director, senior management team, quality department, unit managers, radiation protection officers and unit radiation safety committees in the provision of a safe service to service users.

On discussion with senior management, a medical physics expert and staff in the clinical area inspectors were satisfied that the structures in place were well understood by management at Alliance Medical Diagnostic Imaging Ltd. and Merlin Park Imaging Centre staff.

Inspectors were informed that facility specific radiation safety committees monitored radiation protection at local level. Documentation reviewed by inspectors defined roles and responsibilities of the radiation safety committee, terms of reference and frequency of meetings. Radiation safety committee minutes from the last three unit radiation safety committee meetings were also reviewed by inspectors.

It was noted that despite indicating that unit radiation safety committees would meet twice yearly, the Merlin Park Imaging Centre radiation safety committee only met once in 2019. This point was acknowledged by senior management on the day of inspection.

Inspectors were also informed that monthly staff meetings with unit managers and staff provided another level of assurance that relevant radiation safety related information is communicated appropriately within the organisation. Inspectors reviewed minutes of monthly meetings during the course of inspection, radiation safety was a standing agenda point.

It was noted that these meeting did not occur monthly as suggested. Inspectors were informed that staff shortages had temporarily interrupted the consistency of the monthly meetings. A clear allocation of responsibility for ensuring monthly meetings are occurring as suggested, and escalation process if this is not the case, would give Alliance Medical Diagnostic Imaging Ltd. further assurances that radiation safety issues are effectively communicated within Merlin Park Imaging Centre.

Judgment: Compliant

## Regulation 10: Responsibilities

Inspectors reviewed radiation safety procedures and policies which clearly outlined the responsibilities of people involved in the exposure of service users to ionising radiation including the referrer, the practitioner, the radiographer and the medical physics expert. Following document review and meetings with senior management inspectors were satisfied that all medical exposures took place under the clinical responsibility of a practitioner at Merlin Park Imaging Centre.

Documents reviewed by inspectors outlined the responsibilities of referrers, practitioners and medical physics experts in the optimisation and justification of medical exposures. Inspectors were informed that Merlin Park Imaging Centre did not delegate practical aspects of medical exposures to non-radiology staff.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were informed that Merlin Park Imaging Centre retained the services of a single medical physics expert, who acted as both medical physics expert and radiation protection advisor. Inspectors were informed by senior management that the service level agreement ensured medical physics cover, when necessary, at all times during the normal working hours of Merlin Park Imaging Centre. Inspectors were satisfied that necessary arrangements were in place to ensure continuity of expertise of medical physics staff.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Documents reviewed by inspectors detailed the specific responsibilities of the medical physics expert which satisfied regulatory requirements. Records of acceptance testing, performance testing and QA policies were reviewed by inspectors during inspection. Appropriate MPE contribution to the analysis of accidental or unintended medical exposures was evidenced and articulated during inspection. Inspectors were satisfied that the undertaking ensured that medical physics responsibilities, advice and contributions were appropriate for the medical radiological practise.

Judgment: Compliant

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

Inspectors were satisfied through document review and discussion with senior management, that Merlin Park Imaging Centre ensured appropriate involvement of the medical physics expert commensurate with the radiological service provided.

Judgment: Compliant

### Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by Alliance Medical Diagnostic Imaging Ltd.at Merlin Park Imaging Centre ensured the safe

delivery of medical exposures. No significant risks to the safety, health or welfare of service users were identified during the inspection.

Evidence of comprehensive procedure protocols and promotion of referral guidelines provided assurances that medical exposures were delivered in a safe, well defined manner at Merlin Park Imaging Centre.

Inspectors found a strong company approach to the establishment and use of diagnostic reference levels at Alliance Medical Diagnostic Imaging Ltd. but appropriate investigation and corrective actions was not evidenced on the day of inspection at Merlin Park Imaging Centre. This was seen as an area for improvement to facilitate Merlin Park Imaging Centre achieving full regulatory compliance.

Inspectors saw evidence of a strong culture of audit including radiation safety specific audit within Alliance Medical Diagnostic Imaging Ltd. and Merlin Park Imaging Centre. An example of good practice seen during inspection was Alliance Medical Diagnostic Imaging Ltd.'s annual regulatory compliance audits which served as a gap analysis facilitating and driving regulatory compliance across the company.

Other examples of good and indeed novel practice noted on inspection was the use of a dose alert system which informs the radiographer when a patient dose is going to exceed a trigger value and allows them to reassess scanning parameters where necessary. This system served as a further opportunity for patient dose optimisation. Merlin Park Imaging Centre also uses referral criteria business cards for referrers facilitating availability and ease of access to Merlin Park Imaging Centre referral criteria.

Inspectors were satisfied that systems were in place to ensure and record the appropriate justification of medical exposures as well as to apply and record measures to ensure special protection during pregnancy. However, although not considered practitioners by Merlin Park Imaging Centre, documents reviewed by inspectors clearly outlined the responsibilities of radiographers. These responsibilities gave radiographers significant roles relating to procedure justification, patient dose optimisation, application of the As Low As Reasonably Achievable (ALARA) principle and pregnancy status enquiry and recording. Local documentation should be updated to reflect the role of the radiographer for justification and pregnancy workflows. Inspectors found that there was no documentary evidence that information relating to patient exposure formed part of the report of the medical procedure at Merlin Park Imaging Centre. This was also highlighted as an area for improvement by Alliance Medical Diagnostic Imaging Ltd. to ensure regulatory compliance.

## Regulation 8: Justification of medical exposures

Inspectors reviewed documentation and referral records and were satisfied that all individual medical exposures are justified in advance at Merlin Park Imaging Centre. Documentation reviewed clearly defined the justification process and responsibilities

of people involved. All referrals for radiological procedures reviewed were accompanied by rationale for imaging and sufficient medical data to satisfy regulatory requirements

Inspectors were informed that previous diagnostic information was accessible to local practitioners via digital pathways. The regulatory need to access this data was well documented in referrer and practitioner responsibilities as well as the justification pathway.

Inspectors reviewed patient information handouts available throughout the department. These handouts detailed the risks associated with CT scanning and communicated this in an easy to understand fashion. In the clinical area, staff demonstrated confidence in discussing risks with patients to inspectors.

Inspectors reviewed justification audits undertaken in September 2019 which demonstrated 93% of referrals satisfying total compliance with referral criteria.

The justification process was also clearly articulated by staff to inspectors during the course of inspection and in the clinical area. Although records of practitioner or radiographer justification in advance of procedure were present for all referrals reviewed by inspectors, local policy has not designated radiographers as practitioners to fulfil the justification function. Documentation should be updated to reflect local practice.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

Inspectors reviewed documentation evidencing the establishment of diagnostic reference levels (DRLs) at Merlin Park Imaging Centre. Inspectors saw that DRLs was a standing agenda point on the facility radiation safety committee. Merlin Park Imaging Centre DRLs were observed by inspectors in the clinical area with National DRLs and a local trigger value used as part of a dose alert system. Merlin Park Imaging Centre management and staff in the clinical area consistently demonstrated good knowledge of Merlin Park Imaging Centre DRLs and dose alerts to inspectors over the course of the inspection.

On review of the 2019 Merlin Park Imaging Centre DRLs, it was noted by inspectors that some DRLs exceeded the national values. No record of this was recorded in the radiation safety committee minutes from September 2019. On discussion with senior staff, inspectors were informed that the appropriate investigations were informal and took place predominantly over the phone and as a result no record existed. Inspectors highlighted the importance of creating and maintaining records relating to DRL review, investigation and corrective actions, and this was acknowledged by Merlin Park Imaging Centre senior staff.

Judgment: Substantially Compliant

### Regulation 13: Procedures

Written protocols for every type of standard medical radiological procedures were reviewed by inspectors. Staff in the clinical area demonstrated knowledge of protocols and were able to locate protocols when requested by inspectors. Inspectors were informed that standard protocols were also programmed into the CT scanner.

Inspectors saw evidence that referral guideline were available online for all referrers. Senior management informed inspectors of the online iRefer Business card available to referrers. Inspectors agreed that this was a positive initiative in making referral criteria readily available to referrers.

Inspectors saw evidence of a comprehensive audit report for financial year 2019 and a detailed clinical audit plan for 2020. Audit records demonstrated a comprehensive audit process surrounding the patient journey with specific emphasis on radiation safety issues. Clinical audit was a standing agenda point of the radiation safety committee minutes reviewed by inspectors and staff in the clinical area demonstrated to inspectors that they had direct access to radiation safety committee minutes via an online data management system. Evidence of regulatory compliance audits was seen by inspectors, these were used as a regulatory gap analysis tool by Merlin Park Imaging Centre which was seen as another positive initiative by inspectors.

Inspectors were informed by senior management and clinical staff that information relating to patient exposure did not routinely form part of the radiological report, which was evidenced by reports reviewed by inspectors.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Documentation relating to the quality assurance programme implemented by Merlin Park Imaging Centre was reviewed by inspectors. Documentation reviewed also included the need for acceptance testing by the medical physics expert before new equipment was used. Inspectors reviewed records of acceptance testing and annual medical physics expert quality assurance testing. Inspectors were satisfied that the Alliance Medical Diagnostic Imaging Ltd. kept its equipment at Merlin Park Imaging Centre under strict surveillance regarding radiation protection.

An up-to-date inventory of medical radiological equipment at Merlin Park Imaging

Centre was supplied to inspectors.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Documentation detailing the Alliance Medical Diagnostic Imaging Ltd. approach to special protection of patients during pregnancy was reviewed by inspectors. Radiation safety procedures reviewed by inspectors clearly outlined the responsibilities of each member of staff involved in the protection of patients during pregnancy.

Clinical staff consistently articulated a clear understanding of the approach to protection of patients during pregnancy to inspectors during the inspection. Individual patient records seen by inspectors during a document review and clinical area visit included the appropriate records consistent with local policy. Inspectors saw protection of patients during pregnancy compliance audits undertaken in 2019, reporting a 95% compliance rate. Inspectors observed multilingual public notices were prominently displayed in the waiting area and changing room of the facility. Patient information handouts reviewed by inspectors also gave CT specific information for patients on pregnancy.

Although not considered practitioners by Merlin Park Imaging Centre, the radiographer's role in the establishment and recording of pregnancy status was clearly evident. Documentation should be updated to reflect regulatory requirements and local practice at Merlin Park Imaging Centre.

Judgment: Substantially Compliant

### Regulation 17: Accidental and unintended exposures and significant events

Documentation reviewed by inspectors demonstrated a comprehensive approach by Merlin Park Imaging Centre to identify, record, analyse and mitigate accidental and unintended exposures and significant risks. Policies and procedures seen by inspectors clearly outlined the reporting pathways and responsibilities of all staff involved. Incident reports and risk assessment were standing agenda points on the radiation safety committee meetings reviewed by inspectors.

Staff in the clinical area demonstrated good knowledge of the incident reporting process via the electronic data management system. Inspectors were informed that this system automatically notified the unit manager, radiation protection officer and quality manager once a radiation incident was recorded. Documents reviewed detailed that the radiation protection officer had responsibility for reporting, review

and investigation of all radiation incidents and clearly defined the relevant people to be involved in the investigation, a role supported by the quality team.

Evidence of radiation incident report trending for the entire undertaking was seen by inspectors, as was a site specific radiation incident trend for 2019. Inspectors were informed that communicating learning outcomes was the responsibility of the quality manager while all radiation incidents were reviewed by the senior management team as part of the risk management committee.

Inspectors did note that a reportable radiation incident reported to HIQA in February of 2019 from Merlin Park Imaging Centre was not included in the radiation safety committee minutes from September 2019 although the incident was included in all incident trending and analysis documentation reviewed by inspectors.

Inspectors also noted after document review and staff communication that responsibility to lead a radiation incident report is not that of the medical physics expert as stated in the radiation safety procedures. Management acknowledged this and gave assurances documentation would be updated to reflect actual practise.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Substantially 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	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Merlin Park Imaging Centre OSV-0005999

Inspection ID: MON-0028256

Date of inspection: 08/01/2020

## 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	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>The role of the radiographer in the justification process will be updated and documented in the Radiation Safety Procedures, in line with the guidance published by the IIRRT on the 20th February 2020.</p> <p>Target date: 31st March 2020</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <ul style="list-style-type: none"><li>• DRLs are a standing agenda item and are discussed at every Radiation Safety Committee meeting.</li><li>• Where DRLs exceed the National DRL because of local protocols, as determined by the requirements of the consultant Radiologists, will be formally documented in the minutes of these meetings.</li><li>• The next Radiation Safety committee meeting is scheduled for March 2020.</li></ul>	

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <ul style="list-style-type: none"> <li>• Radiation doses are currently documented on the patient's images as well as on the RIS system.</li> <li>• Alliance Medical Diagnostic Imaging Ltd are working on an IT solution to record the dose for each examination in the patients report as per Regulation 13 of SI 256 2018. This solution will be in place by 31st December 2020.</li> </ul>	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <p>The role of the radiographer in the inquiry and documentation of pregnancy status has been documented in the Radiation Safety Procedures revision which was published on the 20th February 2020.</p>	

## Section 2:

### Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 8(11)	A practitioner carrying out a 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.	Substantially Compliant	Yellow	31/03/2020
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	Substantially Compliant	Yellow	12/03/2020

	relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
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	Yellow	28/02/2020
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	Yellow	31/03/2020
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	20/02/2020