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:	Rowe Creavin Medical Practice
Undertaking Name:	Rowe Creavin Medical Practice
Address of Ionising Radiation Installation:	Waterford Health Park, Slievekeale Road, Waterford, Waterford
Type of inspection:	Announced
Date of inspection:	06 December 2021
Medical Radiological Installation Service ID:	OSV-0007470
Fieldwork ID:	MON-0031219

About the medical radiological installation:

Rowe Creavin Medical Practice provide a dual-energy X-ray absorptiometry (DXA) scanning service in Waterford.

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 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 doing, we describe the overall effectiveness of an undertaking in ensuring the quality and safe conduct of medical exposures. It examines how the undertaking provides the technical systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential

[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.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

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
Monday 6 December 2021	10:05hrs to 13:55hrs	Maeve McGarry	Lead
Monday 6 December 2021	10:05hrs to 13:55hrs	Noelle Neville	Support

Summary of findings

An announced inspection of the medical exposures service at Rowe Creavin Medical Practice was carried out on the 06 December 2021. On the day of the inspection, inspectors spoke with staff and management involved in the provision of the dual-energy X-ray absorptiometry (DXA) imaging service and reviewed documentation and records. Following the inspection, an urgent compliance plan was issued to the undertaking outlining areas of risk arising from non-compliances with the regulations. The non-compliances identified in the urgent compliance plan required a timely intervention by the undertaking to ensure the safe delivery of DXA imaging procedures carried out at the practice.

The undertaking representative who was a general practitioner (GP) and partner at the practice had overall responsibility for the DXA service. The clinical evaluation of the outcome of DXA procedures was carried out by medical practitioners who worked at the practice. The undertaking had engaged the services of a medical physics expert (MPE) who had contributed to quality assurance (QA) and was available to advise the undertaking on matters relating to radiation protection.

However, a number of non-compliances were identified and inspectors were not assured that the undertaking had allocated responsibilities for radiation protection of service users as per regulations. While external referrals for certain DXA imaging procedures were received from referrers as per Regulation 4, this approach was not consistent and for certain procedures there was an absence of a referral form. In addition, inspectors found that justification of medical exposures was not carried out by a practitioner in advance of medical radiological procedures taking place. Furthermore, some aspects of clinical responsibility including justification of medical exposures were delegated to persons who were not practitioners as per Regulation 5.

Further non-compliances were identified in relation to aspects of Regulation 13, Procedures. Inspectors were informed that written protocols had not been established for all medical radiological procedures and inspectors were not satisfied that referral criteria taking into account radiation doses was available to referrers.

Inspectors found that diagnostic reference levels (DRLs) had been established for most, but not all DXA procedures carried out at the facility. While quality assurance of equipment was carried out on an annual basis and routine quality control checks were also carried out, inspectors determined that the strict surveillance of equipment could be improved by the undertaking. Annual quality assurance was due to be carried out but had not been completed at the time of inspection.

A clinical audit had been carried out in relation to compliance with the local pregnancy check procedures. Inspectors acknowledged that this was a positive initiative and could be further extended to other areas of patient radiation protection. Clinical audit is an important tool as it helps to monitor the performance

of services and to identify opportunities for improvement.

On the day of inspection, inspectors were not assured that the undertaking had allocated responsibilities for radiation protection of service users as per current legislation. As a result, the undertaking was requested to submit an urgent compliance plan under Regulations 4, 8 and 10 to address the urgent risks identified. The undertaking's response did provide assurance that the risks identified were being addressed.

Regulation 4: Referrers

On the day of inspection, inspectors reviewed samples of records of medical exposures to ionising radiation and spoke with staff about the processes in place. Inspectors found that for some bone mineral density DXA procedures, external referrals were received from medical practitioners entitled to refer for medical radiological imaging. However, from the information reviewed on the day of inspection, some medical radiological procedures were found to have been carried out in the absence of a referral from a person entitled to refer as per the regulations.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 5: Practitioners

From speaking with staff and reviewing medical records, inspectors found that medical practitioners registered with the appropriate professional body were responsible for aspects of clinical responsibility such as the clinical evaluation of the outcome of medical exposures. However, other aspects of clinical responsibility, namely, the justification of medical exposures were allocated to individuals who are not recognised within Regulation 5, including nursing and administrative staff.

Judgment: Not Compliant

Regulation 6: Undertaking

Following commencement of the regulations, Rowe Creavin Medical Practice had declared to HIQA as an undertaking. Inspectors were informed that the undertaking

representative who was a GP at the practice had overall responsibility for the DXA service and radiation protection of service users. The designated manager was the practice manager with administrative responsibility. The undertaking had engaged the services of an MPE and inspectors found the MPE to be appropriately involved relative the risk posed by the service.

Inspectors spoke with staff and management on the day of inspection and reviewed documentation provided to determine the allocation of responsibilities for radiation protection of service users. From the information provided, the undertaking had not clearly allocated responsibilities in line with current legislation. For example, justification in advance of DXA procedures was not allocated to a practitioner at the practice. In addition, there was an absence of a referral from a referrer as per Regulation 4 for certain procedures carried out. Furthermore, the allocation of practical aspects of medical exposures was not clearly outlined in documentation as per regulations. Management acknowledged that the allocation of responsibilities for referring patients for DXA procedures, the justification of individual medical exposures and the allocation of practitioner responsibilities required immediate action. In addition, all supporting documentation needs to fully demonstrate the allocation of responsibilities for the radiation protection of service users in line with current legislation.

This absence of a clear allocation of responsibility for the radiation protection for service users was found by inspectors to contribute to other instances of non-compliance on the day of inspection.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of medical records and spoke with staff about the referral and justification process at the facility. Inspectors reviewed records of referrals from external medical practitioners for bone mineral density DXA procedures and found they were in writing and stated the reason for the request. For internal referrals, inspectors were informed that the referral was informal via documentation in notes by the GP. However, inspectors found that there was an absence of a referral for some DXA imaging procedures performed at the practice which were carried out on the basis of self-directed referrals, without the involvement of a referrer. In order to comply with the regulations the undertaking should ensure that all medical radiological procedures are carried out as a result of a referral from a referrer as per Regulations 4 and 8(10).

Furthermore, from the records and documentation reviewed and from speaking with staff, inspectors found that justification in advance of a procedure was not carried out by a practitioner at the practice. Justification is an important safeguard for patients as it ensures that the decision to carry out a medical exposure is based on the patient's individual characteristics with consideration to the risks and benefits of

the procedure and alternative options available. While the dose associated with DXA imaging is generally relatively low, the principle of individual justification applies and is a requirement of the regulations for all medical radiological procedures.

Inspectors communicated their concern over the lack of justification of individual DXA exposures and the absence of referrals for certain procedures to the undertaking representative on the day of inspection. Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 10: Responsibilities

Inspectors were informed that a medical practitioner had overall clinical responsibility for medical exposures at the facility. However, not all aspects of clinical responsibility were carried out by a practitioner. As described in Regulation 5, a practitioner did not justify DXA imaging referrals in advance of the exposure taking place. Inspectors were informed by management that certain procedures were performed on the basis of self-directed referrals and hence justification of these procedures did not involve a practitioner or referrer. In order to come into compliance with Regulation 10(1) and 10(3), the undertaking should ensure that all aspects of clinical responsibility are held by practitioners as recognised within the regulations and that a referrer is involved.

Inspectors were informed that the practical aspects of DXA imaging procedures were carried out by nurses at Rowe Creavin Medical Practice. However, in documentation reviewed by inspectors the delegation of practical aspects to nurses was not outlined and nurses were recognised as practitioners. Management acknowledged on the day of inspection that documentation and the local allocation of clinical responsibilities needed to be updated to ensure compliance with Regulation 10.

Noting the absence of current prescribed radiation safety training requirements as required by Regulation 22(3), inspectors reviewed the training records of the individuals carrying out the practical aspects and found that some training in radiation safety was included in the training completed.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking’s response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Local diagnostic reference levels were recently established for the bone mineral density DXA imaging performed at Rowe Creavin Medical Practice. These local DRLs were available for review on the day of inspection. However, a local DRL had not been established for some DXA procedures which were also carried out at this facility. Inspectors identified that the use of DRLs in practice could be improved and the undertaking should ensure that all staff involved in the practical aspects of procedures are familiar with DRLs and their application in clinical use.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors reviewed results of a clinical audit which had been conducted to assess compliance with pregnancy checks carried out prior to DXA imaging. The audit of 15 samples found 100% compliance with the local procedure. Inspectors acknowledged that the use of clinical audit is a positive initiative by the undertaking and that this could be extended to provide further assurance around the safe delivery of medical exposures to service users.

Inspectors were informed by staff and management that written protocols had not been established for all DXA procedures carried out at the practice. Written protocols must be established by the undertaking as per regulations and can provide assurance that DXA imaging procedures are carried out in a safe and consistent manner.

Inspectors were provided with a list of inclusion criteria for DXA imaging which was used by the administration staff who booked patients and nurses who performed DXA procedures. Although while other lists of inclusion criteria were available in the local *Radiation Safety Procedures* and *Dexa Scanning Guidelines,* improvements could be made to include inclusion criteria for all DXA procedures performed at the practice. The undertaking should ensure that referral guidelines which take into account the radiation doses are available to referrers for all procedures performed at the practice in line with Regulation 13(3).

Inspectors reviewed records and spoke with staff and found that information relating to patient exposure did not form part of the report of DXA scans conducted at the practice.

Judgment: Not Compliant

Regulation 14: Equipment

On the day of inspection, records and documentation provided to inspectors relating to the DXA equipment were reviewed. Records of quality control (QC) performance testing reviewed indicated that this testing had been carried routinely at the facility. Annual quality assurance was due to be carried out at the time of inspection and inspectors were informed that the next QA would take place in January 2022. Inspectors found that the quality assurance programme could be better defined to ensure that the equipment is kept under strict surveillance. The programme should clearly outline the frequency of QA and performance testing and the persons responsible. Furthermore, the undertaking should ensure that annual QA is carried out in a timely manner outlined in the QA programme.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that the undertaking had engaged a medical physics expert recognised within the Regulations to support the service. On the day of the inspection, inspectors spoke with the MPE and staff and were satisfied with the continuity service by the MPE.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Documentation reviewed by inspectors and discussions with staff indicated that the role of the MPE focused on quality assurance of medical radiological equipment and establishing DRLs. The MPE had assisted in the development of local *Radiation Safety Procedures* and inspectors were informed the MPE was available for advice on the optimisation of protocols. While inspectors were satisfied that QA was performed by the MPE on an annual basis, the undertaking should ensure that the MPE contributes to the definition of the quality assurance programme for example, outlining the frequency of testing and by whom.

Judgment: Compliant

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

Inspectors were satisfied with the level of MPE involvement relative to the possible risks posed by 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
Summary of findings	
Regulation 4: Referrers	Not Compliant
Regulation 5: Practitioners	Not Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially 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

Compliance Plan for Rowe Creavin Medical Practice OSV-0007470

Inspection ID: MON-0031219

Date of inspection: 06/12/2021

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 4: Referrers	Not Compliant
Outline how you are going to come into compliance with Regulation 4: Referrers: • A DXA/BMI scan cannot take place without a written referral (including internal referrals) from a doctor or consultant with an IMC (Irish medical council) number or GMC (general medical council) and the doctor/consultants' details must be clear in the referral letter. • A Nurse / Doctor will not carry out a DXA/BMI scan without the correct referral and clinical justification in situ from an eligible referrer.	
Regulation 5: Practitioners	Not Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: • We now updated our procedures with more clearly defined roles • A Practitioner is a member of the clinical team that has an IMC number • Only a Practitioner can refer a patient for a scan • A Nurse can only carry out a scan under the guidance (referral & justification) by a Practitioner • A scan cannot take place without prior referral and justification from an eligible Practitioner	
Regulation 6: Undertaking	Not Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:
• New documentation has been written and implemented clearly defining roles and responsibilities
• A Practitioner is a member of the clinical team that had an IMC number
• Only a Practitioner can refer a patient for a scan
• A Nurse can only carry out a scan under the guidance (referral & justification) by a Practitioner
• A member of the admin team can only book an appointment once they have received instruction from a practitioner who has justified the referral.
• Also, all documentation clearly demonstrates the allocation of responsibilities for radiation protection of service users under current legislation.

Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
We have already implemented the following as of 8th December following on from your visit.

• A DXA/BMI scan cannot take place without a written referral (including internal referrals) from a doctor or consultant with an IMC number or GMC and the doctor/consultants' details must be clear in the referral letter.
• The referral letter must contain the clinical indication to allow a doctor here to carry out a justification assessment.
• All referrals must be justified by a medical doctor here prior to scan and record of this noted on the patients' medical records.
• The Nurse or Practitioner preforming the scan will not do so unless proof of referral and justification is available to see on each patients' records.
• We have now also created a new justification template form that is attached to each new referral which ensures all the steps above have been followed.

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
• A DXA/BMI scan cannot take place without a written referral (including internal referrals) from a doctor or consultant with an IMC number or GMC and the doctor/consultants' details must be clear in the referral letter. This referral must also be justified by a practitioner (internally) and proof of this justification must be seen on the

patients' medical records.
• The Practitioner has overall clinical responsibility to ensure this is adhered to at all times.
• New documentation has been written and implemented clearly defining roles and responsibilities.
• A Nurse is not a practitioner and can only carry out a scan under the guidance (referral & justification) by an eligible Practitioner.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
• DRL's are now in place for all scans in the practice.
• All staff are now aware of the importance of Diagnostic Reference Levels
• This information has been updated in all our policies.
• Patient information sheets that will now be given to every patient will show the DRL for each scan type.
• The results that go back to the referring doctor now contain the DRL for the scan type the patient received.
• DRL for each scan type has also been added to our inclusion criteria for the attention of the referring Practitioner.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
• Written protocols are now in place for all procedures carried out at the practice.
• Inclusion criteria for all DEXA procedures is now available.
• Referral guidelines are now available to all referrers, and these include the DRL for each scan type.
• Patient information sheets that will now be given to every patient will show the DRL for each scan type.
• The results that go back to the referring doctor now contain the DRL received by the patient during their scan.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
• We have updated our QA programme to ensure the equipment is kept under strict surveillance.
• The Annual QA has already been completed for 2022.
• Our policy has been updated; responsibility for booking the Annual QA has been allocated to the Manager in charge in our updated policy. This must be booked before the 7th of December each calendar year with QA taking place in January of each calendar year.
• Our policy has been further updated; we have included step by step guidance for performing daily QA checks on the scanner. This will be only undertaken by a competent Nurse or Practitioner within the practice as defined within our updated roles and responsibilities.

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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Red	17/12/2021
Regulation 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a practitioner unless	Not Compliant	Red	17/12/2021

	the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),			
Regulation 4(1)(c)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),	Not Compliant	Red	17/12/2021
Regulation 4(1)(d)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or	Not Compliant	Red	17/12/2021
Regulation 4(1)(e)	A person shall not refer an individual for medical	Not Compliant	Red	17/12/2021

	radiological procedures to a practitioner unless the person referring ("the referrer") is a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner.			
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	17/12/2021
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Not Compliant	Red	14/01/2022
Regulation 5(b)	A person shall not take clinical responsibility for an individual	Not Compliant	Red	14/01/2022

	medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or			
Regulation 5(c)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).	Not Compliant	Red	14/01/2022
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	Not Compliant	Red	14/01/2022

	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.			
Regulation 8(1)(a)	A person shall not carry out a medical exposure unless it shows a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and	Not Compliant	Red	14/01/2022
Regulation 8(1)(b)	A person shall not carry out a medical exposure unless it takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.	Not Compliant	Red	14/01/2022
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified	Not Compliant	Red	17/12/2021

	in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Red	17/12/2021
Regulation 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	Not Compliant	Red	17/12/2021
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Red	17/12/2021
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall,	Not Compliant	Red	17/12/2021

	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(12)	The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposure.	Not Compliant	Orange	17/12/2021
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Not Compliant	Orange	17/01/2022
Regulation 8(13)(b)	Wherever practicable and prior to a medical exposure taking place, the referrer	Not Compliant	Orange	17/01/2022

	or the practitioner shall ensure that in the case of a patient who is under sixteen years of age, a parent or legal guardian of the patient is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.			
Regulation 8(13)(c)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Not Compliant	Orange	17/01/2022
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five	Not Compliant	Orange	17/01/2022

	years from the date of the medical exposure, and shall provide such records to the Authority on request.			
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Red	14/01/2022
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Red	17/12/2021
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Red	17/12/2021
Regulation 10(5)	An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.	Not Compliant	Orange	24/01/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and	Substantially Compliant	Yellow	13/01/2022

	where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	13/01/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	13/01/2022
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	13/01/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under	Substantially Compliant	Yellow	07/12/2021

	strict surveillance regarding radiation protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	13/01/2022
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Substantially Compliant	Yellow	13/01/2022