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:	Dexascan & Bone Health Unit
Undertaking Name:	Dexascan & Bone Health Unit
Address of Ionising Radiation Installation:	Unit III, Lugh Medical Centre, College Height's, Dundalk, Louth
Type of inspection:	Announced
Date of inspection:	26 May 2021
Medical Radiological Installation Service ID:	OSV-0006883
Fieldwork ID:	MON-0031866

About the medical radiological installation:

Dexascan & Bone Health Unit provide a dual-energy X-ray absorptiometry (DXA) scanning service in Dundalk, Co. Louth.

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
Wednesday 26 May 2021	10:00hrs to 11:30hrs	Kirsten O'Brien	Lead
Wednesday 26 May 2021	10:00hrs to 11:30hrs	Lee O'Hora	Support

Summary of findings

An announced inspection of Dexascan & Bone Health Unit was carried out on the 26 May 2021. During the inspection, inspectors reviewed documentation and records and spoke with individuals involved in the provision of the dual-energy X-ray absorptiometry (DXA) imaging service. 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 at the unit.

On the day of inspection, a person entitled to take clinical responsibility for individual medical exposures was the practitioner with clinical responsibility for all DXA imaging procedures carried out at Dexascan & Bone Health Unit. Similarly, the undertaking had delegated the practical aspects of DXA imaging procedures conducted at the unit to an appropriately registered individual.

However, inspectors were not assured that the undertaking had clearly allocated responsibility to a medical physics expert (MPE) to act and give specialist advice for the radiation protection of service users at the unit. Additionally, all elements of clinical responsibility for DXA imaging procedures were not clearly allocated to a practitioner. A number of non-compliances identified by inspectors during the inspection were found to have arisen as a result of the undertaking not assigning responsibility to specific individuals as required by the regulations. The undertaking should put measures in place to ensure the appropriate involvement of the MPE and practitioner in the radiation protection of service users attending Dexascan & Bone Health Unit.

Inspectors were informed that the majority of referrals to the unit were from general practitioners (GPs) and nurses entitled to refer for medical radiological imaging. However, from the information provided, inspectors were not assured that the undertaking had appropriate measures in place to ensure that DXA imaging procedures were only conducted when referred by persons entitled to act as referrers in the regulations.

While all referrals reviewed by inspectors for DXA imaging procedures to Dexascan & Bone Health Unit were in writing and included medical data to enable the practitioner to carry out a justification assessment, inspectors found that justification by a practitioner was not conducted prior to any DXA imaging procedures being carried out at the unit. This was identified as an area of non-compliance and communicated to the undertaking representative on the day of inspection and as part of the urgent compliance plan issued to the undertaking.

While quality control performance testing had been carried out by the person operating the DXA equipment on the days that the equipment was in use, the undertaking had not ensured that the DXA equipment had been kept under strict

surveillance regarding radiation protection and a QA programme was not implemented and maintained at the unit. Additionally the undertaking had not established DRLs at the unit and had not implemented a programme to assess the radiation dose associated with DXA imaging procedures conducted at the Dexascan & Bone Health Unit. Similarly inspectors found that information related to the patient exposure was not included on the report of the DXA imaging procedures conducted at the unit.

Inspectors spoke with staff and other individuals related to the provision of medical physics expertise at the unit and found that the undertaking did not have arrangements in place to ensure that a registered MPE acted and gave specialist advice in relation to radiation protection. While an MPE had been previously involved, information provided to inspectors, including records of previous quality assurance (QA) testing, indicated that an MPE was not appropriately involved for consultation and advice at the time of inspection. Similarly, inspectors found that Dexascan & Bone Health Unit had not ensured that an MPE took responsibility for dosimetry, in particular the evaluation of dose delivered to service users.

The undertaking was requested to submit an urgent compliance plan under Regulation 8, Regulation 14 and Regulation 20 to address urgent risks identified.The undertaking's response did provide assurance that the risks identified were being addressed. Additionally, a representative of the undertaking provided an assurance to inspectors that the DXA equipment would not be used to conduct medical radiological procedures until such time as a QA review has been conducted by a registered MPE and the equipment deemed fit for clinical use.

Regulation 4: Referrers

Inspectors reviewed a sample of referrals and spoke with staff and found that the majority of referrals for DXA imaging procedures carried out at Dexascan & Bone Health Unit were from medical practitioners and nurses entitled to refer for medical radiological imaging.

However from speaking with staff, including a practitioner, inspectors were informed that referrals were accepted from persons not entitled to refer an individuals for a medical exposure to ionising radiation. As a result of the information provided, inspectors were not assured that the undertaking had adequate measures in place to ensure that all referrals carried out at the unit were from individuals entitled to act as a referrer.

Judgment: Not Compliant

Regulation 5: Practitioners

Inspectors were informed that an individual, registered with the appropriate professional regulator, was the individual responsible for taking clinical responsibility for all individual DXA imaging procedures carried out at Dexascan & Bone Health Unit.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation and records and spoke with a representative of the undertaking regarding the management and oversight structures in place at Dexascan & Bone Health Unit, in particular the allocation of responsibility for aspects of radiation protection of service users attending the unit. Following commencement of the regulations, Dexascan & Bone Health Unit had notified HIQA of its practice as an undertaking as required.

Inspectors were informed that the undertaking representative was the clinical director of the unit and the designated manager was the person responsible for administrative aspects at the unit. The undertaking had delegated the practical aspects of DXA imaging procedures to an appropriately registered individual.

Documentation outlining the overarching and accountability structures in place at the unit was provided to inspectors in advance of the inspection. Additionally, inspectors spoke with staff, including the practitioner, on the day of inspection to determine the allocation of responsibilities for the protection of service users from medical exposure to ionising radiation. From the information provided, inspectors found that the undertaking had not clearly allocated responsibility for all aspects of radiation protection of service users attending the unit. For example, justification of DXA procedures conducted at the unit was not clearly allocated to a practitioner and as a result medical exposures to ionising radiation were not justified in advance as required by Regulation 8.

Additionally, on the day of inspection the undertaking did not have arrangements in place to ensure that an MPE was appropriately involved in the radiation protection of service users as required by the regulations. Documentation reviewed by inspectors indicated that the while an MPE had previously provided medical physics expertise at Dexascan & Bone Health Unit, the undertaking had not ensured that a registered MPE was currently involved, as appropriate, for consultation or advice on matters relating to the radiation protection of service users as required by Regulations 19, 20 and 21.

This absence of a clear allocation of responsibility to appropriate persons for the radiation protection for service users is a non-compliance with the regulations which was found by inspectors to contribute to other non-compliances on the day of inspection.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

Inspectors reviewed records, documentation and spoke with staff at the unit. All referrals reviewed were in writing, and stated the reason for requesting a DXA scan. However, from the records and documentation reviewed and speaking with staff, inspectors found that justification in advance of a procedure was not carried out by a practitioner at the unit.

Justification of a medical exposure to ionising radiation is the decision whether or not to carry out the medical exposure on the basis of benefit to the patient. Justification is an important safeguard for patients and should always take into account the individual characteristics of the patient to ensure that the procedure is the most appropriate option for them. Notwithstanding the low dose associated for the most part with DXA imaging procedures, it is nevertheless important that the principle of individual justification is adhered to for all medical exposure to ionising radiation, regardless of the radiation dose.

Inspectors communicated their concern over the lack of justification of individual DXA referrals 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

On the day of inspection, the practical aspects of carrying out the DXA imaging were delegated to an individual who was registered with the Nursing and Midwifery Board of Ireland. Noting the absence of current prescribed radiation safety training requirements as required by Regulation 22(3), inspectors reviewed the training records of the individual delegated the practical aspects and found that training in radiation safety had been completed.

Inspectors found that while a registered medical practitioner was the practitioner with overall clinical responsibility for medical exposures conducted at the unit, the practitioner did not take responsibility for all aspects of clinical responsibility for individual DXA imaging procedures. For example, the practitioner did not justify DXA imaging referrals in advance of the exposure taking place, as required by the regulations. All medical exposures to ionising radiation require a practitioner to justify each individual medical radiological procedure in advance of the exposure being carried out to determine that the medical exposure provides a sufficient net

benefit to the patient.

Additionally, on the day of inspection, the undertaking had not ensured that an MPE was involved in the optimisation process for all DXA imaging procedures conducted at the unit. Inspectors reviewed records and other documentation and were not assured that an MPE had contributed to the optimisation of the radiation protection of patients and other individuals subject to medical exposure at Dexascan & Bone Health Unit.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Local diagnostic reference levels at Dexascan & Bone Health Unit, requested in advance of, and again on the day of inspection, was not available for review. Consequently, inspectors found that Dexascan & Bone Health Unit had not established diagnostic reference levels for DXA imaging procedures carried out at the unit.

Judgment: Not Compliant

Regulation 13: Procedures

Inspectors were informed that written protocols for DXA procedures carried out at Dexascan & Bone Health Unit had not been established. Written protocols must be established by the undertaking and can provide assurance that DXA imaging procedures are carried out in a consistent and safe manner.

On the day of inspection, inspectors reviewed records and documentation and spoke with staff, including the practitioner, and found that information relating to patient exposure did not form part of the report of DXA scans conducted at the Unit.

Additionally,information about clinical audits conducted at the Unit requested as part of the pre-inspection documentation request was not provided to inspectors. Inspectors were also informed during the inspection that no clinical audits had been conducted at the unit. Clinical audit is an important tool which allows undertakings to identify areas of good practice and areas for improvement in order to ensure safe delivery of medical exposures to service users.

Judgment: Not Compliant

Regulation 14: Equipment

On the day of inspection, records and documentation provided to inspectors relating to the DXA equipment were reviewed. Inspectors also spoke with staff involved in the provision of the DXA service at the unit. Records of quality control performance testing reviewed indicated that this testing had been carried routinely at the unit on the days that the equipment was in use.

However, despite the conduct of routine quality control testing, inspectors were not satisfied that Dexascan & Bone Health Unit had ensured that the DXA equipment was kept under strict surveillance regarding radiation protection. Inspectors requested all documentation and records relating to the equipment's QA programme and found that QA had not been performed since before the commencement of these regulations. Additionally, inspectors found that the equipment had not undergone routine preventative maintenance servicing by the manufacturer since it was first commissioned for clinical use.

The failure of the undertaking to ensure that an appropriate QA programme was implemented and maintained was identified as an area requiring urgent action on the part of the undertaking. Inspectors brought this non-compliance to the attention of the undertaking representative on the day of inspection. The undertaking provided a written assurance to inspectors that the equipment would not be used until such time as an appropriate QA programme deemed the equipment fit for clinical use.

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 19: Recognition of medical physics experts

On the day of inspection, inspectors spoke with staff and other individuals related to the provision of medical physics expertise at the unit. Inspectors also reviewed documentation and records relating to the provision of medical physics expertise at Dexascan & Bone Health Unit and found that the undertaking did not have arrangements in place to ensure the continuity of this expertise.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and other records relating to the involvement of an MPE at Dexascan & Bone Health Unit. Inspectors also spoke with staff and other individuals related to the provision of medical physics expertise at the unit.

On the day of inspection, inspectors found that the undertaking had not ensured that an MPE was sufficiently engaged by the service to act or give specialist advise on matters relating to radiation physics as required by the regulations. For example, Dexascan & Bone Health Unit had not ensured that an MPE had taken responsibility for the evaluation of radiation dose delivered to service users or had contributed to the application and use of DRLs at the unit. Inspectors also found that the undertaking had not ensured that an MPE contributed to the performance of QA of the DXA equipment since the commencement of these regulations in 2019.

The undertaking's failure to ensure that an MPE was appropriately involved in the provision of the DXA service to service users was noted by inspectors as a non-compliance that required an timely response by the undertaking to mitigate against any risks and ensure the safe delivery of DXA imaging procedures.

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 21: Involvement of medical physics experts in medical radiological practices

Based on the evidence reviewed in respect of Regulation 19 and 20, inspectors were not assured that the undertaking had sufficiently involved an MPE for consultation and advice on matters relating to radiation protection concerning medical exposure as required by the regulations.

Judgment: Not 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	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

Compliance Plan for Dexascan & Bone Health Unit OSV-0006883

Inspection ID: MON-0031866

Date of inspection: 26/05/2021

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: The undertaking has reviewed the referral system with a particular view to remove the self-referral clause from the referral form. New referral forms are being prepared where this issue will be addressed and all staff be made aware of this change. The new referral form does not contain the self - referral clause as of 14th July 2021 and this new form has been posted out to all referral sources in the catchment area including all general practitioners	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: A new protocol by the undertaking would ensure the protection of service users by a further layer of scrutinization by the medical director (who is also the designated radiation protection officer) of referrals to make sure that the dexascan is necessary. The MPE (Radiation protection adviser) has so far been consulted for any technical issues will now have contractual obligation to ensure that both service users and the staff are protected in addition to the purely medical physicist expert duties. A new protocol is in place now for the medical director to scrutinise all referral forms establishing whether a person needs a dexascan or not and if so then are the benefits sufficient to justify the risks.	

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 referrals will be further scrutinised by the medical director to ascertain the need for the dexa scan radiation exposure and weight the risk- benefit ratio. It is a policy of the undertaking as well not to repeat the scans before a 2 years' time lapse to compare the BMD changes with the therapeutic interventions so that unnecessary dexa scans are not done. This measure will be a sufficient protection to the service users. This protocol is already implemented and all concerned staff of the facility notified as of 14th July 2021. There is a new referral form which needs to be filled out by the referrers and reviewed by the clinical director regarding the need for a dexascan.

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
The medical director is now involved in the scrutinising process of all referrals and the need for justification of getting the dexa scan done as of 14th July 2021. All the staff of the service provider have been informed accordingly and their duties to inform the unit manager and the medical director if the referral letter has not been scrutinised and signed by the medical director. The MPE has been informed to get involved with the process of optimising the radiation protection procedure of all service users' staff at the undertaking site. The MPE is now bound with a contractual obligation with the service providers since 29th June 2021.

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Diagnostic Reference Level:
Local DRLs for Dexa are set out on the displayed entrance surface dose and set scan area. National DRLs were published by HIQA in July 2021.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
According to the manufacturer the equipment gives a read out of 4.5micro sieverts to 6 micro Sieverts. However, the undertaking will consult with the MPE for getting an idea of the patient effective exposure dose. An audit was conducted to calculate the FRAX from the existing data pertaining to cohort user group a few years ago before the GDPR came in. With GDPR it will be difficult to do clinical audits however service and procedure audits can be done.

Regulation 14: Equipment	Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
These machines prompt problems when water bath QA is done before scans are performed. It is the recommended policy of the service providers to do so and the machine will not scan unless this is done first. As recommended by HIQA a search for any needed part replacement and testing was carried out on site by an engineer from the equipment supplier along with a software testing in June 2021. All were found to be satisfactory and in working order. The MPE has been engaged for an independent QA which was done on site on 29th June 2021 and was found to be satisfactory as the machine was not prompting any failure in its operating capabilities. The GE engineers report has been forwarded to HIQA team along with that of the independent QA report by the MPE. Meanwhile the undertaking is not doing any dexa scans on a voluntary basis.

Regulation 19: Recognition of medical physics experts	Not Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:
The MPE has now been contractually engaged for continuity of the service including the monitoring of the dosimeter and engaging with all the staff of the service provider. This is now operational since 29th June 2021.

Regulation 20: Responsibilities of medical physics experts	Not Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: The MPE has now been engaged to monitor user specific doses, monitor the dosimeter, contribute to the DRLs and suggest specific radiation protection measures to the undertaking.	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: The MPE has been now engaged to provide consultation on the radiation exposure practices on a continuity basis rather than on demand as of 29th June 2021. Consultation will now focus on patient and staff safety towards ionising radiation. Updating technical information on dexa scan procedures. An incident reporting mechanism is in place to contact the service unit manager who will then report to the medical director/MPE and HIQA if need be. Interaction with the MPE for radiological support for any untoward incidents. Engagement with technical staff of the undertaking. Forwarding and discussing any HIQA directives or recommendations so as to maintain compliancy with the regulators	

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(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	05/08/2021
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Red	05/08/2021

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	Red	05/08/2021
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.	Not Compliant	Red	05/08/2021
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Red	05/08/2021
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Red	05/08/2021
Regulation 10(3)(a)	An undertaking shall ensure that	Not Compliant	Red	05/08/2021

	the justification process of individual medical exposures involves the practitioner, and			
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and 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.	Not Compliant	Orange	05/08/2021
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	05/08/2021
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	05/08/2021
Regulation 14(1)	An undertaking shall ensure that all medical	Not Compliant	Red	05/08/2021

	radiological equipment in use by it is kept under strict surveillance regarding radiation protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	05/08/2021
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Red	05/08/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Not Compliant	Orange	05/08/2021
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements	Not Compliant	Red	05/08/2021

	of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Red	05/08/2021
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Red	05/08/2021
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:	Not Compliant	Red	05/08/2021

	(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and			

	other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Red	05/08/2021