

# Health Information and Quality Authority

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

Name of Medical	Pro-Dental
Radiological	
Installation:	
Undertaking Name:	Pro-Riso Dental Clinic Limited
Address of Ionising	340A North Circular Road,
Radiation Installation:	Phibsborough,
	Dublin 7
Type of inspection:	Announced
Date of inspection:	08 March 2023
Medical Radiological	OSV-0008467
Installation Service ID:	
Fieldwork ID:	MON-0038985

# About the medical radiological installation:

Pro Dental is a dental clinic dedicated to provide state-of-the-art technology and topquality care to our patients. One of the key technologies that we offer at Pro Dental is the Cone Beam Computed Tomography (CBCT) device. At Pro Dental we offer a wide range of dental services, including preventive care, restorative dentistry, cosmetic dentistry, and more, all using the latest technologies and techniques.

# How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff 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 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

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

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

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

<sup>&</sup>lt;sup>4</sup> Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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 8 March 2023	11:30hrs to 16:00hrs	Lee O'Hora	Lead
Wednesday 8 March 2023	11:30hrs to 16:00hrs	Margaret Keaveney	Support

## **Summary of findings**

An inspection of Pro-Dental was conducted by inspectors on 08 March 2023 following receipt of information that medical exposures to ionising radiation were being conducted in this practice without notifying HIQA as required by Regulation 6(2). During the inspection inspectors observed that governance structures in Pro-Dental were not well defined or documented, and that this lack of allocation of responsibility resulted in a significant number of non-compliances. It is important that an undertaking has the appropriate arrangements in place to ensure that those carrying out medical radiological procedures comply with the regulations. This ensures that service users receive safe and effective care, in relation to medical exposures to ionising radiation.

Justification records were not available on the day of inspection, specifically records of the reasons for individual medical exposures and associated medical data. Good justification practice aims to ensure that only appropriate medical exposures take place. The undertaking must ensure that the justification process is clearly documented, that the responsibilities of those involved for each step of the process are clear and that there is evidence of justification before the medical exposure is carried out.

After speaking with staff, and reviewing imaging records, the inspectors were not satisfied that the undertaking had systems in place to demonstrate that all medical exposures took place under the clinical responsibility of a practitioner. Records of individual medical exposures were not sufficient to identify the practitioner responsible for each step of clinical responsibility along the patient pathway. The undertaking should have systems in place to ensure that the responsibilities for medical exposures are allocated to appropriate persons and that each step along the service user pathway takes place under the clinical responsibility of a practitioner.

Undertakings are obliged to establish local diagnostic reference levels (DRLs) and regularly review and apply these in daily practice. Although DRLs had been established for some of the equipment, the inspectors noted that the undertaking had not sufficiently satisfied the regulatory requirements for all of the equipment in relation to the establishment, review and use of DRLs. The optimisation of patient protection through the implementation of DRLs ensure that patient doses are as low as reasonably achievable for the clinical purpose of the examination.

Although records of acceptance testing for all equipment were available, inspectors were not assured that the radiological equipment in use by Pro-Dental was kept under strict surveillance or that an appropriate quality assurance (QA) programme had been maintained by the undertaking. The QA programme is a continual process that involves collecting data to determine if medical radiological equipment is meeting criteria of acceptability and is essential to monitor and evaluate the safe delivery of medical exposures and their outcomes for service users.

Inspectors were informed that the services of a medical physics expert (MPE) had lapsed at the practice. As a result the inspectors were not assured that the undertaking had the appropriate systems in place to ensure the continuity, advice and contribution of an MPE at a level commensurate with the risk associated with the practice. The involvement of an MPE in medical exposures to ionising radiation must be addressed by the undertaking to provide assurance to service users about the quality of services provided and ensure compliance with the regulations.

While a number of non-compliances were highlighted on this inspection, no significant risk to the service user was identified. However, substantial action is required by the undertaking to ensure that regulatory requirements are met as highlighted throughout this report.

## Regulation 4: Referrers

Following a review of professional registration information and by speaking with staff, the inspectors were satisfied that Pro-Dental only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

#### Regulation 5: Practitioners

After speaking with staff and reviewing professional registration information, the inspectors were satisfied that at the time of inspection only appropriately qualified individuals operated as practitioners at Pro-Dental.

Judgment: Compliant

#### Regulation 6: Undertaking

During the inspection, inspectors established that the undertaking had been providing medical exposures to ionising radiation and had not declared to HIQA. Therefore, the undertaking had failed to meet the regulatory requirement to notify HIQA that it is carrying out medical radiological procedures. Inspectors requested that the appropriate documentation be completed and submitted immediately. This information was received and processed following the inspection.

After speaking with the staff and management at Pro-Dental, inspectors were not assured that the undertaking had provided a clear allocation of responsibilities for the protection of service users. For example, the MPE had not been engaged by the

undertaking since equipment acceptance testing in October of 2020. Also documented evidence of practitioner involvement in different aspects of clinical responsibility was not available. Similarly records relating to the allocation of responsibility for justification was not available. These non-compliances are discussed further under Regulations 8, 10, 11, 14, 19, 20 and 21 below.

In order to come into compliance with Regulation 6, the undertaking must clearly allocate responsibilities for the protection of service users. This allocation should be documented and all staff working within the service should be aware of their individual and collective responsibilities.

Judgment: Not Compliant

## Regulation 8: Justification of medical exposures

After reviewing imaging records and speaking with staff, inspectors were not assured that the undertaking had the appropriate justification practices in place to ensure that all individual medical exposures were justified in advance and that justification by a practitioner was recorded. Imaging referrals reviewed had no information in relation to the reason for the particular procedure or any medical data which could enable a justification assessment.

In instances where the referring dentist and dentist carrying out the radiological exposure were not the same practitioner, there was no evidence that the practitioner carrying out the procedure satisfied himself or herself that the procedure was justified. Inspectors were informed that records in relation to reasons for imaging, associated medical data and identification of the practitioner responsible for justification were not routinely captured.

To ensure compliance, the undertaking must ensure that all referrals to a practitioner, for a medical radiological procedure, are in writing with a reason for requesting the particular procedure and are accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment. The undertaking must also ensure that there is documented evidence that the justification process, involving a practitioner, has taken place.

Judgment: Not Compliant

## Regulation 10: Responsibilities

The inspectors were not satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner. For example, no record of justification by a practitioner or evaluation of the outcome by a

practitioner was available for individual medical exposure records reviewed by the inspectors. Inspectors were informed that records in relation to the practitioner responsible for justification or clinical evaluation of the outcome were not routinely captured. It is imperative that for each medical exposure that a service user undergoes, the practitioner taking clinical responsibility for each aspect of that exposure is clearly identifiable.

After speaking with management the inspectors were not assured that the optimisation process for all medical exposures involved the MPE as discussed further under regulations 6, 11, 14 and 20. Similarly, after speaking with staff and management the inspectors were not satisfied that the justification process of individual medical exposures always involved the referrer. No evidence was available in imaging records reviewed that the justification process had taken place, this too is discussed further under Regulation 8.

Also inspectors were informed that certain practical aspects of medical radiological procedures were delegated to persons other than dentists at the practice. Inspectors were informed that these practical aspects were limited to patient positioning before exposure which is considered a supporting aspect of the physical conduct of a medical exposure and therefore a practical aspect. Although persons other than a practitioner, as identified in the regulations, can be delegated the practical aspects by the undertaking or a practitioner, these persons must be registered with the associated professional body, in this case the dental council, and a record of the delegation must be retained. However, no evidence of professional registration or record of delegation for the persons involved in patient positioning was available at the time of inspection. If delegating practical aspects the undertaking should ensure the requirements of the regulations are met.

Judgment: Not Compliant

# Regulation 11: Diagnostic reference levels

Although DRLs had been established for cone beam computed tomography (CBCT) equipment in October 2020, no subsequent records of review or use were available. No records for the establishment, regular review or use of DRLs for the intra-oral dental equipment were available to inspectors.

Inspectors noted that DRLs established for the OPG adult dental radiological procedure were higher than national DRLs, however, no records of subsequent optimisation reviews or corrective actions were available.

Judgment: Not Compliant

Regulation 14: Equipment

From the evidence available, inspectors were not satisfied that the medical radiological equipment in use at Pro-Dental was kept under strict surveillance by the undertaking. In addition, the inventory of medical radiological equipment supplied to inspectors in advance of this inspection was incomplete and not up to date.

The records reviewed satisfied the inspectors that all radiological equipment had undergone acceptance testing. However, no records of subsequent regular performance testing by the MPE for the intra-oral unit or the CBCT unit, which was due in October 2022, were available. Such testing is required to ensure that medical radiological equipment in clinical use is safe for use and fit for purpose.

There was no evidence available to assure inspectors that the undertaking had an appropriate QA programme in place to monitor and evaluate the radiological equipment on an ongoing basis as required by the regulations.

Judgment: Not Compliant

# Regulation 19: Recognition of medical physics experts

While a MPE had previously been involved with the undertaking for commissioning purposes, the mechanisms in place to provide continuity of medical physics expertise were not available for review. After speaking with staff it was established that the MPE continuity of service had lapsed.

Judgment: Not Compliant

# Regulation 20: Responsibilities of medical physics experts

From speaking with staff at the practice, inspectors were not satisfied that arrangements were in place to ensure that the MPE took responsibility for dosimetry, gave advice on radiological equipment or contributed to the service as required by the regulations.

Judgment: Not Compliant

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

After document review and communication with staff, inspectors noted that the involvement of the MPE had lapsed and must be reinstated, developed and

formalised to ensure that the MPE's involvement is commensurate with the level of radiological risk at Pro-Dental.

Judgment: Not Compliant

# Regulation 22: Education, information and training in field of medical exposure

On the day of inspection, evidence of training completed by the practitioners involved in the use of CBCT, as prescribed by the Dental Council, was not available for review. The undertaking must ensure that practitioners who take clinical responsibility for CBCT have completed training, as prescribed by the Dental Council, and successful completion of such training must be documented and retained.

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	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 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
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

# Compliance Plan for Pro-Dental OSV-0008467

**Inspection ID: MON-0038985** 

Date of inspection: 08/03/2023

#### **Introduction and instruction**

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

#### A finding of:

- **Substantially compliant** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance or where the non-compliance poses a significant risk to the safety, health and welfare of service users will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

#### **Section 1**

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. Specific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

## **Compliance plan undertaking response:**

Regulation Heading	Judgment			
Regulation 6: Undertaking	Not Compliant			
Outline how you are going to come into compliance with Regulation 6: Undertaking: We have reengaged with the MPE, with a Service Level Agreement in place. All staff have been made aware of their individual and collective responsibilities for the safety of patients in our care, with revised Radiation Safety Procedures developed with the assistance of the MPE.				
Regulation 8: Justification of medical exposures	Not Compliant			
Outline how you are going to come into compliance with Regulation 8: Justification medical exposures:  All internal referrals will be accompanied by a referral in the clinical notes External referrals will be asked to complete a referral form which shall include the justification for x-ray which shall be approved by our dentist at Pro-Dental prior to imaging. In our practice all the patients that go to radiation exposure are recorded soft management, including reason, prescriber, performer and findings.  An intern audit of records have been established which contains in details inform about each case.				
Regulation 10: Responsibilities	Not Compliant			

Outline how you are going to come into compliance with Regulation 10: Responsibilities: MPE section

An MPE has been engaged and has assessed the performance of the CBCT system, and reviewed the optimisation of technique and diagnostic reference levels. The MPE service level agreement assures that Pro-Dental has access to MPE advice on optimisation. Practical aspects will only delegated to persons registered with the Dental Council and records of their registration will be held on file.

In our practice all the patients that go to radiation exposure are recorded in the soft management, including reason, prescriber, performer and findings.

All the outside referred patients will get a full diagnostic assessment.

Patients referred from an outside dentist will have the respective copy of referral letter digitally recorded in the clinic management software.

All the referrals will be checked in detail and sighed as 'authorised as justified' by the dentist responsible for CBCT facilities.

Regulation 11: Diagnostic reference levels

**Not Compliant** 

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

The MPE was engaged and carried out an assessment of the CBCT imaging system. The MPE assisted us with the establishment of Diagnostic Reference Levels for CBCT. The MPE was satisfied that the DRL was consistent with the equipment and digital detector in use. The local DRLs are on display adjacent to the x-Ray unit.

Intra-oral x-rays are not taken at this clinic and no DRLs are set for intra-oral x-ray

Regulation 14: Equipment

**Not Compliant** 

Outline how you are going to come into compliance with Regulation 14: Equipment: The CBCT unit was assessed for performance and suitability for clinical use on the 21/3/23.

The intra-oral unit is not in use and has been decommissioned. The MPE has made recommendations on routine regular performance testing for the CBCT unit, including annual service and routine checks of the safety features. The recommendations of the MPE will be followed in this regard.

Regulation 19: Recognition of medical physics experts	Not Compliant
medical physics experts:	compliance with Regulation 19: Recognition of cted to the clinic and a service level agreement
Regulation 20: Responsibilities of medical physics experts	Not Compliant
of medical physics experts: The service level agreement with MPE coof service with the MPE is assured for the	compliance with Regulation 20: Responsibilities wers all aspects of SI 256(2018) and a continuity next two years. The clinic intends to continue expiration of the current contract in March 2025
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
medical physics experts in medical radiological	vers all aspects of SI 256(2018) including
Regulation 22: Education, information and training in field of medical exposure	Not Compliant
Outline how you are going to come into c	compliance with Regulation 22: Education,

information and training in field of medical exposure: One of our nominated dentist will undertake training in the practical aspects, justification for an interpretation of CBCT imaging Level 1 on the 30th of May and Level 2 will be completed by the end of June.

#### **Section 2:**

# Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(1)	Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	31/03/2023
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	Not Compliant	Orange	31/03/2023

	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	Orange	31/03/2023
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	Orange	31/03/2023
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	Not Compliant	Orange	31/03/2023

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	specific objectives			
	of the exposure			
	and the			
	characteristics of			
	the individual			
	involved.			
Regulation	A referrer shall not	Not Compliant	Red	07/04/2023
8(10)(a)	refer an individual	'		, ,
	to a practitioner			
	for a medical			
	radiological			
	procedure unless			
	the referral is in			
	writing,			
Pogulation	A referrer shall not	Not Compliant	Red	07/04/2023
Regulation		Not Compliant	Reu	07/04/2023
8(10)(b)	refer an individual			
	to a practitioner			
	for a medical			
	radiological			
	procedure unless			
	the referral states			
	the reason for			
	requesting the			
	particular			
	procedure, and			
Regulation	A referrer shall not	Not Compliant	Red	07/04/2023
8(10)(c)	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).			
Regulation 8(11)	A practitioner	Not Compliant	Orange	07/04/2023
	carrying out a		21290	
	medical			
	radiological			
	procedure on foot			
	of a referral shall,			
	having taken into			
	_			
	account any			

	medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Red	07/04/2023
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	07/04/2023
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Not Compliant	Orange	31/03/2023
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	21/04/2023
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be	Not Compliant	Orange	31/03/2023

	delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) 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, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			01/04/2022
Regulation 10(4)(b)	Practical aspects of a medical radiological procedure may be delegated by the practitioner as appropriate, to one or more individuals, (i) registered by	Not Compliant	Orange	01/04/2023

	the Dental Carrail			
	the Dental Council,			
	(ii) registered by			
	the Medical			
	Council,			
	(iii) registered by			
	the Nursing and			
	Midwifery Board of			
	Ireland,			
	(iv) 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, or			
	(v) recognised by			
	the Minister under			
	Regulation 19,			
	as appropriate,			
	provided that such			
	person has			
	completed training			
	in radiation safety			
	prescribed or			
	approved pursuant			
	to Regulation			
	22(3) by the			
- 1 · · · · · · · · · · · · · · · · · ·	appropriate body.			2 / /22 /222
Regulation 11(5)	An undertaking	Not Compliant		21/03/2023
	shall ensure that		Orange	
	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.			
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 relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Orange	01/04/2023
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	01/04/2023
Regulation 14(1)  Regulation	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.  An undertaking	Not Compliant  Not Compliant	Orange	21/03/2023

14(2)(a)	shall implement		Orange	
	and maintain appropriate quality			
	assurance			
	programmes, and	N . 6 . !! .		24 (22 (222
Regulation 14(2)(b)	An undertaking shall implement	Not Compliant	Orange	21/03/2023
11(2)(0)	and maintain			
	appropriate			
	programmes of			
	assessment of dose or verification			
	of administered			
	activity.			
Regulation	An undertaking	Not Compliant	Red	21/04/2023
14(3)(b)	shall carry out the following testing			
	on its medical			
	radiological			
	equipment,			
	performance testing on a			
	regular basis and			
	after any			
	maintenance			
	procedure liable to affect the			
	equipment's			
	performance.			
Regulation 14(10)	An undertaking	Not Compliant	Orange	31/03/2023
	shall provide to the Authority, on			
	request, an up-to-			
	date inventory of			
	medical			
	radiological equipment for			
	each radiological			
	installation, in such			
	form and manner			
	as may be prescribed by the			
	Authority from			
	time to time.			
Regulation 19(9)	An undertaking	Not Compliant	Oranga	21/03/2023
	shall put in place the necessary		Orange	
	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.			
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 of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Orange	21/03/2023
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	Orange	21/03/2023
Regulation 20(2)(b)	An undertaking shall ensure that,	Not Compliant	Orange	21/03/2023

	depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical	Not Compliant	Orange	21/03/2023

	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	Orange	21/03/2023
Regulation 22(1)(a)	Subject to paragraph (2), an undertaking shall ensure that practitioners have adequate	Not Compliant	Red	31/07/2023

education,	
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information and	
theoretical and	
practical training	
for that purpose,	
as well as relevant	
competence in	
radiation	
protection, in	
accordance with	
the provisions of	
this Regulation.	