



**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:	Cabra Dental Centre
Undertaking Name:	Darragh Mulrooney
Address of Ionising Radiation Installation:	82 New Cabra Road, Dublin 7
Type of inspection:	Announced
Date of inspection:	20 April 2022
Medical Radiological Installation Service ID:	OSV-0006046
Fieldwork ID:	MON-0035859

About the medical radiological installation:

Cabra Dental Centre carries out intra oral procedures for root canal treatments, crown and bridge work and suspected pathologies. In addition, OPG's are carried out for assessment of suspected pathologies.

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 users⁴ 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 20 April 2022	11:40hrs to 13:15hrs	Noelle Neville	Lead

Summary of findings

An on-site inspection of Cabra Dental Centre was carried out by an inspector on 20 April 2022. The focus of this inspection was limited to the assessment of compliance with the regulations outlined in this report. The inspection was initiated as a result of a failure to return a regulatory self-assessment questionnaire that had been issued to the undertaking.

The inspector was informed that although the dental practice had made recent efforts to engage a Medical Physics Expert (MPE), an MPE had not been engaged by the practice since the commencement of the regulations in 2019. The absence of an MPE since 2019, meant that not all responsibilities were allocated by the undertaking as required by Regulation 6(3).

The absence of an MPE since 2019 resulted in a number of non-compliances with the regulations, including Regulations 6, 11, 14, 19, 20 and 21. The inspector was not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14. In addition, the inspector was not satisfied that an OPG unit, installed in June 2021, had acceptance testing carried out. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of service users undergoing dental radiological procedures. Management accepted and acknowledged this finding. While the inspector acknowledges that the radiological risk of the dental procedures conducted at the dental practice was relatively low, ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures is maintained.

Despite the issues outlined above, inspectors noted compliance with Regulations 4 and 5. Cabra Dental Centre ensured that referrals were from registered dentists and that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at the dental practice.

Following this inspection, Cabra Dental Centre was required to submit an urgent compliance plan to address urgent risks relating to equipment and MPE involvement. The undertaking's response did provide assurance that the risks identified on the day of inspection were adequately addressed following the inspection.

Regulation 4: Referrers

From discussions with management at Cabra Dental Centre, the inspector was satisfied that referrals were from registered dentists.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found some allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) at Cabra Dental Centre. However, the absence of engagement of an MPE at the practice since the commencement of the regulations in 2019, meant that not all responsibilities were clearly allocated as required by the regulations, for example, responsibilities under Regulation 20.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

The inspector was not satisfied from discussions with management that diagnostic reference levels (DRLs) had been established, regularly reviewed and used at Cabra Dental Centre.

Judgment: Not Compliant

Regulation 14: Equipment

The inspector was not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Cabra Dental Centre.

Although requested, the inspector did not receive an inventory of dental radiological equipment in advance of the inspection. However, on the day of inspection, the inspector was informed that the dental practice had two intra-oral units and one OPG unit. In the absence of engagement of an MPE since the commencement of the regulations in 2019, the inspector found that an appropriate quality assurance

programme as required by Regulation 14(2) had not been maintained. In addition, inspectors were not satisfied that the OPG unit, installed in June 2021, had been acceptance tested. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of service users undergoing dental radiological procedures. Management acknowledged and accepted this finding.

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 following the inspection.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

The inspector was not satisfied that Cabra Dental Centre had put in place the necessary arrangements to ensure the continuity of an MPE since the commencement of the regulations in 2019. Management acknowledged this finding and informed the inspector that several recent attempts had been made to engage an MPE at the dental practice.

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 following the inspection.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector was not satisfied that Cabra Dental Centre had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1) since the commencement of the regulations in 2019. The inspector found that the absence of an MPE since 2019 resulted in deficits in the areas identified in Regulation 20(2), including optimisation, DRLs, acceptance testing of medical radiological equipment, and the definition and performance of quality assurance of medical radiological equipment.

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 following the inspection.

Judgment: Not Compliant

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

The inspector was not satisfied that Cabra Dental Centre had arrangements in place to ensure that an MPE was appropriately involved in the dental practice as an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019.

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 following the inspection.

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 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

Compliance Plan for Cabra Dental Centre OSV-0006046

Inspection ID: MON-0035859

Date of inspection: 20/04/2022

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 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: MPE - Engaged and appointed.	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: DRL levels has been tested by on all radiological equipment and are in order with national requirements.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: All radiological equipment has been tested by and operate in proper manner and report was submitted to HIQA. New X-ray machine was commissioned in positive manner.	

Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: Medical Physics expert was appointed.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: All new equipment has been tested in positive way and working in proper order including DRL levels, performance and quality assurance. Annual evaluation and service will be carried out.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: MPE has been appointed.</p>	

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 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	Orange	29/04/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	29/04/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	19/05/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	19/05/2022
Regulation 14(3)(a)	An undertaking shall carry out the following testing on its medical radiological equipment, acceptance testing before the first use of the equipment for clinical purposes; and	Not Compliant	Red	19/05/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to	Not Compliant	Red	19/05/2022

	affect the equipment's performance.			
Regulation 14(4)	A person shall not use medical radiological equipment for clinical purposes unless testing in accordance with paragraph (3)(a) has been carried out.	Not Compliant	Red	19/05/2022
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	Red	19/05/2022
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	Red	19/05/2022
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the	Not Compliant	Red	19/05/2022

	<p>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,</p>			
Regulation 20(2)(b)	<p>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</p>	Not Compliant	Red	19/05/2022
Regulation 20(2)(c)	<p>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</p>	Not Compliant	Red	19/05/2022

	<p>use of diagnostic reference levels;</p> <p>(ii) the definition and performance of quality assurance of the medical radiological equipment;</p> <p>(iii) acceptance testing of medical radiological equipment;</p> <p>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 20(3)	The medical physics expert referred to in paragraph (1)	Not Compliant	Red	19/05/2022

	shall, where appropriate, liaise with the radiation protection adviser.			
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	19/05/2022