



**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:	Dublin Dentist Clinic (Dublin 1)
Undertaking Name:	Dublin Dentist LTD
Address of Ionising Radiation Installation:	43/44 Lower Dorset Street, Dublin 1
Type of inspection:	Announced
Date of inspection:	30 August 2023
Medical Radiological Installation Service ID:	OSV-0006115
Fieldwork ID:	MON-0039748

## About the medical radiological installation:

Dublin Dentist Clinic (Dublin 1) is a dental practice owned by Dublin Dentist LTD. A number of different dental radiological procedures are carried out at the practice. This includes intra-oral radiographs, orthopantomograms (OPG) and cone-beam computed tomography (CBCT).

## How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff 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

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

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

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

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

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 30 August 2023	12:00hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 30 August 2023	12:00hrs to 15:30hrs	Kirsten O'Brien	Support

## Summary of findings

An inspection of Dublin Dentist LTD at Dublin Dentist Clinic (Dublin 1) was conducted by inspectors on the 30 August 2023 to assess compliance against the regulations following previous inspections carried out on the 10 January 2023 and 7 March 2023. On the day of inspection, inspectors visited the X-ray room at the practice and assessed compliance with the regulations relating to the use of intra-oral radiography (X-ray), orthopantomogram (OPG) and cone-beam computed tomography (CBCT) procedures.

On the day of inspection, inspectors noted that some improvements had been made since the last inspections. For example, recent changes implemented by the undertaking in the areas of diagnostic reference levels (DRLs), patient protocols and recording of information relating to the patient exposure on patients' reports satisfied regulatory requirements at the time of inspection. Improvements had also been made with relevant patient information now being recorded and the staff members with clinical responsibility also being clearly identifiable.

However, the allocation of responsibility for all relevant staff was not yet formally documented for the practice. Subsequently, the issue with the allocation of responsibilities relating to the radiation protection of patients and services users as pointed out on previous inspections, had still not been addressed.

While inspectors were satisfied that quality assurance (QA) checks had been completed by the medical physics expert (MPE) and the manufacturer preventative maintenance had been completed, some equipment QA testing, as defined by the MPE, had not been completed at the time of inspection. Information about who was assigned responsibility by the undertaking for completing this equipment testing was not available or documented. It is imperative that the undertaking take steps to ensure that systems are in place to facilitate the timely completion of all recommended QA on the radiological equipment. Recent staff changes may have contributed to this gap but this further highlights the importance of clearly documenting all staffs' roles and responsibilities for radiation safety.

Finally, based on the evidence provided throughout the inspection, inspectors were not satisfied that the undertaking had taken the appropriate steps to ensure that dentists involved in the conduct of CBCT procedures had successfully undertaken training as prescribed by the Dental Council. The undertaking's failure to successfully address this non-compliance under Regulation 22 resulted in the issue of a compliance notice directing the undertaking to ensure that practitioners conducting CBCT procedures at Dublin Dentist Clinic (Dublin 1) have successfully completed training in relation to CBCT as prescribed by the Dental Council.

## Regulation 6: Undertaking

Inspectors reviewed documentation and records, and spoke with staff regarding the management and oversight structures in place at Dublin Dentist Clinic (Dublin 1). In particular, the allocation of responsibility for the radiation protection of service users attending the dental practice was examined.

Inspectors noted that the appointment of a clinic manager with specific radiation safety roles had led to improvements in the documented allocation of responsibility of practitioners. This in turn resulted in improvements in record keeping in relation to Regulations 8, 10, 11 and 13. However, inspectors were informed that this role was now temporarily filled by a new member of staff due to recent staff changes. While inspectors were informed on the day that this role had important responsibilities in relation to the radiation protection of service users this was not formally documented by the undertaking. Therefore, on the day of inspection the undertaking had not taken adequate steps to document the controls in place for oversight of compliance with the regulations in Dublin Dentist Clinic (Dublin 1).

Additionally, inspectors found that Dublin Dentist LTD had not ensured that individuals conducting CBCT procedures at Dublin Dentist Clinic (Dublin 1) had completed the appropriate level of training to conduct these procedures. Although some training had been completed since the previous inspection, the CBCT specific training records supplied during the inspection process did not assure the inspectors that this training was sufficient to meet the requirements prescribed by the Dental Council.

Dublin Dentist LTD must ensure that the allocation of responsibility for the radiation protection of service users is clearly documented and made known to all staff working at the practice. Additionally, the undertaking must ensure that dentists operating CBCT equipment have completed training as specified by the Dental Council to enable the safe use of this type of equipment.

Judgment: Not Compliant

## Regulation 8: Justification of medical exposures

On the day of inspection, inspectors reviewed a sample of dental radiological procedures conducted at Dublin Dentist Clinic (Dublin 1). Inspectors noted improved record keeping since the previous inspection in March 2023. These records showed compliance with this regulation for the medical exposures carried out at this practice.

Inspectors were informed and subsequently observed that a record of dental exposures was made by dentists on the practice's electronic information system and formed part of the patients' notes. A written record of dental radiological exposures

in paper format in the X-ray room also supplemented the electronic patient notes. As a result, inspectors were satisfied that all internal and external referrals for medical exposures included a record of justification in advance by a practitioner, contained the reason for the request and were accompanied by medical data to allow a practitioner to justify a dental medical procedure.

Additionally, the improvements in record keeping showed that information relating to the practitioner (dentist) who completed the exposure, the clinical evaluation of the outcome and the associated information relating to patient exposure were available in the sample of records reviewed.

Judgment: Compliant

### Regulation 9: Optimisation

Inspectors found that improvements to ensure that doses due to medical exposure were kept as low as reasonably achievable had been implemented since the last inspection. This was largely due to the changes implemented after systematically reviewing patient dose and optimising procedures as detailed under Regulation 11. However, inspectors noted that some work was still required by the undertaking to ensure further optimisation through QA, as advised by the MPE, and further detailed under Regulation 14.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

Inspectors were satisfied that only registered dentists carried out the practical aspects of dental radiological procedures. Inspectors also found that the improvements in record keeping provided the evidence of who had taken clinical responsibility for each aspect of individual dental exposures.

From a review of records of dental exposures, inspectors found evidence to demonstrate that a referrer and a practitioner were involved in the justification process for individual dental exposures.

Inspectors were also assured that the MPE and practitioners were now involved in the optimisation process for all dental exposures carried out at Dublin Dentist Clinic (Dublin 1).

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

Inspectors were satisfied that the undertaking had completed the necessary patient dose reviews and implemented the necessary changes to optimise patient dose by establishing, reviewing and using DRLs. Evidence reviewed by inspectors showed the corrective actions taken to ensure that patient doses were broadly comparable to national DRLs.

Judgment: Compliant

## Regulation 13: Procedures

On the day of inspection written protocols were now available for all dental procedures. In addition, in the sample of records reviewed the clinical evaluation of the outcome included information relating to patient exposure.

Judgment: Compliant

## Regulation 14: Equipment

On the day of inspection, inspectors spoke with the management staff at Dublin Dentist Clinic (Dublin 1) about the radiological equipment. Inspectors also requested all documentation and records relating to the dental radiological equipment surveillance at the practice.

Inspectors were satisfied that the undertaking had a system to ensure that MPE QA testing and routine manufacturer preventative maintenance were completed. However, in-house QA tests as defined by the MPE had not been completed. Inspectors were informed that the recent staff changes detailed under Regulation 6 were the reason in-house QA had not been completed. While inspectors saw evidence of improvements in the strict surveillance of all radiological equipment, areas for improvement still existed. This included the formal allocation of responsibility for in-house QA testing to ensure it is completed when required and this must be addressed by the undertaking to ensure compliance with this regulation.

Judgment: Substantially Compliant

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



On the day of inspection, inspectors were informed that only three dentists were involved in the conduct of CBCT procedures. Records of training in CBCT were supplied for these three dentists. While the information reviewed demonstrated that all three dentists has some training in relation to the conduct of CBCT, the documentation supplied did not satisfy the relevant training requirements as prescribed by the Dental Council.

Inspectors found that Dublin Dentist LTD had not ensured that staff conducting CBCT procedures had successfully undertaken or completed training as prescribed by the Dental Council. This resulted in the issue of a compliance notice.

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
<b>Summary of findings</b>	
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

# Compliance Plan for Dublin Dentist Clinic (Dublin 1) OSV-0006115

Inspection ID: MON-0039748

Date of inspection: 30/08/2023

## 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. **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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:            As achieved before the last inspection, Dublin-Dentist has prepared a list of responsibilities for the practitioner taking the x-ray and OPG including: ensuring that the patient fills out the relevant consent form before taking the x-ray, justifying the x-ray being taken, informing the patient and recording in writing about the clinical finding from the x-ray and the corresponding dose of the x-ray taken on the electronic system and the x-ray record sheet.</p> <p>In order to be compliant with Regulation 6, Dublin-Dentist Clinic (Dublin 1) will:</p> <ol style="list-style-type: none"> <li>1) Prepare a clear formal documentation of the allocation of responsibility within the clinic, especially in the area of radiation protection. An oversight structure for Dublin-Dentist Clinic (Dublin 1) will be drawn out, and an official dental radiology officer will be elected before the 29th of November. The said officer will be provided with a detailed copy of his/her responsibilities: this includes being responsible for the clear documentation of ALL patient clinical cards, ensuring that all patients for x-ray have signed the consent form, maintenance of records for patient x-rays at the end of each day (both on our electronic system and on paper), actively research and encourage the relevant practitioners to take the necessary online courses related to radiology, and to strictly ensure that all practitioners who carry out dental radiological procedures have the relevant and up-to-date qualifications. This document will be signed by the said officer, as well as all the staff working at the practice.</li> <li>2) A written copy of this documentation will be printed out and pinned to the wall of the x-ray room to ensure that all staff is aware of their own responsibilities and the responsibilities of the dental radiology officer.</li> <li>3) This will be done before Sunday, 5th of November.</li> </ol>	
Regulation 9: Optimisation	Substantially Compliant

<p>Outline how you are going to come into compliance with Regulation 9: Optimisation: In order to be compliant with Regulation 9, Dublin-Dentist Clinic (Dublin 1) will:</p> <p>1) Continue to keep doses as low as possible and review the patient doses systematically. This has already been achieved in the last inspection with the guideline for the recommended dosage being printed out and pinned to the wall of the x-ray room. On top of this an official dental radiology officer will be responsible for conducting regular and continuous internal audits of radiation exposure procedures and in-house QA testing.</p> <p>2) Since the last inspection, we have already added a radiology consent form to our electronic system for all patients to sign before taking X-rays. This digital version of the consent form will be kept for our records, and a printed copy will be provided to the patient as proof that they have been made aware of the potential risks and benefits of x-rays before performing the procedure.</p> <p>3) Furthermore, we have already placed a halt on performing cone-beam computed tomography (CBCT) procedures on our patients until our practitioners have completed the appropriate level of training as prescribed by Dental Council (see details later in regulation 22).</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: In order to be compliant with Regulation 14, Dublin-Dentist Clinic (Dublin 1) will:</p> <p>1) Allocate the responsibility for in-house QA testing to our official dental radiology officer. The said officer's roles and responsibilities will be clearly defined and documented. This will be done before Sunday, 5th of November.</p> <p>2) A schedule for in-house QA testing will be developed and implemented to ensure that all in-house QA testing of radiological equipment are performed as required. The findings of the QA tests will be recorded on the 'Equipment Maintenance Log' paper sheet, safely stored in the x-ray room to track completed tests and upcoming ones. This sheet will be made formally with the first record log added before Sunday, 12th of November.</p>	
Regulation 22: Education, information and training in field of medical exposure	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure: In order to be compliant with Regulation 22, Dublin-Dentist Clinic (Dublin 1) will:</p>	

- 1) Ensure that all practitioners conducting cone-beamed computed tomography (CBCT) procedures on patients meet the training requirements set by the Dental Council. This means that our official dental radiology officer will identify the relevant online radiology courses for our radiology practitioners to take, ensure that all practitioners take complete the relevant courses and training before conducting x rays and make maintain an up-to-date database of staff training and certification status.
- 2) An up-to-date copy of all training and certifications for practitioners of intra-oral radiography (x-ray) and orthopantomogram (OPG) will be stored in a folder in the x-ray room by 31st of January 2024.
- 3) In terms of cone-beam computed tomography (CBCT) procedures, Dublin-Dentist Clinic (Dublin 1) has already ceased to perform CBCT procedures on patients. Before we hire a radiologist who has the necessary qualifications, or until our practitioners have completed the appropriate level of training as prescribed by the Dental Council, we will not conduct any CBCT procedures

## 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	05/11/2023
Regulation 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent	Substantially Compliant	Yellow	12/11/2023

	production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	12/11/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	12/11/2023
Regulation 22(1)(a)	Subject to paragraph (2), an undertaking shall ensure that practitioners have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation	Not Compliant	Red	31/01/2024



	protection, in accordance with the provisions of this Regulation.			
Regulation 22(3)	Subject to paragraph (4), the persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection— (a) prescribed by the Dental Council, (b) prescribed by the Irish College of Physicists in Medicine, (c) prescribed by the Nursing and Midwifery Board of Ireland, (d) prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, or (e) approved by the Radiographers Registration Board under Part 5 of the Health and Social Care Professionals Act 2005, as appropriate,	Not Compliant	Red	31/01/2024

	having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).			
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