



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Renmore Dental
Undertaking Name:	Renmore Dental
Address of Ionising Radiation Installation:	5 Dublin Road, Galway
Type of inspection:	Announced
Date of inspection:	24 November 2022
Medical Radiological Installation Service ID:	OSV-0006237
Fieldwork ID:	MON-0038227

## About the medical radiological installation:

Renmore Dental, purchased in 2008, is a general dental practice offering a wide range of treatments. Radiological services may be indicated following an initial clinical examination. Each of our seven surgeries has its own wall mounted intra-oral machine for bitewing and periapical radiographs. We have a custom built X-ray room for extra-oral panoramic and cone beam computed tomography (CBCT) imaging. We accept CBCT referrals from a local multi-disciplinary specialist practice to facilitate endodontic, prosthodontic and surgical treatment planning and diagnosis.

## 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
Thursday 24 November 2022	12:30hrs to 14:30hrs	Lee O'Hora	Lead

## Summary of findings

An on-site inspection of the undertaking and practice Renmore Dental was completed on 24 November 2022.

The inspector found effective management arrangements at Renmore Dental with a clear allocation of responsibility for the protection of service users undergoing dental radiological exposures. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspector on the day of inspection.

The inspector was satisfied that only dentists referred patients for dental radiological procedures, however, the undertaking must take some additional measures to ensure that all aspects of dental radiological procedures take place under the clinical responsibility of a practitioner at Renmore Dental.

The inspector was assured that the undertaking had processes in place to ensure that all dental procedure referrals were accompanied by the relevant information and the record of justification by a practitioner was consistently documented. Information for service users on risks and benefits of dental radiological exposures was available throughout the practice on the day of inspection.

Practical aspects of dental radiological procedures were delegated by the undertaking to individuals registered by the dental council. All associated documentation, professional registration and radiation safety training records assured the inspector that all regulatory requirements were satisfied by Renmore Dental in the delegation of this responsibility.

The inspector was confident that the undertaking ensured that diagnostic reference levels (DRLs) were established, reviewed and used. Written protocols for every type of standard dental radiological procedure were available and the inspector was satisfied that information relating to patient exposure formed part of the report of dental radiological procedures.

The inspector was assured that all dental radiological equipment was kept under strict surveillance regarding radiation protection. Medical physics expert (MPE) professional registration, continuity of expertise and involvement was well documented and articulated to the inspector satisfying the associated regulatory requirements.

Overall the inspector found that the undertaking demonstrated good levels of compliance with the regulations considered on the day of inspection.

## Regulation 4: Referrers

Documentation reviewed by the inspector indicated that referrals for dental radiological procedures were only accepted from dentists. Professional registration information was supplied to the inspector for all dentists working at Renmore Dental. Documentation reviewed by the inspector detailed that Renmore Dental accepted external referrals from a small number of named dentists for cone beam computed tomography (CBCT) procedures. After reviewing documents and referral records and by speaking with staff the inspector was satisfied that processes were in place to ensure external referrals were from appropriately recognised professionals.

Judgment: Compliant

## Regulation 5: Practitioners

The inspector reviewed professional registration details of all practitioners operating at Renmore Dental. All professional registration information was up to date and satisfied all regulatory requirements.

Judgment: Compliant

## Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users at Renmore Dental. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector by staff and management during the course of the inspection.

Judgment: Compliant

## Regulation 8: Justification of medical exposures

On the day of inspection, the inspector spoke with staff who explained how medical exposures are justified in advance. All referrals reviewed by the inspector on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The inspector was satisfied that the undertaking had systems in place to ensure that all referrals were reviewed and

justified by a dentist operating at Renmore Dental and this was recorded in the patient notes for internal and external referrals.

Information posters with information on the benefits, risks and associated patient dose for dental radiological procedures were observed throughout the practice. The document *Protocol for Taking Radiographs* also included both patient effective dose and plain English explanations of the dose and associated risk. This was seen as a useful resource for practitioners and staff delegated the practical aspects to improve their understanding of the associated risks and facilitate effective patient communication.

Judgment: Compliant

## Regulation 10: Responsibilities

After documentation review and communication with staff and management, the inspector was satisfied that the undertaking had procedures in place to ensure that all medical exposures referred by dentists operating within Renmore Dental took place under the clinical responsibility of a practitioner. However, referrers external to Renmore Dental, as discussed under Regulation 4, were provided with imaging only and no associated evaluation of the outcome, thus the undertaking could not ensure that this took place under the responsibility of a suitably qualified practitioner. This was highlighted as an area for improvement on the day of inspection. The undertaking must ensure that all aspects of clinical responsibility, including evaluation of the outcome, are allocated to practitioners appropriately and as per the regulations.

After documentation review and communication with staff and management, the inspector was satisfied that the practitioner and referrer were involved in the justification process. The inspector was also assured that practitioners and the MPE were involved in the optimisation process of dental radiological exposures.

Document review and communication with staff and management noted that practical aspects of dental radiological procedures were delegated to named staff members at Renmore Dental. Records of the associated professional registration and radiation safety training was supplied to the inspector on the day of inspection satisfying the requirements of Regulation 10(4).

The inspector was also supplied with information on relevant cone beam computed tomography (CBCT) specific training, as prescribed by the dental council, undertaken by dentists operating CBCT equipment at Renmore Dental.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

The inspector was satisfied that the undertaking had established, regularly reviewed and used DRLs at Renmore Dental. The inspector observed equipment specific DRLs displayed in the clinical area for all equipment.

Judgment: Compliant

## Regulation 13: Procedures

The inspector reviewed written protocols for every type of standard dental radiological procedure carried out at the practice.

After a review of a sample of imaging reports the inspector was assured that the undertaking had implemented a system to routinely include information relating to patient exposure on the report of the medical radiological procedure. During the inspection the inspector was informed that this routine inclusion of information relating to patient exposure on the report was implemented after communication with the MPE in relation to procedure optimisation and regulatory compliance.

The inspector also reviewed a record of audits undertaken by all practitioner dentists operating at Renmore dental and was supplied with the document *Audit Protocol*. The inspector was subsequently assured that the undertaking at Renmore Dental took a systematic and well defined approach to the routine audit of a number of areas including image quality, justification, reporting, repeat radiographs and DRLs, enhancing the undertakings ability to safely deliver medical exposures at Renmore Dental.

Judgment: Compliant

## Regulation 14: Equipment

An up-to-date inventory of dental radiological equipment was supplied to the inspector and validated on site. All information relating to equipment including policies and procedures, MPE quality assurance (QA) records and MPE acceptance testing records was reviewed. All equipment QA was up to date at the time of inspection.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking.



Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The inspector was satisfied that the necessary arrangements were put in place to ensure the continuity of MPE expertise. This arrangement was formalised in documentation reviewed ensuring the maintenance of MPE services until 31 July 2024.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Records of MPE contributions to equipment QA, DRL establishment and review as well as bespoke radiation safety training for relevant staff were reviewed by the inspector. MPE registration details were supplied and these were up to date. After relevant document review and staff communication, the inspector was satisfied that the responsibilities and contributions of the MPE at Renmore Dental satisfied regulatory requirements in relation to Regulation 20.

Judgment: Compliant

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

The inspector was assured that the involvement of the MPE was commensurate with the radiological risk at Renmore Dental.

Judgment: Compliant

## Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

# Compliance Plan for Renmore Dental OSV-0006237

Inspection ID: MON-0038227

Date of inspection: 24/11/2022

## 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 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: To ensure all radiographic exposures are reported by an adequately trained clinician, for patients who have been referred to our practice for CBCT or OPG images the clinician taking the image will be responsible for reporting on this image. A copy of this report will be sent with the image to the referring clinician.	

## 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 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	02/01/2023