



**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:	Tramore Dental
Undertaking Name:	Sorcha White
Address of Ionising Radiation Installation:	2 Queen Street, Tramore, Waterford
Type of inspection:	Announced
Date of inspection:	22 February 2023
Medical Radiological Installation Service ID:	OSV-0006427
Fieldwork ID:	MON-0038975

## About the medical radiological installation:

Tramore Dental uses intra-oral radiographs and panoramic radiographs for diagnostic purposes. These are only used if prescribed by a dentist. They may only be taken by qualified personnel. There are two intra-oral units in surgeries at street level. There is one intra-oral unit and one OPG in the basement.

## 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 22 February 2023	11:50hrs to 13:15hrs	Noelle Neville	Lead

## Summary of findings

An inspection of Tramore Dental was carried out by an inspector on 22 February 2023 to assess compliance with the regulations. As part of this inspection, the inspector spoke with staff and management, reviewed documentation and visited the dental practice's clinical rooms. The inspector noted compliance with each regulation reviewed, namely Regulations 4, 5, 6, 8, 10, 11, 13, 14, 17, 19, 20 and 21.

Overall, the inspector was satisfied that the undertaking, Sorcha White, had systems in place to ensure the safe and effective delivery of medical radiological exposures at Tramore Dental and a commitment to the radiation protection of service users was evident from discussions with staff and management and a review of documentation.

### Regulation 4: Referrers

From a discussion with management and a review of documentation at Tramore Dental, the inspector was satisfied that referrals were from staff working within this dental practice, where the referrer and practitioner was the same person and entitled to act as referrer and practitioner as per the regulations.

Judgment: Compliant

### Regulation 5: Practitioners

The inspector was satisfied that only those entitled to act as practitioner had taken responsibility for medical exposures conducted at Tramore Dental.

Judgment: Compliant

### Regulation 6: Undertaking

There was a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3). The inspector reviewed a document titled *Radiation Safety Compliance File, October 2022* which outlined the allocation of responsibilities and structure in place for the

radiation protection of service users at the dental practice. This document also noted that dentists at the dental practice acted as referrer and practitioner and the practical aspects of medical procedures were delegated to a registered dental nurse who had completed a course in radiation safety. Tramore Dental also engaged the services of a medical physics expert (MPE).

Judgment: Compliant

### Regulation 8: Justification of medical exposures

From a sample of referrals reviewed, the inspector was satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff informed the inspector that previous diagnostic information from procedures was also reviewed if available. Information relating to the benefits and risks associated with radiation was available to service users and displayed in poster format in the waiting area and clinical rooms of the dental practice.

Judgment: Compliant

### Regulation 10: Responsibilities

The inspector was satisfied that a practitioner took responsibility for all medical exposures to ionising radiation at Tramore Dental as required by Regulation 10(1). The optimisation process at Tramore Dental included the practitioner and MPE as required by Regulation 10(2) and the justification process for all medical radiological procedures carried out at Tramore Dental involved the referrer and practitioner as required by Regulation 10(3). In addition, the practical aspects of medical radiological procedures were delegated to a registered dental nurse who had completed a course in radiation safety as required by Regulation 10(4) and a record of this delegation was available for review as required by Regulation 10(5).

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The inspector was satisfied that Tramore Dental had established, regularly reviewed and used DRLs, having regard to national DRLs, as required by Regulation 11(5). In addition, where a DRL in Tramore Dental had exceeded the national DRL, the undertaking had ensured that appropriate corrective action was taken as required by

Regulation 11(6) and the DRL was reduced to below the national DRL.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols for standard dental radiological procedures were available at Tramore Dental as required by Regulation 13(1). These protocols can provide assurance that medical radiological procedures are carried out in a safe and consistent manner. Information relating to the medical exposure as required by Regulation 13(2) was available in a sample of reports reviewed. In addition, the inspector reviewed evidence of clinical audit carried out at Tramore Dental which allows for the identification of areas of good practice and areas of improvement to ensure the safe delivery of medical radiological exposures to service users.

Judgment: Compliant

### Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Tramore Dental as required by Regulation 14(1). The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that an appropriate quality assurance programme was in place for equipment at Tramore Dental as required by Regulation 14(2). In addition, the inspector was satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

The inspector reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Management explained the radiation incident management process to the inspector and a template for recording incidents was available for review. Although no incidents relating to accidental or unintended exposure had been identified or reported at Tramore Dental, the inspector was satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Tramore Dental as required by Regulation 19.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE at Tramore Dental and was satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted involvement in radiation protection by the MPE across a range of responsibilities as outlined in Regulation 20(2) at the dental practice. The MPE took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to the definition and performance of a quality assurance programme. The MPE was involved in optimisation including the application and use of DRLs. In addition, the MPE contributed to the training of staff in relation to radiation protection. The inspector noted that the MPE also acted as radiation protection adviser for Tramore Dental and therefore satisfied the requirements of Regulation 20(3).

Judgment: Compliant

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

The inspector was satisfied that an MPE was appropriately involved in Tramore Dental, with the level of involvement commensurate with the radiological risk posed by the dental practice as required by Regulation 21.

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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	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 Tramore Dental OSV-0006427

Inspection ID: MON-0038975

Date of inspection: 22/02/2023

## 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
Outline how you are going to come into compliance with :	

**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).

<b>Regulation</b>	<b>Regulatory requirement</b>	<b>Judgment</b>	<b>Risk rating</b>	<b>Date to be complied with</b>