



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Belvedere Dental
Undertaking Name:	Dr Orla Dunford
Address of Ionising Radiation Installation:	54 Belvedere Drive, Waterford, Waterford
Type of inspection:	Announced
Date of inspection:	20 February 2024
Medical Radiological Installation Service ID:	OSV-0006960
Fieldwork ID:	MON-0039834

## About the medical radiological installation:

Belvedere Dental is a general dental practice located in Waterford city. There are currently three dentists that practice at the facility with three X-ray units used for intra-oral X-rays.

## 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
Tuesday 20 February 2024	11:50hrs to 12:50hrs	Noelle Neville	Lead

## Summary of findings

An inspection was carried out at Belvedere Dental on 20 February 2024 by an inspector to assess compliance with the regulations at the facility. As part of the inspection, the inspector visited the clinical areas, spoke with staff and management and reviewed documentation. The inspector noted compliance with Regulations 4, 5, 6, 8, 10, 11, 13, 17, 19, 20 and 21 and substantial compliance with Regulation 14.

The inspector found that the undertaking, Dr Orla Dunford, had good governance arrangements in place to ensure the safe delivery of medical exposures at Belvedere Dental. Only individuals entitled to act as referrer and practitioner referred and took clinical responsibility for medical radiological procedures at Belvedere Dental. The inspector was also satisfied that the undertaking had arrangements in place to ensure access to and continuity of medical physics expert (MPE) services at the facility.

Overall, the inspector was satisfied that a culture of radiation protection was embedded at Belvedere Dental and clear and effective management structures were in place to ensure the radiation protection of service users.

### Regulation 4: Referrers

From a review of documentation and speaking with staff and management at Belvedere Dental, the inspector was satisfied that referrals were from staff working within the dental facility, 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 from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Belvedere Dental.

Judgment: Compliant

## Regulation 6: Undertaking

The inspector was satisfied that 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) at Belvedere Dental. The inspector reviewed documentation and spoke with staff and management in relation to governance arrangements in place at Belvedere Dental. The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) across a range of responsibilities at the facility. In addition, the inspector noted that responsibilities were clearly allocated to referrers and practitioners with regard to medical radiological exposures taking place at Belvedere Dental. Overall, the inspector was satisfied that the undertaking, Dr Orla Dunford, had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the facility.

Judgment: Compliant

## Regulation 8: Justification of medical exposures

The inspector reviewed a sample of records of medical exposures and noted that they were in writing, stated the reason for requesting the procedure and justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

## Regulation 10: Responsibilities

The inspector noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at Belvedere Dental by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, the inspector was also satisfied that referrers and practitioners, who were the same person, were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

The inspector was satisfied that diagnostic reference levels (DRLs) had been established at Belvedere Dental, were regularly reviewed and used, having regard to national DRLs, as required by Regulation 11(5).

Judgment: Compliant

## Regulation 13: Procedures

Written protocols for standard dental radiological procedures were available at Belvedere 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. Referral guidelines which were available to staff and referrers were adopted at the facility as required by Regulation 13(3). In addition, the inspector reviewed evidence of clinical audit carried out at Belvedere Dental which allows for the identification 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 received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that three units of equipment were in place at Belvedere Dental. A document titled *Radiation Safety Compliance Manual*, the most recent version of which was issued in February 2024, outlined the quality assurance and maintenance programme in place at the facility. This programme outlined that acceptance tests and two-yearly routine quality assurance tests should be carried out on equipment at Belvedere Dental. The inspector was satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes and two-yearly quality assurance testing was also carried out.

The quality assurance and maintenance programme also noted that equipment should be maintained in accordance with the manufacturer's instructions. Despite this, the inspector was informed that servicing by the vendor of the medical radiological equipment at the facility, for preventative and maintenance purposes, had not been carried out at Belvedere Dental in line with MPE recommendations. Regular preventative maintenance and servicing is important to ensure that all medical radiological equipment is maintained in good working condition. Despite this

area of improvement required to come into full compliance with Regulation 14, the inspector was satisfied that equipment was kept under strict surveillance at Belvedere Dental as required by Regulation 14(1).

Judgment: Substantially 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 and was satisfied from discussions with staff and management that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented at Belvedere Dental. Although no incidents relating to accidental or unintended exposures had been identified or reported at Belvedere Dental, the inspector was satisfied that the 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 discussions with staff and a review of documentation that the undertaking at Belvedere Dental had arrangements in place to ensure access to and continuity of MPE services 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 Belvedere Dental and was satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted that the MPE was involved across a range of responsibilities outlined in Regulation 20(2). The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE had been assigned the role of radiation protection

adviser (RPA) at the facility, therefore satisfying the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, the inspector was satisfied that the level of MPE involvement at Belvedere Dental was commensurate with the radiological risk posed by the facility 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	Substantially 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 Belvedere Dental OSV-0006960

Inspection ID: MON-0039834

Date of inspection: 20/02/2024

## 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 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: We will continue to carry out our visual inspections of the equipment on a regular basis. On an annual basis we will have our medical radiological equipment validated by a service engineer. On a bi annual basis we will continue to engage the services of our radiation protection adviser to provide a report on medical radiological equipment.	

**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>
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	30/06/2024