



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dental Care Ireland - Reva Kells
Undertaking Name:	Dental Care Ireland Management Ltd
Address of Ionising Radiation Installation:	Bective Square, Townparks, Kells, Meath
Type of inspection:	Announced
Date of inspection:	11 August 2022
Medical Radiological Installation Service ID:	OSV-0008247
Fieldwork ID:	MON-0036785

## About the medical radiological installation:

Dental Care Ireland - Reva Dental is a dental practice located in Kells, Co. Meath. The practice was established in 2002 and was recently acquired by Dental Care Ireland in April 2022. Reva Dental has two general dentists, a visiting endodontist, and two dental hygienists. Dental Care Ireland - Reva Dental provides general dental treatment and also some specialist dental services. The practice has two intra-oral X-ray machines and one orthopantomogram (OPG) on-site.

## 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 and management 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 complying with regulations, we group and report on the regulations under two dimensions:

### **1. Governance and management arrangements for medical exposures:**

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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.

This section describes HIQA’s findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

**2. Safe delivery of medical exposures:**

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

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 11 August 2022	12:00hrs to 13:00hrs	Kirsten O'Brien	Lead

## Governance and management arrangements for medical exposures

An inspection of Dental Care Ireland Management Ltd (Dental Care Ireland) at Dental Care Ireland - Reva Dental (Reva Dental) was carried out on the 11 August 2022 to assess compliance with the regulations. As part of the inspection, an inspector visited the practice and spoke with staff and management. The inspector also reviewed documentation and records relating to dental exposure to ionising radiation at the practice.

The inspector found that Dental Care Ireland had good governance arrangements in place to ensure the safe delivery of dental exposures at Reva Dental. The undertaking representative, radiation protection officer, compliance officer (who is also the designated manager) and medical physics expert (MPE) were members of the radiation safety committee (RSC) which was the main forum for providing oversight of radiation protection for service users by Dental Care Ireland. Documentation reviewed also provided evidence of a clear allocation of the reporting structure from the practice to the undertaking.

Only an individual entitled to act as a referrer and a practitioner referred and took clinical responsibility for dental radiological procedures at Reva Dental. This individual, who was found to be the same person in the samples of records reviewed on the day of inspection, took responsibility as a practitioner for the justification and optimisation of individual dental exposures. The inspector was also satisfied that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at Reva Dental, including optimisation, assessment of dose and diagnostic reference levels (DRLs).

### Regulation 4: Referrers

From a review of documentation and speaking with management and staff at Reva Dental, the inspector was satisfied that only referrals for dental radiological procedures from individuals entitled to refer as per Regulation 4 were carried out at the practice.

Judgment: Compliant

### Regulation 5: Practitioners

On the day of the inspection Dental Care Ireland had ensured that only practitioners, as defined in the regulations, took clinical responsibility for individual

medical exposures at Reva Dental.

Judgment: Compliant

### Regulation 6: Undertaking

The inspector reviewed the governance and management arrangements in place at Reva Dental. Documentation submitted in advance of the inspection, which included a diagram of the line management and reporting structures for the practice to the undertaking, was reviewed by the inspector. The inspector also spoke with staff and a representative from Dental Care Ireland's management who clearly communicated the management and oversight structure in place for dental exposures to ionising radiation at the practice. Additionally, the inspector was assured that Dental Care Ireland had clearly allocated responsibility for the radiation protection of patients at Reva Dental to appropriate individuals as required by the regulations.

The undertaking representative was a member of the RSC which was the main forum for providing oversight of the radiation protection of service users for Dental Care Ireland. The radiation protection officer, compliance officer (who is also the designated manager of Reva Dental) and MPE were also members of the RSC. The inspector reviewed minutes from recent RSC meetings and found that topics relating to radiation protection, such as DRLs, quality assurance of equipment and staff training were discussed.

Judgment: Compliant

### Regulation 10: Responsibilities

From speaking with staff and management, and reviewing documents and other records, the inspector was satisfied that only registered dentists took clinical responsibility for dental radiological procedures at Reva Dental. Similarly, the referrer and practitioner, who were the same person, were involved in the justification process of individual dental exposures. The MPE and a practitioner were also involved in the optimisation process for all dental exposures. Additionally, the practical aspects of medical radiological procedures were only carried out at the practice by individuals entitled to act as practitioners in the regulations.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

On the day of inspection, the inspector spoke with staff and management about the provision of medical physics expertise at the practice. The inspector was informed that a formal arrangement was in place to ensure the provision of medical physics expertise at Reva Dental and written records and documentation which confirmed same were also reviewed. The inspector was therefore satisfied that the undertaking had appropriate arrangements in place to ensure the continuity of this expertise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Dental Care Ireland had ensured that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users at Reva Dental. An MPE was found to contribute to optimisation, including the establishment of DRLs, evaluation of dose delivered to service users and quality assurance at the practice. The inspector was also informed that the compliance officer (who was also the designated manager for the practice) had weekly meetings with the MPE which provided an added assurance that an MPE was available to act and give specialist advice as appropriate on matters relating to the radiation protection of service users.

Judgment: Compliant

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

The inspector found that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at Reva Dental.

Judgment: Compliant

### Safe Delivery of Medical Exposures

As part of the on-site inspection of Reva Dental, the inspector reviewed the measures put in place by Dental Care Ireland to ensure the safe delivery of medical exposures. Posters and information leaflets were observed in the waiting area and rooms where dental exposures were carried out to provide information to service users about the benefits and risks of having a dental X-ray. A sample of patient records were reviewed and these records were found to include a referral in writing

with the reason for requesting the particular radiological procedure.

Written protocols had been established for standard dental radiological procedures and referral guidelines (selection criteria) were also available for referrers at Reva Dental. Dental Care Ireland had established a programme of clinical audit and a sample of audits and other records were reviewed on the day. The inspector found that Dental Care Ireland had policies and procedures in place for dental exposures, and staff could communicate the process at Reva Dental for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures.

An area of good practice identified related to the inclusion of information about the patient dose as part of the patient report. Dental Care Ireland had incorporated a list of dental exposures into its electronic patient record system which allowed dentists to select and add this information into the report of the dental exposure to ensure compliance with Regulation 13(2). This was noted as an example of good practice by the inspector as the undertaking had proactively identified and implemented this measure to ensure compliance with the regulations.

Dental radiological equipment was found to be kept under strict surveillance at Reva Dental and a quality assurance programme for dental radiological equipment had been implemented and maintained at Reva Dental. The quality assurance programme included an assessment of dose and the inspector found that local DRLs had been established at the practice. These local DRLs were available at the X-ray controls in each room where dental exposures were carried out.

Overall, from the findings on the day of inspection, the inspection was satisfied that good systems were in place at Reva Dental to ensure the safe delivery of dental exposures to ionising radiation.

## Regulation 8: Justification of medical exposures

On the day of inspection, posters and information leaflets were observed in the waiting room and in the X-ray and orthopantomogram (OPG) room to provide information relating to the risks and benefits associated with dental exposures to service users. This leaflet also included a reminder for service users to inform the dentist if they have had recent dental X-rays to avoid unnecessary exposures.

The inspector spoke to a dentist at the practice and reviewed a sample of records of dental radiological procedures during the on-site inspection. The records of dental exposure referrals reviewed were in writing and included the reason for requesting the particular procedure. Additionally, the inspector found that the referrals reviewed as part of the inspection were justified in advance of being carried out by a practitioner.



Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs had been established for individual radiological equipment at Reva Dental. These local DRLs reflected national DRLs and were available at the X-ray controls in each room where dental radiological procedures were carried out.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols had been established for standard dental radiological procedures carried out at the practice and were available in each room where dental exposures were conducted. Written protocols can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice. Referral guidelines (selection criteria) were also available for referrers at Reva Dental.

From a sample of records reviewed, the inspector was satisfied that information relating to the patient exposure formed part of the report of dental radiological procedures as required by Regulation 13(2). Staff and management at Reva Dental demonstrated how Dental Care Ireland had configured its electronic patient record system to include a list of dental exposures. This list facilitated dentists at the practice to incorporate information about the exposure into reports by selecting the relevant examination from the list. The proactive implementation of this measure by the undertaking to ensure compliance with Regulation 13(2) was noted as a example of good practice by the inspector.

Additionally Dental Care Ireland had a clinical audit programme in place for dental exposures across its practices. A sample of clinical audits conducted at Reva Dental were reviewed by the inspector on the day of inspection. Clinical audit is an important tool which allows undertakings to identify areas of good practice and areas for improvement in order to ensure safe delivery of dental exposures to service users.

Judgment: Compliant

### Regulation 14: Equipment

On the day of inspection, records and documentation provided to the inspector relating to the radiological equipment were reviewed. An up-to-date inventory of

equipment was provided to the inspector as requested in advance of the inspection. Dental radiological equipment was found to be kept under strict surveillance at Reva Dental.

A quality assurance programme, which included an assessment of dose, had been implemented and maintained at Reva Dental. This included a quality assurance assessment of the dental radiological equipment every two years by an MPE, regular quality control checks by staff at the practice and servicing by the vendor for preventative and maintenance purposes by the vendor to ensure that the equipment was maintained in good working condition.

Judgment: Compliant

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

Documentation and policies relating to accidental and unintended exposures were reviewed by the inspector. Additionally, management and staff at Reva Dental communicated the process for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures at the practice.

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>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	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