



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Bernard Twomey Dental
Undertaking Name:	Bernard Twomey
Address of Ionising Radiation Installation:	Unit 4 Bury Central, Bury St, Ballina, Mayo
Type of inspection:	Announced
Date of inspection:	25 January 2023
Medical Radiological Installation Service ID:	OSV-0007945
Fieldwork ID:	MON-0038776

About the medical radiological installation:

Bernard Twomey Dental is a general dental surgery that carries out Intra Oral Radiographs only.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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

¹ 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.

² A medical radiological installation means a facility where medical radiological procedures are performed.

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

⁴ 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 25 January 2023	11:00hrs to 13:00hrs	Lee O'Hora	Lead

Summary of findings

An on-site inspection of the undertaking Bernard Twomey operating at Bernard Twomey Dental was completed on 25 January 2023.

The inspector found effective management arrangements at Bernard Twomey 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 assured that processes were in place to ensure the safe conduct of dental radiological procedures by the undertaking. The inspector was satisfied that dentists operating at the practice acted as the referrer and the practitioner, and took clinical responsibility for all dental radiological procedures. The practical aspects of dental radiological procedures were not delegated to any other individuals at the time of inspection.

Medical physics expert (MPE) continuity of expertise and involvement was well documented and articulated to the inspector. The inspector noted that Bernard Twomey Dental had used a regulatory self-assessment questionnaire, that had been issued to the undertaking, to form the basis of a quality improvement initiative driving improvements in relation to MPE involvement and subsequent regulatory compliance for a number of regulations.

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

Regulation 4: Referrers

Following review of referral documentation, a sample of referrals for dental radiological procedures and by speaking with staff, the inspector was satisfied that Bernard Twomey Dental only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Following review of a sample of referrals for dental radiological procedures and by

speaking with staff, the inspector was satisfied that Bernard Twomey Dental had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

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

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referral records for dental imaging on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance by a practitioner, all referrals were available in writing and stated the reason for the imaging and that all relevant details were recorded in a manner that satisfied the requirements of Regulation 8.

All referrals reviewed also included a practitioner note that the X-ray procedure was explained and the patient was asked for consent before imaging. Staff spoken with on the day informed the inspector that this routine step for all dental imaging gives an opportunity for the dentist to provide the patient with adequate information relating to the benefits and risks associated with the radiation dose from the dental exposure. The inspector was informed that this practice had been adopted following completion of a HIQA self assessment questionnaire which formed the basis of a gap analysis and subsequent quality improvement initiative.

On the day of inspection patient information posters were displayed in the patient waiting area. These posters provided service users with information relating to the benefits and risks associated with the radiation dose from dental exposures.

Judgment: Compliant

Regulation 10: Responsibilities

Following review of radiation safety documentation, a sample of referrals for dental radiological procedures and by speaking with staff, the inspector was satisfied that the undertaking ensured that all dental exposures took place under the clinical responsibility of a practitioner. The inspector was satisfied that the nature of the patient pathway ensured that all imaging was considered, justified, conducted and reviewed by the same dentist. However, while the inspector was assured that the clinical evaluation of the outcome consistently took place under the clinical responsibility of a dentist, the evaluation of the outcome was not consistently recorded in the patient notes reviewed on site, this was noted as an area for improvement and discussed with the undertaking on the day of inspection.

The inspector was assured that the optimisation process involved the practitioner and the medical physics expert. Similarly, the inspector was satisfied that the justification process involved the practitioner and the referrer who were the same individual for all individual dental exposures reviewed.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRLs, the inspector was assured that DRLs have been established, were compared to national levels, and were used in the optimisation of dental radiological procedures at this practice.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, written protocols for standard dental radiological procedures were not available. This non-compliance was highlighted as an area that needed to be addressed by the undertaking.

The inspector spoke with staff and reviewed a sample of patient imaging records on the day of inspection. The inspector observed, for the records reviewed, that information relating to patient exposure consistently formed part of the report for dental imaging procedures. The inspector was informed that this practice had also been adopted following completion of a HIQA self assessment questionnaire, associated gap analysis and subsequent quality improvement initiative.

Judgment: Substantially Compliant

Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a quality assurance programme. Including appropriate acceptance and regular performance testing.

The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation available highlighted the relevant staff and process for the provision of information to HIQA in the case of an accidental and unintended exposure or significant event occurring. No such events had been reported to HIQA by the undertaking however, the inspector was satisfied that this was due to the nature of the patient pathway and there were no concerns in relation to an absence of reporting.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documentation ensuring MPE continuity until May 2023. This arrangement was also discussed with staff and all evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. From reviewing the documentation and speaking with staff at the practice, the inspector was satisfied that the undertaking had arrangements in place to ensure the involvement and contribution of the MPE was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with staff and following radiation safety document review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Bernard Twomey 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
Summary of findings	
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	Substantially 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 Bernard Twomey Dental OSV-0007945

Inspection ID: MON-0038776

Date of inspection: 25/01/2023

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 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Written Protocols are now in place for every type of dental radiological procedures and are accessible to all practitioners. 14/3/23	

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 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Yellow	14/03/2023