



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Mullane Dental
Undertaking Name:	Shane Mullane
Address of Ionising Radiation Installation:	No 3 Bishop Street, Newcastlewest, Limerick
Type of inspection:	Announced
Date of inspection:	17 November 2022
Medical Radiological Installation Service ID:	OSV-0005969
Fieldwork ID:	MON-0038508

## About the medical radiological installation:

Mullane Dental is a general dental practice with a specialist prosthodontist in-house. We have a visiting orthodontist who provides a service at our practice three days a month. The radiological services we provide are for general dental needs which primarily uses intraoral radiographs. The visiting prosthodontist would primarily use cone beam computer tomography (CBCT) imaging for planning implant placements. We also receive some referrals from endodontists for CBCT imaging.

## 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 17 November 2022	12:00hrs to 13:35hrs	Kay Sugrue	Lead

## Summary of findings

An inspection was carried out at Mullane Dental facility on 17 November 2022 to assess its compliance with the regulations. The inspector spoke with staff and management, reviewed documentation and visited dental surgeries containing dental radiological equipment within this facility. The inspector was satisfied from documentation reviewed and discussions with staff that dentists practicing in this installation acted as the referrer, the practitioner and took clinical responsibility for all dental radiological medical exposures conducted there.

While the inspector found that certain aspects relating to the allocation of responsibilities were clear, there was however, some ambiguity in relation to the undertaking status for Mullane Dental Practice. This was mainly due to the number of co-located undertakings operating from this facility. The inspector found that the principal dentist was the owner of Mullane Dental Practice and all the dental radiological equipment in the facility. This principal dentist was the radiation protection officer and designated manager for the practice and took responsibility for ensuring the maintenance and quality assurance(QA) of dental radiological equipment was regularly completed as per the regulations.

From the information provided to the inspector, the inspector advised the undertakings to review the status of co-located undertakings and who takes responsibility for regulatory compliance in this facility. Subsequently, HIQA received notifications of cessation forms from other undertakings at this facility, as deemed appropriate, by the dentists working here. Policy documentation should now be reviewed to reflect the recent changes in the allocation of responsibilities outlined to the inspector, on the day of inspection, and ensure it aligns with the regulations.

Patient records reviewed by the inspector provided evidence that information relating to patient exposure formed part of the report of dental radiological procedures and a record of justification in advance was also documented for each dental X-ray. The inspector found that the undertaking was compliant with Regulations 19, 20 and 21 and had ensured the continuity of MPE expertise and appropriate involvement as per these regulations. However, the inspector identified from discussions with staff that the undertaking should proactively avail of and act on advice offered by the MPE in relation to regulatory compliance. For example, staff informed the inspector that advice was offered by the MPE on the need to review the undertaking status for the practice and the requirement to establish paediatric DRLs which had not been addressed prior to the inspection.

The undertaking had ensured that written protocols for every standard dental radiological procedure for adults were available, however, paediatric protocols for procedures provided at the facility had not been developed. Similarly, while facility diagnostic reference levels (DRLs) had been established, reviewed and used for adult dental radiological procedures, paediatric DRLs had yet to be established. Therefore these gaps in compliance must be addressed to ensure full compliance

with Regulation 13(1) and Regulation 11(5) respectively.

Overall, notwithstanding the gaps in compliance identified during this inspection, the inspector was satisfied that Mullane Dental had systems in place to ensure the safe and effective delivery of dental radiological procedures to its service users.

#### Regulation 4: Referrers

The inspector reviewed documentation and spoke with staff on the day of the inspection and was satisfied that all referrals for dental radiological procedures were from registered dentists as per regulations. The undertaking had a documented referral process for dental X-rays which was aligned with the process described by staff to the inspector on the day. External and internal requests for cone beam computer tomography (CBCT) imaging were individually reviewed by the principal dentist who would also complete a clinical assessment of the service user before proceeding with the requested CBCT procedure.

Judgment: Compliant

#### Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures at Mullane Dental Practice. Local policy outlined individuals entitled to act as a practitioner, all of whom were dentists as per regulations.

Judgment: Compliant

#### Regulation 6: Undertaking

During this inspection, the inspector spoke with staff including the undertaking who was the principal dentist and also filled the role of the designated manager and radiation protection officer for this facility. From these discussions and documentation reviewed, the inspector was satisfied that a dentist was the referrer and practitioner with clinical responsibility for dental radiological procedures conducted at this facility, as per the regulations. Local radiation safety procedures outlined the names of practitioners entitled to use the CBCT, the orthopantomogram (OPG) and the intra oral radiological equipment.

While the allocation of responsibilities for referrers and practitioners at the practice was clear, the inspector found that there was some ambiguity evident in relation to

who the undertaking was for Mullane Dental. Documentation reviewed prior to this inspection and discussions with staff on the day indicated that there were a number of co-located undertakings working at this medical radiological facility. However, it was difficult to identify the undertaking for this practice in the documented radiation protection management structure viewed by the inspector. Further discussion with staff during the inspection provided greater clarity with this regard. Staff articulated to the inspector that the overall responsibility for the medical radiological equipment, its quality assurance and procedures performed at Mullane Dental rested with the practice owner and principal dentist (also an undertaking). The principal dentist engaged the MPE services for the practice and co-located undertakings adhered to local rules developed by the owner of the practice. The inspector was informed by the management that the MPE had advised that the undertaking status for this facility should be reviewed to align with regulatory requirements but this advice had not been acted upon up to the time of the inspection. The inspector concluded from the information received that a review of the undertaking status of co-located undertakings declared to HIQA was required. Subsequently, following this inspection, co-located undertakings operating at this facility submitted cessation notifications to HIQA leaving only one undertaking (the principal dentist) taking regulatory responsibility for all dentists working at this medical radiological installation. The undertaking should update local radiation safety procedures to align with the revised allocation of responsibilities, to align with regulations and to provide greater clarity to staff working at Mullane Dental Practice. These findings were discussed with the undertaking during the inspection and assurances were provided to the inspector that any issues identified would be addressed.

Judgment: Substantially 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. The inspector found from a sample of patient records reviewed, that medical exposures were justified in advance and a record of this justification was available for review in these records. In addition, posters containing information relating to the benefits and risks associated with dental X-rays was available to service users in the waiting areas.

Judgment: Compliant

### Regulation 10: Responsibilities

The inspector was satisfied following review of documentation and speaking with staff that all dental exposures took place under the clinical responsibility of the

dentists operating in this facility. The inspector saw evidence that a dentist was the referrer and practitioner for all medical radiological procedures conducted at Mullane Dental facility and a dentist was involved in the justification process for each medical exposure as per regulations. In addition, the inspector was satisfied that the optimisation process included the practitioner and MPE and was also informed that practical aspects of dental X-rays were not delegated to other individuals at the time of the inspection.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The inspector was satisfied that there was a system and process in place for the establishment of DRLs at Mullane Dental however, improvements were required. DRLs for adult common medical radiological procedures performed in the dental surgeries at this facility had been established and were displayed on the walls of each X-ray room assessed. The inspector was informed that paediatric dental X-rays were also regularly performed in this practice however paediatric DRLs had not yet been established despite advice offered by the MPE on this issue. Therefore, following on from this inspection, paediatric DRLs should be established to fully meet regulatory compliance.

Judgment: Substantially Compliant

### Regulation 13: Procedures

Written protocols were established for each type of standard adult medical radiological procedure provided by this undertaking, a sample of which were viewed by the inspector. However, the inspector was informed that although paediatric dental X-rays were performed in this facility, paediatric protocols had not been established as required under Regulation 13(1).

The inspector viewed a sample of patient records and found that details relating to the patient dose were recorded for each procedure in each record viewed.

The practice had referral criteria available to the dentists working at Mullane Dental Practice which were viewed by the inspector on the day.

The inspector saw evidence that demonstrated that clinical audits were conducted at Mullane Dental Practice.

Judgment: Substantially Compliant

## Regulation 14: Equipment

The inspector received an up-to-date inventory of medical radiological equipment in advance of this inspection. Documentation viewed demonstrated to the inspector that there was an appropriate quality assurance programme in place. Medical radiological equipment was subject to QA by an MPE once every two years and there was evidence that the equipment was maintained annually by a service engineer. The inspector was informed that there was an ongoing issue with the accuracy of the dose area product (DAP) meter on the CBCT unit which was performing outside tolerance levels despite a recent review by a service engineer. While this equipment has been deemed suitable for clinical use by the MPE, this issue should be resolved in a timely way. The inspector found that the undertaking met the requirements of this regulation but noted that consideration should be given to any guidance from the manufacturer or MPE in relation to regular quality control checks on all medical radiological equipment to further enhance the QA programme.

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 should they occur. At the time of the inspection, no incidents relating to accidental or unintended exposure had been identified or reported at Mullane Dental Practice. Staff explained the process for managing any potential radiation incidents to the inspector and a template for recording incidents was available.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

The inspector found that there were documented arrangements in place ensuring the continuity of a medical physics expert to support Mullane Dental Practice as per regulations.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

A professional registration certificate for the MPE engaged for Mullane Dental was viewed by the inspector which was found to be in date and demonstrated that a recognised MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector saw evidence of MPE involvement in the quality assurance of equipment, advice on medical radiological equipment, acceptance testing, optimisation including the application and use of DRLs and also contributed to the training of staff in relevant aspects of radiation protection. Overall, the inspector was satisfied that the undertaking had ensured that an MPE contributed to the radiation protection of service users attending for X-ray at Mullane Dental as outlined in this regulation.

Judgment: Compliant

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

The inspector found that as per evidence outlined in Regulation 20, that an MPE was appropriately involved at Mullane Dental, with the level of involvement commensurate with the level of 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	Substantially Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially 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 Mullane Dental OSV-0005969

Inspection ID: MON-0038508

Date of inspection: 17/11/2022

## 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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: A review of the undertaking status has been completed and there is now one undertaking for this facility. Documentation has been updated to reflect the changes made to the management structure.	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Diagnostic reference levels for paediatric procedures were established by the MPE for Mullane Dental.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Procedures have since been updated to include paediatric protocols. A meeting will take place on Wednesday 25/01/23 to ensure all operators are updated on these protocols.	



## 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 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	30/11/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	25/01/2023

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	Orange	25/01/2023