



**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:	Monaghan Dental Centre
Undertaking Name:	Colm Smith Dental Unlimited Company
Address of Ionising Radiation Installation:	Plantation Road, Monaghan, Monaghan
Type of inspection:	Announced
Date of inspection:	12 July 2021
Medical Radiological Installation Service ID:	OSV-0006494
Fieldwork ID:	MON-0033345

## About the medical radiological installation:

Colm Smith Dental Unlimited Company operates two dental practices, Colm Smith Dental, Cootehill and Monaghan Dental Centre. Colm Smith Dental Unlimited Company at Monaghan Dental Centre offers a full spectrum of dental treatments and conducts a range of dental X-rays, including orthopantomograms (OPGs) and lateral cephalometric radiographs.

## 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
Monday 12 July 2021	13:00hrs to 14:30hrs	Kirsten O'Brien	Lead

## Summary of findings

On the day of inspection, management and staff at Colm Smith Dental Unlimited Company (Colm Smith Dental) clearly described the allocation of responsibility for the radiation protection of service users at Monaghan Dental Centre. This allocation of responsibility was also clearly outlined in documentation submitted to HIQA in advance of the inspection. The inspector was satisfied that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice. Additionally all referrals for dental radiological procedures were in writing.

A recognised medical physics expert (MPE) was appropriately involved and provided medical physics expertise as required by the regulations at Monaghan Dental Centre. A quality assurance programme had been implemented and maintained with a quality assurance (QA) assessment of all dental radiological equipment carried out every two years by an MPE. The inspector also found that preventative maintenance and servicing of dental radiological equipment had been carried out at the practice by the vendor. Diagnostic reference levels (DRLs) had also been established, which had regard for the national DRLs.

Written protocols had been established at the practice and were available in each surgery. A review of records on the day of inspection found that information relating to patient exposure formed part of patients' reports. This had recently been identified by Colm Smith Dental as an area for improvement and policies have been updated to ensure that information relating to patient exposure is included on all reports going forward. Clinical audits related to dental exposures had also been carried out at the practice

Overall, there was a high level of compliance at Monaghan Dental Centre which provides assurance regarding the safe delivery of dental exposures at the practice.

### Regulation 4: Referrers

From a review of documentation and speaking with management at the practice, 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

An inspector spoke with staff and reviewed a sample of records and other documentation and found that only registered dentists took clinical responsibility for dental radiological exposures at the practice.

Judgment: Compliant

### Regulation 6: Undertaking

From communicating with staff on the day of inspection, the inspector was satisfied that a clear allocation of responsibility for the radiation protection of service users had been provided by Colm Smith Dental. Documentation, including a diagram of the allocation of responsibility, was also reviewed. Management informed inspectors that the oversight arrangements at the practice had been clearly communicated to all staff working at Monaghan Dental Centre and that all associate dentists were practitioners at the practice operating under the governance of Colm Smith Dental. Colm Smith Dental had documented the allocation of responsibility to each practitioner which also included dental council registration information.

Management also informed the inspector that prior to the current public health emergency, regular staff meetings had been held where radiation protection issues were discussed and the intention is to resume such meetings in the future. As an interim measure, all policy updates and other issues were communicated to all staff by email and a virtual meeting had also been held. A clear method of communication to facilitate shared learning and important updates is important to ensure a standardised and coherent approach to radiation protection of service users. Additionally, a regular forum for discussion of radiation protection matters was seen as a positive additional assurance mechanism for undertakings to strengthen their governance, management and oversight arrangements for dental exposures, especially where undertakings have more than one dental practice.

Judgment: Compliant

### Regulation 8: Justification of medical exposures

A sample of patient records and other documentation were reviewed on the day of inspection. All referrals for dental X-rays were in writing and were accompanied by the reason for the exposure and sufficient clinical data. Additionally, the practice had a policy in place for accepting external referrals at Monaghan Dental Centre.

Information about the risks and benefits of dental radiological procedures was available to service users in the form of posters in the waiting room. Additionally, staff at the practice informed the inspector that practitioners also spoke to service

users before an X-ray was conducted and provided further information about dental exposures as necessary.

Judgment: Compliant

### Regulation 9: Optimisation

On the day of inspection, the inspector was satisfied that all dental radiological procedures conducted at the practice were optimised. Staff at Monaghan Dental Centre informed inspectors about how the practical aspects of orthopantomograms (OPG) procedures and other dental X-rays were optimised to ensure that all exposures were as low as reasonable achievable. Clinical audits which assessed the consistent production of adequate diagnostic information had also been carried out. Additionally, a QA programme had been implemented with included an assessment of patient dose.

Judgment: Compliant

### Regulation 10: Responsibilities

From speaking with management, and reviewing documents and other records, the inspector was satisfied that only registered dentists took clinical responsibility for dental radiological procedures at Monaghan Dental Centre. Similarly, the referrer and practitioner, who were the same person, were involved in the justification process. The medical physics expert (MPE) and the practitioner were also involved in the optimisation process for all dental exposures.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs had been established for dental radiological procedures conducted at Monaghan Dental Centre. These DRLs reflected national DRLs and were available at the X-ray controls in each surgery.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols had been established for standard dental radiological procedures carried out at the practice. 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 Monaghan Dental Centre.

On the day of inspection, information relating to patient exposure formed part of the report of the dental radiological procedure. The inspector was informed by management that they had recently updated their policies to ensure that information related to the patient exposure was included on the report of each dental radiological procedure. The proactive identification of this area for improvement and implementation of corrective actions to achieve compliance was seen as an example of good practice.

Additionally, a sample of clinical audits conducted at Monaghan Dental Centre were reviewed by the inspector. 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

The inspector reviewed records and documentation and spoke with staff and found that all dental radiological equipment at Monaghan Dental Centre was kept under strict surveillance with regards to radiation protection. Colm Smith Dental had implemented and maintained an appropriate QA programme which included a quality assurance assessment every two years by an MPE. This quality assurance assessment also included an assessment of patient doses.

Records of services by the vendor of dental radiological equipment at the practice, carried out for preventative and maintenance purposes, were also reviewed. Regular preventative maintenance and servicing is important to ensure that all dental radiological equipment is maintained in good working condition, as per the manufacturers' instructions.

Judgment: Compliant

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

Documentation and policies relating to the the record keeping of accidental and unintended exposures were reviewed by the inspector. Additionally, staff and



management at Monaghan Dental Practice communicated the process for recording any events involving, or potentially involving, accidental or unintended dental exposures at the practice.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Colm Smith Dental had appropriate arrangements in place to ensure the continuity of medical physics expertise at Monaghan Dental Centre.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

On the day of inspection, the undertaking, Colm Smith Dental had ensured that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users at Monaghan Dental Centre. The MPE was found to contribute to optimisation, including the establishment of DRLs, evaluation of dose delivered to service users, quality assurance and training of staff at the practice.

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 Monaghan Dental 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>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	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 Monaghan Dental Centre OSV-0006494

Inspection ID: MON-0033345

Date of inspection: 12/07/2021

## 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>