



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dental Surgery
Undertaking Name:	Amelia Davis
Address of Ionising Radiation Installation:	6 Abbeyville, Station Road, Adare, Limerick
Type of inspection:	Announced
Date of inspection:	09 February 2023
Medical Radiological Installation Service ID:	OSV-0006764
Fieldwork ID:	MON-0038980

About the medical radiological installation:

This radiological installation is film based. There is one intra-oral machine only which is located in the dental surgery. The dental surgery operates on a part-time basis only. The types of dental X-rays taken include periapical, bite-wing and occasionally occlusal radiographs provided mainly to adult service users.

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
Thursday 9 February 2023	10:00hrs to 11:15hrs	Kay Sugrue	Lead

Summary of findings

The inspector viewed patient records and documentation and spoke to the dentist during the course of the inspection carried out at Dental Surgery on the 9 February 2023. The evidence gathered demonstrated a high level of compliance with the regulations assessed during this inspection. The inspector found that Dental Surgery had policies and procedures in place for the radiation protection of service users undergoing dental X-rays. This included the clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation. There was one dentist who was the owner, the sole practitioner and referrer operating from this facility. The inspector found that the undertaking had ensured that a medical physics expert (MPE) was engaged for this service and there were appropriate arrangements in place to ensure the continuity of access to MPE specialist advice as required. The process for the management of accidental and unintended exposures was evident in documentation viewed and articulated by staff to the inspector.

The inspector found there was a process in place to record justification in advance for each dental X-ray conducted at this facility. Clinical audit was undertaken, results of which were viewed by the inspector. Diagnostic reference levels (DRLs) had been established, were in use and corrective actions taken for DRLs found to be consistently above national DRLs. The inspector found that dental X-ray equipment had undergone quality assurance (QA) by a MPE and was also serviced by an engineer in October 2022. However, regular quality control checks of equipment were not routinely carried out or evident in documentation viewed which impacted on compliance with Regulation 14.

Overall, the inspector found that the undertaking, Dr Amelia Davis, demonstrated a commitment to ensuring that appropriate systems were in place for the radiation protection of service users undergoing medical radiological exposures at Dental Surgery.

Regulation 4: Referrers

The inspector reviewed professional registration records of the dentist for this facility and spoke with the dentist who was also the undertaking for Dental Surgery. From the evidence gathered, the inspector was satisfied that the dentist, as a sole practitioner, acted as the referrer for all dental X-rays undertaken at this practice.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that the dentist for this practice acted as practitioner with clinical responsibility for medical exposures conducted at Dental Surgery, thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found from records reviewed and discussions with the undertaking, that there was a clear allocation of responsibility for the radiation protection of services users which was reflected in documentation viewed as required by Regulation 6(3). The undertaking had ensured that there were appropriate policies, procedures and guidelines to support radiological practices at this facility.

The undertaking had also ensured a MPE was engaged for the service and MPE involvement was proportionate to the radiological risk posed by the service. Records viewed showed that radiation protection refresher training had recently been completed by the dentist of this practice.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector reviewed a sample of hard copy records of medical radiological procedures conducted in this facility and spoke to staff responsible for performing the X-rays there. All referrals reviewed by the inspector on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient clinical data to inform the justification process. Previous imaging was stored in each patient record and justification in advance was also clearly documented as per the requirements of this regulation.

Information for service users on the the risks and benefits associated with exposure to ionising radiation from X-rays were displayed in the dental surgery.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that the dentist who was the referrer and practitioner at Dental Surgery justified and took responsibility for all medical exposures to ionising radiation conducted there. In addition, the inspector was satisfied that the MPE and the dentist were involved in the optimisation process.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs for intraoral dental Xrays were established as per Regulation 11(5). These local DRLs were displayed in the dental surgery and viewed by the inspector. The inspector noted that local DRLs were marginally above national DRLs. The inspector was informed by the undertaking that a review was carried out in consultation with the MPE. This review included optimisation of the dose to the service user and resulted in the reduction of the facility DRL to its current level, without compromising the image quality of the exposure. These actions taken by the undertaking demonstrated a commitment to the optimisation of protection and safety of service users as per Regulation 11(6).

Judgment: Compliant

Regulation 13: Procedures

From documentation viewed and discussions with staff, the inspector found that the undertaking met the requirements set out in Regulation 13. For example, the radiation safety procedures viewed included protocols for all standard medical radiological procedures carried out in this practice as per Regulation 13(1). Referral criteria applied for each of these procedures was also clearly evident in documentation viewed and articulated by the dentist. Information relating to the patient exposure was contained in the dental X-ray reports viewed. There was sufficient documentary evidence to show that regular clinical audit was undertaken and corrective actions implemented as required.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided to the inspector as requested in advance of the inspection. Documentation reviewed and discussion with the

undertaking demonstrated that medical radiological equipment had been subject to performance testing by a MPE and maintenance of this equipment had also been completed by a service engineer in October 2022. The reports viewed showed that equipment was maintained in satisfactory working order and fit for clinical use. However, the inspector found that regular quality control checks by staff at the practice were not routinely carried out as per Regulation 14(3)(b), therefore greater assurance is needed to ensure that equipment is kept under strict surveillance by the undertaking as required by Regulation 14(1).

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector discussed the process for the management of accidental and unintended exposures and significant events with the undertaking and reviewed the associated policy and incident reporting template. Staff informed the inspector that no radiation safety incidents had occurred at Dental Surgery. The evidence gathered satisfied the inspector that there was an appropriate system in place to identify and manage an incident or near miss should one occur thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documented arrangements which demonstrated that the undertaking had appropriate continuity arrangements in place to ensure this service had access to a MPE if needed and as required by Regulation 19(9).

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The medical physics expert's (MPE) up-to-date professional registration certificate was viewed by the inspector which provided evidence that a MPE supported this service as per Regulation 20(1).

Evidence viewed in documentation and discussion with the undertaking demonstrated to the inspector that the MPE fulfilled a range of responsibilities as per Regulation 20(2) relevant to the practice. These included optimisation, application

and use of DRLs and the QA of medical radiological equipment.

Judgment: Compliant

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

From discussions with the undertaking and documentation viewed, the inspector found that level of involvement of the MPE at Dental Surgery was appropriate and proportionate to the radiological risk posed by this dental practice, thereby complying with 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
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	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 Dental Surgery OSV-0006764

Inspection ID: MON-0038980

Date of inspection: 09/02/2023

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 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: The medical radiological equipment will be checked in house on a monthly basis and inspected for any obvious electrical faults such as frayed cables/damaged plugs and keep record of these in-house inspections.</p> <p>On an annual basis to have medical radiological equipment checked and validated by service engineer.</p> <p>On a biannual basis engage the services of RPA to provide report on the medical radiological equipment.</p>	

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 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	01/03/2023
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	01/03/2023