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:	Zita Geaney Dental Care
Undertaking Name:	Zita Geaney Dental Care
Address of Ionising Radiation Installation:	1 Clover Lawn, Skehard Road, Blackrock, Cork
Type of inspection:	Announced
Date of inspection:	02 March 2023
Medical Radiological Installation Service ID:	OSV-0007978
Fieldwork ID:	MON-0038977

About the medical radiological installation:

At Zita Geaney Dental Care we take intra-oral radiographs. A maximum of 40 intra-oral exposures are taken per month.

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[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] 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 2 March 2023	11:55hrs to 13:25hrs	Kay Sugrue	Lead

Summary of findings

An inspection of Zita Geaney Dental Care was carried out by an inspector on 2 March 2023. This inspection was initiated as a result of the non-return of a regulatory dental self-assessment questionnaire requested by HIQA.

Documentation viewed and discussion with the undertaking satisfied the inspector that the undertaking was compliant with Regulations 4, 5, 8,10,13, 17, 19, 20 and 21 however, the undertaking needed to take further action to become fully compliant with Regulations 6, 11 and 14.

The inspector found that Zita Geaney was the undertaking for this practice and as the only dentist working there, acted as the referrer and practitioner taking clinical responsibility for all medical exposures conducted in this service. Formal arrangements were in place that demonstrated a medical physics expert (MPE) was appropriately involved in this service with a provision ensuring the continuity of access to the MPE also evident. The inspector was satisfied from documentation viewed and discussion with the undertaking that a clear allocation of responsibilities for medical exposures was in place as per Regulation 6(3). However, as part of the allocation of responsibilities, the undertaking must also ensure there are effective means to facilitate communication between the undertaking and HIQA. This was an area that required further attention by the undertaking to ensure that the established communication pathways are maintained and regularly monitored.

The undertaking had ensured that justification of dental X-rays was recorded in patient records which was verified by the inspector in a sample of dental X-ray records reviewed during the inspection. Radiation Safety Procedures viewed demonstrated that there was a process in place for the management of accidental and unintended exposures should any arise. The inspector saw evidence that clinical audit was undertaken in this practice. There was also documentary evidence provided demonstrating that facility DRLs had been established and recently reviewed as per Regulation 11(5). However, the inspector identified that facility DRLS were not accessible at the point of care and staff awareness on their use in daily practice could be improved following this inspection.

The inspector saw evidence to show that an appropriate quality assurance (QA) programme for medical radiological equipment had been defined and the equipment was deemed fit for clinical use following QA by a MPE. Regular in-house QA was also evident in records provided to the inspector. However preventative maintenance of medical radiological equipment had not been carried out within defined time frames as recommended by the manufacturer. The undertaking must therefore implement and maintain all elements of the QA programme to ensure equipment in use is kept under strict surveillance as per Regulation 14(1).

Overall, the inspector found the undertaking had achieved good compliance with the regulations. While there are some areas for improvement outlined in this report,

they did not compromise the radiation protection of service users. The inspector was assured by the steps taken by the undertaking thus far, to address gaps in compliance regarding the safe delivery of dental exposures at the practice.

Regulation 4: Referrers

From discussions with the undertaking and review of professional registration documentation, the inspector was satisfied that referrals were from a registered dentist. Referrals originated internally and external referrals were not accepted in this dental practice.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that the dentist, as the sole practitioner in this service, took clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found that the undertaking had ensured that persons recognised under Regulation 4 and Regulation 5 acted as the referrer and practitioner in this facility. The inspector was satisfied from documentation viewed and discussion with the undertaking that a clear allocation of responsibilities was in place as per Regulation 6(3) for the conduct of medical exposures. This included formal arrangements demonstrating that a MPE was appropriately involved in this service. However, as part of the allocation of responsibility, the undertaking should ensure that there are appropriate communication channels maintained to ensure communication to and from HIQA. This is an area that requires attention as evident in the failure of the undertaking to submit a regulatory dental self-assessment questionnaire requested by HIQA previously in 2022 and again in 2023 prior to this inspection.

Medical radiological facilities planning to conduct medical exposures to ionising radiation are required to notify HIQA one month before commencing practices as required by Regulation 6(1). The inspector found from a review of medical exposure records conducted between mid October 2020 and early February 2021 that dental X-rays had been conducted during this period prior to notifying HIQA on 4 February 2021. This finding meant that the undertaking had not declared to HIQA in advance

of conducting X-rays as required and therefore was not compliant with Regulation 6(1).

Overall, the inspector was satisfied that the undertaking had taken sufficient action to address the non-compliance outlined above and demonstrated a strong commitment during the inspection to address the gaps in compliance with respect of Regulation 6(3).

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

The inspector reviewed a sample of patient records and found that the undertaking had a process in place to record justification in advance which was evident in each of the records viewed.

Judgment: Compliant

Regulation 10: Responsibilities

Professional registration records and documentation viewed demonstrated that the dentist operating in this service acted in the dual role of referrer and practitioner and was involved in the justification process in addition to taking clinical responsibility for all medical exposures to ionising radiation conducted there. The inspector was also satisfied that the optimisation process included the practitioner and MPE as per this regulation.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs for dental equipment at this practice were established, reviewed and compared to national DRLs. The inspector noted that facility DRLs were not readily accessible to the practitioner with responsibility for optimisation at the point of care as per the MPE's recommendation. Therefore greater assurance is required to show that facility DRLS are used locally as per Regulation 11(5). The undertaking informed the inspector that this issue would be addressed immediately.

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspector found the undertaking to be fully compliant with this regulation. For example, written protocols for every type of standard dental radiological procedure conducted in this service were established as per Regulation 13(1) and displayed on the wall beside the dental X-ray equipment. Referral criteria was included in the radiation safety procedures viewed by the inspector which was consistent with the rationale for dental X-rays articulated by the practitioner for this service. The inspector viewed a sample of patient records and found that information relating to the medical exposure was consistently recorded as per Regulation 13 (2). Finally, the inspector saw evidence of a clinical audit schedule for this service and viewed an image quality clinical audit carried out for medical exposures provided in October 2022 thereby demonstrating compliance with Regulation 13.

Judgment: Compliant

Regulation 14: Equipment

An up to date inventory of medical radiological equipment was provided prior to the inspection which was verified on site by the inspector. Records showed that acceptance testing of dental X-ray equipment installed in September 2020 was carried out by a MPE prior to clinical use in line with Regulation 14(3)(a). An appropriate quality assurance programme had been established and outlined in documentation viewed by the inspector. Quality assurance of equipment was carried out by the MPE in October 2022 in line with defined time lines detailed in the QA programme. Records also demonstrated that in-house quality assurance and quality control checks were regularly performed on the equipment by the dentist. However, the inspector found that annual preventative maintenance as recommended by the manufacturer of the equipment and outlined in the QA programme had not been undertaken since the equipment had been commissioned for clinical use. The undertaking informed the inspector that this was an oversight and acted swiftly to address this gap in compliance. Documentary evidence provided after the inspection provided assurance that preventative maintenance was carried out by a service engineer the day after this inspection. The undertaking must ensure that medical radiological equipment in use is kept under strict surveillance as per Regulation 14(1) to ensure all aspects of the programme including regular performance testing are carried out.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector was informed that no incidents relating to accidental or unintended exposure had been identified since commencing practices at this facility. The undertaking described the processes that were in place to manage and report any incidents or near misses should one occur. The processes described were consistent with documented processes viewed by the inspector and also included a radiation incident reporting template.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector found from records viewed prior to and during the inspection that a MPE was engaged to provide expert advice on radiological matters for this practice. The undertaking confirmed that continuity arrangements were also in place, thereby meeting the requirements of Regulation 19(9).

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The medical physics expert's (MPE) up-to-date professional registration certificates were 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 this practice. These included optimisation, establishing and reviewing 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 the level of involvement of the MPE at Zita Geaney Dental Care 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	Substantially Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially 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 Zita Geaney Dental Care OSV-0007978

Inspection ID: MON-0038977

Date of inspection: 02/03/2023

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: I had declared to HIQA on 04/02/2021 and had taken action to comply with this regulation	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: The facility DRL's are readily available and accessible to me at the point of care, as per the MPE's recommendations. I carried this out 02/03/2023	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: The annual preventative maintenance as recommended by the manufacturer of the equipment was carried out - 03/03/2023 and the report was sent to HIQA. I have made arrangements to do this annually as per the manufacturer's regulations.	

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(1)	Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	02/03/2023
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	Substantially Compliant	Yellow	02/03/2023

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	03/03/2023
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	03/03/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	03/03/2023
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance	Substantially Compliant	Yellow	03/03/2023

	testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			