



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dalkey Dental
Undertaking Name:	Dr Hugh O'Broin
Address of Ionising Radiation Installation:	23 Castle Street, Dalkey, Co. Dublin
Type of inspection:	Announced
Date of inspection:	14 March 2022
Medical Radiological Installation Service ID:	OSV-0007036
Fieldwork ID:	MON-0035887

About the medical radiological installation:

Dalkey Dental is a long-established dental practice specialising in family-centred general dentistry. The principal dentist and a part-time associate dentist provide general dental care for adults and children, as well as orthodontics and implant surgery. The practice is located on the upper floor of a two-storey commercial building. It is a two-surgery practice, with an intra-oral X-ray machine in each surgery.

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
Monday 14 March 2022	14:00hrs to 16:00hrs	Agnella Craig	Lead

Summary of findings

This inspection of Dalkey Dental was carried out remotely on 14 March 2022 to assess compliance with the regulations. The inspection was initiated as the undertaking had not submitted a self-assessment questionnaire which was issued as part of HIQA's regulatory assessment process. The inspector was informed that this was an oversight on the undertaking's part and was the result of some email communications not being noticed in a timely manner. Following the announcement of this inspection, the undertaking updated HIQA with the details of a new designated manager to facilitate timely communication between the undertaking and HIQA.

The process of referring and carrying out medical exposures was described by the undertaking. The referrer and practitioner were the same person and the practitioner completed the practical aspects and took clinical responsibility for medical exposures. The inspector was informed that this dental practice did not accept referrals for dental imaging from external sources. On the recent advice of the medical physics expert (MPE), the undertaking had developed policy and procedure documents and had begun to conduct clinical audits. These measures were viewed by the inspector as examples of good practice which may help to provide the undertaking with oversight of the radiation protection of those using this service. The inspector was satisfied that all staff had read the policy documents. However, some documents would benefit from a review and update to ensure full alignment of the day-to-day practice, the documented allocation of responsibilities, and the regulations.

On the day of inspection, the inspector spoke with the MPE who was re-engaged by the undertaking following the announcement of this inspection. The MPE, who was registered with the Irish College of Physicists in Medicine (ICPM), described their recent involvement in this facility and the inspector was satisfied that their level of involvement was now in line with the level of risk posed by a dental service such as this. However, the inspector was informed that an MPE had not been involvement in this practice since the commencement of the regulations in 2019 up to February 2022 when this inspection was announced. The undertaking accepted the lack of continuity in accessing medical physics expertise but had addressed this by making a new arrangement with the MPE service.

Notwithstanding the non-compliances identified in this facility, the inspector was assured by the undertaking's recent actions that they were committed to addressing the compliance gaps to ensure the safe delivery of ionising radiation.

Regulation 4: Referrers

From discussions with management staff and from reviewing documentation provided in advance of the inspection, the inspector was satisfied that only referrals for dental radiological procedures, from individuals entitled to refer as per Regulation 4, were carried out at this facility. The inspector was informed that all referrals for medical radiological procedures came from within this service and the registered dentists acted as both the referrer and practitioner for all medical radiological exposures.

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 this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

From the discussion with the undertaking on the day of inspection, it was clear that the undertaking had allocated clinical responsibility for individual medical exposures to the two dentists who were entitled to act as referrers at Dalkey Dental. Similarly, the inspector was informed that these dentists, registered with the Dental Council, took clinical responsibility for all dental radiological procedures, and were therefore also acting as practitioners. The inspector was informed that the practical aspects of conducting medical exposures were only carried out by these practitioners. However, although the day-to-day practices were in compliance with the regulations, a slight misinterpretation of the regulations was evident in the documentation. The undertaking recognised this and accepted that the documentation provided in advance of this inspection should be updated to clearly reflect the current allocation of responsibilities. Similarly, the documentation should be updated to clearly detail the allocation of key responsibilities to the MPE who was re-engaged for this facility after the inspection was announced.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector was satisfied that only practitioners recognised by the Dental Council took clinical responsibility for all medical exposures to ionising radiation in this

facility.

From speaking with staff and reviewing the documents provided for this inspection, the inspector was satisfied that the optimisation process included the practitioner and the MPE and the justification process for dental exposures involved the dentists acting as both referrer and practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

From the documentation reviewed in advance of the inspection, the inspector was satisfied that DRLs were recently established for the equipment at this dental practice. These DRLs had been reviewed and compared to national DRLs in advance of this inspection.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was provided in advance of this inspection. In addition, the reports of the quality assurance and performance testing of the equipment recently carried out by the MPE were also provided. The inspector noted that the testing had occurred after this inspection was announced and the undertaking confirmed this on the day of inspection. The reports reviewed by the inspector identified that the equipment was safe for clinical use. Evidence of recent testing in March by the service engineer was also provided.

However, up to this time, no records or other evidence of quality assurance or performance testing from an MPE were available since 2016. Therefore, although these issues had recently been rectified by the undertaking, the inspector was not satisfied that medical radiological equipment had been kept under strict surveillance as required by Regulation 14(1), or that performance testing and appropriate quality assurance programmes had been implemented and maintained prior to the announcement of this inspection. Similarly, no evidence was available to demonstrate that an appropriate programme had been implemented to assess dose or that regular performance testing had been carried out.

Although the undertaking was found to be not in compliance with this regulation, the actions taken subsequent to the announcement of this inspection demonstrated that the equipment was safe for clinical use.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Although evidence was provided of an engagement with an MPE service in 2016, no evidence was available of engagement between 2019, when the regulations commenced, to the time this inspection was announced in February 2022. On the day of inspection, the undertaking confirmed that the services of an MPE had lapsed. However, on receiving details of this inspection, the undertaking had re-engaged the services of the MPE.

Management staff acknowledged the requirement for continuity of medical physics expertise and the inspector was informed that an arrangement was now in place with an MPE service to provide continuity.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector recognised the work recently completed by the MPE who was re-engaged after the announcement of this inspection. This work included taking responsibility for dosimetry and optimisation, establishing and reviewing DRLs, and completing performance testing and quality assurance of the medical radiological equipment.

However, before the announcement of this inspection the undertaking had not ensured that an MPE acted or gave specialist advice as required by Regulation 20(1) since the regulations commenced in 2019. Similarly, up to February 2022, an MPE had not taken responsibility for aspects such as dosimetry, optimisation, quality assurance, the surveillance of equipment or training.

Judgment: Not Compliant

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

The inspector was informed that although an MPE had previously been involved in this practice, this engagement had lapsed in recent years. The MPE who spoke with the inspector also confirmed that they had not been involved in this service since before the regulations commenced in 2019. However, management staff communicated to the inspector that arrangements had now been put in place by the undertaking to ensure involvement of the MPE in this service in the future.

Recognising the undertaking's commitment and recent actions taken to address the gaps identified above, the undertaking was found to be substantially compliant with this regulation.

Judgment: Substantially 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 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Compliance Plan for Dalkey Dental OSV-0007036

Inspection ID: MON-0035887

Date of inspection: 14/03/2022

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Undertaking recognises that the Associate Dentist is a practitioner with clinical responsibility. In order to ensure regulatory compliance, the practice policies and procedures are communicated to, and followed by, all practitioners. The practice policies and procedures documents are currently being updated to ensure a clear arrangement is in place between the Undertaking and the Associate Dentist, in accordance with the requirements of Regulation 6(3). The practice policies and procedures documents are currently being updated to clearly detail the allocation of key responsibilities to the MPE.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: The MPE was originally engaged by the Undertaking in 2016, and re-engaged on 17.02.22, to ensure that all medical radiological equipment in use by the Undertaking is kept under strict surveillance regarding radiation protection. A radiation risk assessment, and quality assurance assessment, of the equipment was carried out by the MPE on 18.02.22. A policy is in place to ensure that, going forward, a quality assurance program will be carried out by the MPE at least every 24 months. A quality control policy and procedures are in place to ensure that, since February 2022, all radiological equipment is serviced and maintained in accordance with the manufacturer’s recommendations. The most recent service of the equipment was carried out by a service engineer on 09.03.22. A quality control policy and procedures are in place to ensure that, since February 2022, periodic visual inspections of all radiological equipment are carried out, and recorded, by the Undertaking/RPO.</p>	

A policy and procedures are in place, since February 2022, for each practitioner to carry out, record and review periodic clinical audits. Clinical audits will be meaningful and appropriate, with the objectives being the assessment of radiation dose and the improvement of patient care and outcome.

All radiological equipment is operated by each practitioner in accordance with the manufacturer's recommendations outlined in the equipment manuals

Regulation 19: Recognition of medical physics experts	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:

In accordance with the requirements of Regulations 19(9), the Undertaking has put in place the necessary arrangements to ensure the continuity of expertise of a recognised MPE. The MPE was originally engaged by the Undertaking in 2016, and re-engaged on 17.02.22.

Regulation 20: Responsibilities of medical physics experts	Not Compliant
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Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:

The Undertaking has put in place the necessary arrangements to ensure the continuity of expertise of a recognised MPE. The MPE was originally engaged by the Undertaking in 2016, and re-engaged on 17.02.22. The arrangements with the MPE include the provision of services in accordance with the requirements of Regulation 20(1) and Regulation 20(2)(c).

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:

In accordance with the requirements of Regulation 21(1), the Undertaking has put in place the necessary arrangements to ensure the continuity of expertise of a recognised MPE. The MPE was originally engaged by the Undertaking in 2016, and re-engaged on 17.02.22. A policy is in place to ensure that, going forward, a quality assurance program will be carried out by the MPE at least every 24 months, commensurate with the radiological risk posed by the practice.

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	31/05/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Not Compliant	Orange	17/02/2022

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	17/02/2022
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Orange	17/02/2022
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.	Not Compliant	Orange	17/02/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	17/02/2022
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered	Not Compliant	Orange	17/02/2022

	<p>in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.</p>			
<p>Regulation 20(2)(c)</p>	<p>An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none"> (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the 	<p>Substantially Compliant</p>	<p>Yellow</p>	<p>17/02/2022</p>

	<p>preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.</p>	Substantially Compliant	Yellow	17/02/2022