



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Ballsbridge Dental Clinic
Undertaking Name:	Donal O'Mahony
Address of Ionising Radiation Installation:	26 Wellington Road, Dublin 4
Type of inspection:	Announced
Date of inspection:	26 January 2022
Medical Radiological Installation Service ID:	OSV-0006886
Fieldwork ID:	MON-0034876

About the medical radiological installation:

Ballsbridge Dental Clinic operates 10 days per month as a general dental practice. The service uses intra oral X-ray equipment and X-rays taken include periapical or bite wing X-rays.

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
Wednesday 26 January 2022	12:22hrs to 13:25hrs	Kay Sugrue	Lead
Wednesday 26 January 2022	12:22hrs to 13:25hrs	Lee O'Hora	Support

Summary of findings

A remote inspection of Ballsbridge Dental Clinic was carried out by inspectors on 26 January 2022. Due to the manner in which this inspection was conducted, the focus was limited to the assessment of compliance with the regulations outlined in this report. This inspection was initiated as the result of the non-return of a regulatory dental self-assessment questionnaire requested by HIQA which was acknowledged by the undertaking as an unintentional oversight.

Inspectors found that the undertaking as a sole trader and a registered dentist was the referrer and practitioner taking clinical responsibility for all medical exposures conducted at the dental practice and was therefore compliant with Regulations 4 and 5.

Documentation requested prior to the inspection was not provided within required time lines. The lack of documentation, together with discussion with the undertaking did not provide assurance that there was appropriate allocation of responsibility by the undertaking as required by Regulation 6(3). For example, inspectors determined that a recognised Medical Physics Expert (MPE) had only been engaged by the undertaking to provide consultation and advice as per regulations in the days prior to the inspection. These arrangements as described to inspectors did not provide assurance that they were formalised to provide a sustainable engagement with an MPE in line with Regulation 19(9). In addition, the absence of engagement of an MPE since commencement of the regulations in 2019 up until the 24 January 2022 impacted compliance levels with a number of regulations including 6, 11, 14, 19, 20 and 21.

Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14. Specifically, the undertaking did not ensure that acceptance testing had been carried out by an MPE on medical radiological equipment installed in April 2021 and before it was first used for clinical purposes as required. In addition, there was little evidence to show that there was an appropriate quality assurance programme in place up to the 24 January 2022. However, the measures taken by the undertaking to address regulatory compliance in advance of the inspection provided some assurance of the undertaking's commitment to coming into compliance. In addition, inspectors were informed that Ballsbridge Dental Clinic would take immediate actions to address all advisory and critical actions identified in the MPE quality assurance report submitted to HIQA following this inspection.

Overall, while inspectors acknowledge that the radiological risk of the dental procedures conducted at the dental practice was relatively low, it was clear from discussions with the undertaking that greater attention was required by Ballsbridge Dental Practice to ensure compliance with regulatory requirements is maintained following on from this inspection. The findings of this inspection were acknowledged and accepted by the undertaking during the inspection and a commitment given that

non-compliances outlined would be addressed without delay.

Regulation 4: Referrers

From discussions with management at Ballsbridge Dental Clinic and review of professional registration documentation, inspectors were satisfied that referrals were from a registered dentist. External referrals were not accepted by this dental practice.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that the undertaking ensured that a registered dentist as per the regulations was the referrer and an individual entitled to take clinical responsibility for dental radiological procedures acted as a practitioner at the Ballsbridge Dental Clinic. This meant that some aspects relating to the allocation of responsibility to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) were met. However, more needed to be done to ensure the clear allocation of responsibilities of an MPE at the practice was appropriately maintained as per regulatory requirements. From discussions with the undertaking, inspectors were not satisfied that there were appropriate arrangements in place for the allocation of responsibility of an MPE at the practice since the commencement of the Regulations in 2019 and up to the 24 January 2022. Inspectors were informed by the undertaking that the recent engagement of an MPE was only initiated when prompted by the announcement of this inspection and had yet to be formalised.

Overall, inspectors found that measures taken to address regulatory non-compliance in advance of this inspection demonstrated that the undertaking had initiated steps to address areas of non-compliance at the dental practice. However, inspectors determined that awareness in relation to regulatory requirements with respect of the undertaking responsibilities and the clear allocation of responsibilities needed to be strengthened at Ballsbridge Dental Clinic to enable full compliance to be achieved.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

QA records supplied to inspectors after the inspection clarified that DRLs had been established on 24 Jan 2022, however no evidence was available to demonstrate that these were used. For example, where local facility DRLs were above national DRLs, no evidence was available of further review or corrective action to address this issue. Recommendations relating to DRLs included in the MPE QA report provided to inspectors had not been acted on at the time of inspection.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Ballsbridge Dental Clinic. From discussions with the undertaking and records reviewed, inspectors determined that medical radiological equipment installed in April 2021 had not been subject to acceptance testing by an MPE before clinical use. However, this issue had been addressed by the undertaking prior to the inspection. In addition, an appropriate QA programme, including an assessment of dose, was not implemented and maintained on a regular basis as required by the regulations. These findings were acknowledged by the undertaking during the inspection.

A report of MPE QA testing including acceptance testing undertaken on 24 January 2022 was provided to inspectors following the inspection. This report demonstrated that the equipment was safe for continued clinical use provided the undertaking addressed recommendations contained in the report. Inspectors sought further assurance from the undertaking and received a commitment that all actionable items included in this report would be addressed as a priority.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were not satisfied that Ballsbridge Dental Clinic had put in place the necessary arrangements to ensure the continuity of expertise of an MPE. While the undertaking had taken steps to engage the services of an MPE on the days leading up to the inspection, the undertaking acknowledged to inspectors that an MPE had

only been engaged in response to the announcement of this inspection. The undertaking acknowledged that these arrangements needed to be strengthened to ensure the continuity of medical physics expertise at the dental practice and was committed to rectifying this deficit following on from this inspection to ensure full compliance with this regulation.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions and review of documentation prior to and following this inspection, inspectors were not satisfied that Ballsbridge Dental Clinic had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1). Inspectors found that the absence of engagement of an MPE since the commencement of the regulations in 2019 resulted in deficits in the areas identified in Regulation 20(2), including optimisation, DRLs and the definition and performance of quality assurance of medical radiological equipment. While acknowledging that an MPE had completed QA of medical radiological equipment at the dental practice on 24 January 2022, recommended actions from this report had yet to be completed. The undertaking informed inspectors that all recommended actions included in the MPE report would be fully addressed without delay.

Judgment: Not Compliant

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

Inspectors found that an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019 up to 24 January 2022. Recent arrangements in relation to medical physics expertise service described to inspectors need to be formalised to ensure that an MPE is appropriately involved at Ballsbridge Dental Clinic following this inspection and to ensure full compliance is achieved against this regulation.

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

Compliance Plan for Ballsbridge Dental Clinic OSV-0006886

Inspection ID: MON-0034876

Date of inspection: 26/01/2022

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	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: We have engaged the services of an MPE since 20 January 2022. Site visit and QA testing was completed on 24th of January 2022. We have arranged for biennial site visits and consultation availability at any time in the interim.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: QA testing was completed on Jan 24th 2022. MPE's advice on optimisation was received and acted upon and DRLs established; e.g. radiation dose at cone tip for a maxillary molar at 1.2 mGy for an adult, using fast film. Diagnostic reference levels will be reviewed every two years by the MPE or more often if there's a change in equipment or practice.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:</p>	

The MPE has now been engaged for advice on a continuing basis since 20 January 2022. QA testing was completed on 24th January 2022. The MPE will be asked to review the performance of our equipment every two years and will advise of any need for replacement if necessary. Our current radiation equipment is brand new and state of the art.

Regulation 19: Recognition of medical physics experts	Not Compliant
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Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:
 We have engaged the services of the MPE for advice on a continuing basis. Our MPE is ICPM registered and has qualified peers to assist in the event of not being available at any time, thus ensuring continuity of support to our practice.

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 MPE has been engaged on a continuing basis from 21 January 2022. The MPE will also act as our RPA service. QA testing was completed on 24th January 2022. The MPE's advice was received and acted upon in relation to definition and performance of appropriate quality assurance of our dental radiological equipment. The MPE will be engaged for advice on a continual basis. QA testing was completed and the report acted upon. The MPE's advice on optimisation was received and acted upon immediately. DRLs have been established and put in place. The MPE assessment will be done every 2 years or more frequently if needed. No accidental or unintended exposures have occurred at our practice. The MPE is available to advise in the event of an incident.

Regulation 21: Involvement of medical	Not Compliant
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physics experts in medical radiological practices	
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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:

The MPE has been engaged for advice on a continual basis.

QA testing and compliance review was completed on 24th January 2022 and all recommendations were put into effect.

We are committed to twice yearly review of equipment performance and compliance by the MPE.

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.	Not Compliant	Orange	30/01/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	30/01/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Orange	24/01/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	24/01/2022
Regulation 14(3)(a)	An undertaking shall carry out the following testing on its medical radiological equipment, acceptance testing before the first use of the equipment for clinical purposes; and	Not Compliant	Orange	24/01/2022
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	Not Compliant	Orange	24/01/2022

	affect the equipment's performance.			
Regulation 14(4)	A person shall not use medical radiological equipment for clinical purposes unless testing in accordance with paragraph (3)(a) has been carried out.	Not Compliant	Orange	24/01/2022
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.	Not Compliant	Orange	30/01/2022
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.	Not Compliant	Orange	21/01/2022
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or	Not Compliant	Orange	24/01/2022

	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.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Orange	21/01/2022
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Orange	21/01/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological	Not Compliant	Orange	21/01/2022

	<p>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 preparation of technical specifications for medical radiological equipment and installation design;(v) the surveillance of the medical radiological installations;(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;(vii) the selection of equipment			
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	<p>required to perform radiation protection measurements; 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>	Not Compliant	Orange	21/01/2022