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:	Phibsboro Dental Care
Undertaking Name:	Phibsboro Dental Care
Address of Ionising Radiation Installation:	22 Phibsboro Shopping Centre, Phibsboro, Dublin 7
Type of inspection:	Announced
Date of inspection:	22 February 2022
Medical Radiological Installation Service ID:	OSV-0007143
Fieldwork ID:	MON-0035864

About the medical radiological installation:

As part of routine general dental practice, intra-oral radiographs including bitewing and periapical radiographs are conducted at this service.

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
Tuesday 22 February 2022	12:00hrs to 13:30hrs	Lee O'Hora	Lead

Summary of findings

An inspection was conducted remotely by an inspector on the 22 February 2022 to assess compliance against the regulations. This inspection was initiated as a result of the failure of the undertaking to submit a completed regulatory self assessment questionnaire to HIQA when requested to do so.

The inspector was assured that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibly for dental radiological procedures at the practice and that a recognised medical physics expert (MPE) was appropriately involved to provide consultation and advice as required by the regulations.

After speaking with staff and reviewing communications with the MPE, the inspector was satisfied that radiological equipment at the practice was kept under strict surveillance regarding radiation protection. However records of service engineer and electrical supply reviews were not available at the time of inspection. In order to ensure full regulatory compliance the undertaking must retain all records in relation to radiological equipment and provide these records to the Authority on request.

Overall, for the specific regulations considered by the inspector, there were areas of good practice noted on inspection. For example a number of documented MPE recommendations made in June 2021, relating specifically to regulatory compliance, had been implemented by the undertaking at the time of inspection.

Regulation 4: Referrers

From speaking with the undertaking on the day of 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 the practice. Up to date professional registration documentation was requested and subsequently supplied to the inspector for all dentists working at the practice.

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 the dental practice. Professional registration for all practitioners was reviewed by the inspector and

satisfied requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Phibsboro Dental Care operated as a partnership. During the inspection, staff spoken with clearly articulated allocation of responsibility and associated communication pathways for the radiation protection of service users attending the practice. Only referrals from individuals entitled to refer as per the regulations were conducted at the practice. Similarly, only individuals entitled to take clinical responsibility for dental radiological procedures acted as practitioners. The inspector was satisfied that the undertaking allocated responsibility to an MPE to provide consultation and advice on matters relating to medical physics as required by the regulations.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed the MPE QA report, which established local facility DRLs and compared with national DRLs, dated 7 June 2021. The records reviewed indicated that local facility DRLs had been reviewed with support from the MPE. For one examination which was above the national reference value, an investigation concluded that further optimisation was limited due to the age of the equipment and to prevent compromising the diagnostic quality of radiological images.

The inspector was assured that DRLs were established and reviewed, subsequent investigations of local facility DRLs exceeding national DRLs involved the appropriate staff and established that no further corrective actions were available at the time of inspection.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for standard dental radiological procedures were supplied to the inspector, these were bespoke for the practice and equipment. The inspector noted after document review and confirmed on site with staff that these protocols were established as a result of actions recommended in the MPE's quality assurance (QA)

report dated 7 July 2021. This was seen as a positive use of MPE's specialist advice by the undertaking to ensure regulatory compliance in relation to Regulation 13(1).

Judgment: Compliant

Regulation 14: Equipment

Documents reviewed by the inspector mandated the routine assessment of dental radiological equipment every two years by the MPE. QA records dated 7 June 2021 were supplied to the inspector. QA documentation noted the need for further investigation by the undertaking of an equipment performance measure that was found to be slightly outside of tolerance. The MPE report suggested that this may be caused by a fluctuating power supply and should be investigated further by the service engineer.

The inspector was subsequently informed that the service engineer agreed with the MPE and advised that the undertaking have an electrician investigate the power supply. The inspector was informed that the power supply to the practice was then reviewed by the electrical supplier and was deemed to be a feature of the dated power supply to the entire business complex, an issue that the undertaking could not address. However, records evidencing the input and findings of the service engineer or electrician were not available for review at the time of inspection.

The inspector subsequently reviewed e mail communications between the undertaking and the MPE detailing patient dose and image quality assessment, by the MPE, which established that the highlighted electrical supply issue was not adversely affecting the radiation safety or diagnostic performance of the unit.

Although the inspector was satisfied that the equipment performance issues raised by the MPE were addressed appropriately by the undertaking, all records in relation to equipment must be retained and provided to the authority on request to ensure that the undertaking meets full regulatory compliance. In addition, the undertaking should maintain additional vigilance on the performance of the X-ray equipment noting the circumstances concerning the electrical supply to the building.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The inspector spoke with staff and reviewed documentation and records relating to the provision of medical physics expertise at the dental practice and was assured that the undertaking had arrangements in place to ensure the continuity of medical physics expertise at the dental practice.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector spoke with staff and reviewed documentation and found that appropriate measures were in place on the day of inspection to ensure that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users. Documentation reviewed gave further assurances that the MPE's responsibilities, advice and contributions aligned well with regulatory requirements under regulation 20.

Judgment: Compliant

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

From speaking with staff and from a review of documentation provided, the inspector was satisfied that Phibsboro Dental Care ensured that an MPE was appropriately involved with the provision of service at the time of inspection.

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 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially 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 Phibsboro Dental Care OSV-0007143

Inspection ID: MON-0035864

Date of inspection: 22/02/2022

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 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: A new protocol for record keeping in relation to all equipment, MPE, services, electrical supply issues and any relevant factors has been put in place immediately following inspection. A dedicated file securely stored on site contains all original records or copies. Scanned copies are also saved on practice computers. Any and all documents relating to the radiography equipment are stored here, from commissioning, including validation and testing, servicing and any issues. This is stored alongside similar documents such as practice safety statements, dentists registrations etc. Each administrative staff member is aware of this new protocol and how to record and store any records. The overall responsibility for this record keeping is with the practice principal dentist.	

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(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.	Substantially Compliant	Yellow	22/02/2022