



**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:	The Plaza Dental Practice
Undertaking Name:	The Plaza Dental Practice
Address of Ionising Radiation Installation:	Unit 13 The Plaza, Main Street, Blanchardstown Village, Dublin 15
Type of inspection:	Announced
Date of inspection:	01 March 2022
Medical Radiological Installation Service ID:	OSV-0007168
Fieldwork ID:	MON-0035865

About the medical radiological installation:

The Plaza Dental Practice carries out complex diagnostic, surgical, endodontic and implant dentistry in Blanchardstown Village, Dublin. Medical radiological imaging, which includes dental radiography (X-rays), orthopantomogram (OPG) and cone-beam computed tomography (CBCT) is conducted at the practice.

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
Tuesday 1 March 2022	12:00hrs to 12:30hrs	Kirsten O'Brien	Lead

Summary of findings

An inspection was conducted remotely on the 1 March 2022 to assess compliance against the regulations. This inspection was carried out because the undertaking had not submitted a regulatory self-assessment questionnaire when requested by HIQA.

On the day of inspection, management at The Plaza Dental Practice clearly described the allocation of responsibility for the radiation protection of service users attending the practice. This allocation of responsibility was also clearly outlined in documentation submitted to HIQA in advance of the inspection and included information about who can act as a practitioner, refer for, and conduct dental radiological procedures, including cone beam computed tomography (CBCT) at the practice. From the documentation reviewed, and communicated with management, the inspector was satisfied that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice.

A recognised medical physics expert (MPE) was appropriately involved and provided medical physics expertise as required by the regulations at The Plaza Dental Practice. The inspector also found that quality assurance (QA) testing was carried out every two years by an MPE. However, the inspector was not satisfied that preventative maintenance and servicing of dental radiological equipment by the vendor had been carried out on radiological equipment at the practice. Regular preventative maintenance and servicing is important to ensure that all dental radiological equipment is maintained in good working condition. Additionally, while the inspector was satisfied that diagnostic reference levels (DRLs) had been established, the undertaking must take steps to ensure that where individual DRLs at the practice exceed the relevant national DRL, a review to ensure the optimisation of dental radiological procedures, with implementation of appropriate corrective actions where required, is carried out.

Written protocols were available for each type of standard procedure and selection criteria (referral guidelines) were available to referrers at the practice. Clinical audits had also been carried out at the practice. The conduct of clinical audit is seen as a positive measure which allows undertakings to identify areas of good practice and areas for improvement in order to ensure safe delivery of dental exposures to service users.

Overall, the inspector found a good level of compliance at The Plaza Dental Practice, and was assured that appropriate governance and management arrangements were in place to ensure the safe delivery of dental radiological procedures at the practice.

Regulation 4: Referrers

From a review of documentation and speaking with management at the practice, 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.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

A clear allocation of responsibility for the radiation protection of patients was in place at The Plaza Dental Practice. The inspector reviewed documentation provided in advance of the inspection and spoke with a representative from the undertaking who clearly communicated the management and oversight structure in place for dental exposures to ionising radiation at the practice. Information about who can act as a practitioner, refer for, and conduct dental radiological procedures, including CBCT, was included in the practice's documentation. This was noted as a positive measure to ensure the clear allocation of responsibility for the radiation protection of service users at the practice.

Judgment: Compliant

Regulation 10: Responsibilities

From speaking with management, and reviewing documents and other records, the inspector was satisfied that only registered dentists took clinical responsibility for dental radiological procedures at The Plaza Dental Practice. Similarly, the practitioner with clinical responsibility for the conduct of CBCT procedures had completed specific training for that purpose and the certificate of completion for this training was available for review during the inspection.

The inspector was also satisfied that the referrer and practitioner, who were the

same person in some cases, were involved in the justification process. The MPE and the practitioner were involved in the optimisation process for all dental exposures. The inspector was also informed that practical aspects of dental radiological procedures were only conducted by a practitioner and were not delegated to other individuals at the practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Documentation and records in relation to the DRLs were provided to the inspector in advance of the inspection. The inspector found that DRLs had been established for dental radiological procedures conducted at The Plaza Dental Practice. However, where individual practice DRLs were found to exceed the relevant national DRLs, the undertaking had not carried out an appropriate review to ensure the optimisation of protection and safety of the dental radiological procedures for patients. This finding was discussed with management at the practice on the day of inspection and an assurance was provided to the inspector that the undertaking would carry out this review in a timely fashion.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols had been established for standard dental radiological procedures carried out at the practice. Written protocols can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice. Referral guidelines (selection criteria) were also available for referrers at The Plaza Dental Practice.

Additionally, a sample of clinical audits conducted at the practice were reviewed by the inspector. Clinical audit is an important tool which allows undertakings to identify areas of good practice and areas for improvement in order to ensure safe delivery of dental exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

The Plaza Dental Practice had implemented a quality assurance programme at the

practice which included a quality assurance assessment of the radiological equipment and an assessment of patient doses every two years by an MPE . An up-to-date inventory of dental radiological equipment was also available for review by the inspector.

However, the inspector was not satisfied that dental radiological equipment at the practice received regular services for preventative and maintenance purposes and that no schedule for such services was in place at the time of inspection. To ensure that all dental radiological equipment is maintained in good working condition, regular preventative maintenance and servicing, as per the manufacturers' instructions, should be carried out in line with codes of best practice.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation and policies relating to accidental and unintended exposures were reviewed by the inspector. Additionally, management at The Plaza Dental Practice communicated the process for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures at the practice.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The Plaza Dental Practice had engaged a recognised MPE and the inspector was assured that the practice had appropriate access to medical physics expertise as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, The Plaza Dental Practice had ensured that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users at the practice. The MPE was found to contribute to optimisation, including the establishment of DRLs, evaluation of dose delivered to service users and quality assurance at the practice.

Judgment: Compliant

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

The inspector found that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at The Plaza Dental Practice.

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 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 The Plaza Dental Practice OSV-0007168

Inspection ID: MON-0035865

Date of inspection: 01/03/2022

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 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <p>I have discussed reducing the DRL for a maxillary molar with the technical people at our supplier. They have suggested using a shorter acquisition time of 7 seconds and increasing the voxel size from 150 to 300 plus reducing the mA from 5mA to 3.2mA. This will reduce the machine based mGy reading from 665mGy to 199mGy. Pending advice from my RPA I have decided to make this part of the new maxillary molar protocol pending the approval of my RPA. I am awaiting a response from our RPA XX and will confirm this alteration to our protocol as soon as XX gives their opinion</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:</p> <p>All our X-ray equipment had a physical inspection on 12th March by our supplier who confirmed that they were all in condition as appropriate for their use as recommended by the manufacturer. We have arranged to have annual physical inspections of all our X-ray equipment by our supplier on an ongoing basis.</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 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Orange	12/04/2022
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	Substantially Compliant	Yellow	12/03/2022

	maintenance procedure liable to affect the equipment's performance.			
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