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:	Dublin Orthodontics - Swords
Undertaking Name:	Dublin Orthodontics
Address of Ionising Radiation Installation:	29-31 North Street, Swords, Co. Dublin
Type of inspection:	Announced
Date of inspection:	23 October 2024
Medical Radiological Installation Service ID:	OSV-0007297
Fieldwork ID:	MON-0044641

About the medical radiological installation (the following information was provided by the undertaking):

Dublin Orthodontics – Swords is a specialist orthodontic practice. We see children, adolescents and adults for orthodontic fixed appliances and orthodontic aligner therapy, we also carry out some lingual fixed orthodontics. Dublin Orthodontics – Swords carries out in-house referrals for radiographic imaging. The X-ray room houses a digital Planmeca orthopantomography (OPG)/cephalometric (Ceph) X-ray unit.

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, as amended. 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
Wednesday 23 October 2024	10:30hrs to 13:45hrs	Kirsten O'Brien	Lead
Wednesday 23 October 2024	10:30hrs to 13:45hrs	Agnella Craig	Support

Summary of findings

An inspection of Dublin Orthodontics at Dublin Orthodontics - Swords was carried out by inspectors on the 23 October 2024 to assess compliance against the regulations. On the day of inspection, inspectors found that only Orthopantomography (OPG) and Cephalometric X-ray procedures were carried out at the practice. As part of this inspection, inspectors reviewed documentation and records and spoke with staff and management at the practice.

From the evidence reviewed as part of this inspection, inspectors found that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibly for medical radiological procedures at the practice. However, some gaps were identified in the referral records. Inspectors found that a referral in writing from an easily identifiable referrer was not available in all cases on the day of inspection. Similarly, improvements in the allocation of responsibility for positioning of patients were also required so that all elements of the practical aspects are only conducted by appropriate individuals to ensure full compliance with the regulations. Overall, Dublin Orthodontics should review the allocation of responsibilities and ensure that these are clearly documented and implemented at the practice in line with regulatory requirements.

The undertaking, Dublin Orthodontics, had ensured that a medical physics expert (MPE) was available to provide medical physics expertise in relation to the radiation protection of service users at the practice. Inspectors also found that preventative maintenance and servicing of X-ray equipment had been carried out annually at the practice, and quality assurance testing by an MPE was carried out every two years.

Local facility diagnostic reference levels (DRLs) had been established and reviewed with regard to the national DRLs where available. As part of the review of records, inspectors identified that the radiation dose displayed by the equipment exceeded the doses established by the MPE for the local facility for OPG procedures. Following the inspection, the undertaking provided evidence that a review of doses had been carried out by the MPE and all doses delivered to patients where in line with local facility and national DRLs. The timely nature of this review by the undertaking and MPE following the inspection was noted by inspectors as positive and demonstrated the undertaking's commitment to radiation protection at the practice.

Overall inspectors were satisfied that the undertaking had oversight measures in place, notwithstanding the issues identified which need to be addressed in order to come fully into compliance with the regulations assessed.

Regulation 4: Referrers

From a review of documentation and speaking with management at the practice, inspectors were satisfied that referrals for medical 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 practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

During the inspection, management at Dublin Orthodontics - Swords described the allocation of responsibility for the radiation protection of service users attending the practice. Inspectors also reviewed documentation and records regarding the management and oversight structures in place at Dublin Orthodontics. Inspectors found that the undertaking representative was also the designated manager and radiation protection officer and was the person responsible for radiation protection at the practice.

Documentation outlining the allocation of responsibilities for the radiation protection of service users was provided to inspectors, however as an area for improvement, this should be expanded upon to include details and information about who took responsibility for carrying out different roles at the Dublin Orthodontics - Swords. For example, documentation such as the *Policy on Quality Assurance and Quality Control* would benefit from additional information such as which staff members where responsible for different tasks.

In addition, while inspectors were informed that an orthodontist conducted and checked patients' positioning prior to each medical exposure, Dublin Orthodontics should review the allocation of duties for positioning patients to ensure that all elements of the practical aspects are only carried out by persons entitled to be allocated responsibility for the practical aspects.

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, posters were present in the waiting room and dedicated X-ray room to provide information relating to the risks and benefits associated with medical exposures to patients. A sample of records of medical radiological procedures were also reviewed during the on-site inspection, in addition to speaking with staff and management.

Inspectors were informed that a dentist or orthodontist, registered with the Dental Council, referred for and took clinical responsibility for justifying all individual procedures. However, while medical data was available in the patients' notes to allow the practitioner to justify the procedure, inspectors found that referrals for some medical exposures were not always clearly documented in writing by the referrer and therefore a record of justification was not available for every exposure. Similarly, the dentist justifying the procedures was not always easily identifiable and this must be addressed in order to come into compliance with this regulation.

Judgment: Not Compliant

Regulation 10: Responsibilities

From speaking with management, and reviewing documents and other records, the inspectors were satisfied that only registered dentists took clinical responsibility for medical radiological procedures at Dublin Orthodontics - Swords. Similarly, the referrer and practitioner, who were the same person for each exposure, were involved in the justification process.

From discussions with management on the day of inspection, inspectors were informed that while practitioners conducted medical radiological procedures, staff not allocated responsibility for the practical aspects carried out duties such as positioning patients which included the handling and use of the medical radiological equipment. While management at the practice assured inspectors that the orthodontist with clinical responsibility for the medical exposure checked the positioning and conducted the medical exposure, the undertaking should review the allocation of duties to ensure that only those personnel entitled to be allocated responsibility carry out the different elements of the practical aspects of each medical radiological procedure.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for medical radiological procedures conducted at Dublin Orthopaedics - Swords. These local facility DRLs reflected national DRLs and were available at the X-ray equipment controls. These DRLs had been reviewed by the

MPE and the radiation protection officer in April 2024. The DRLs had been assessed and reviewed against the national DRLs as part of the QA programme, however the undertaking was not aware that there was a difference between the dose displayed and the actual radiation dose delivered, as measured by the MPE. As this difference had not been identified or investigated prior to the inspection, Regulation 11(6) was judged as not compliant.

Following the inspection the MPE carried out an assessment of doses delivered and found that these aligned with previously established local facility DRLs. Evidence of this review was provided to inspectors after the inspection who were subsequently assured that the typical doses delivered at the practice were in line with the typical national doses.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols had been established for standard dental radiological procedures carried out at the practice. Inspectors identified that the written procedures were detailed and included step-by-step instructions and clinical indications for both examination types which was seen as good practice. Referral and selection criteria had been identified for use in a policy by the undertaking also. Inspectors also noted that information about the patient dose formed part of the report of the medical radiological procedure.

Inspectors also reviewed Dublin Orthodontics' *Clinical Audit Strategy* and a sample of recently conducted clinical audits. Inspectors found that the undertaking had put arrangements in place to align their clinical audit strategy with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, published by HIQA in November 2023. However, inspectors found that some areas for improvement to further enhance the role of clinical audit to ensure the safe delivery of medical exposures at the practice were required. For example, the undertaking should ensure that clinical audit topics are planned and prioritised to allow the undertaking to proactively identity any areas for improvement or gaps in compliance relating to the radiation protection of service users. Determining and planning the clinical audit topics to be carried out as part of the clinical audit strategy should cover the full service user pathway and be selected based on their importance to the facility, such as optimisation and patient dosimetry. This will provide an assurance to the undertaking that clinical audits carried out at the practice are meaningful and allow for continuous improvement.

Judgment: Substantially Compliant

Regulation 14: Equipment

On the day of inspection, records and documentation provided to inspectors relating to the medical radiological equipment were reviewed. An up-to-date inventory of medical radiological equipment was provided to inspectors in advance of the inspection as requested. A quality assurance programme which included a quality assurance assessment every two years by an MPE and an annual preventative maintenance and servicing schedule was in place.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation and policies relating to the management of any possible accidental and or unintended exposures were reviewed by the inspectors. Additionally, management at the practice communicated the process for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures at the practice. Inspectors noted that a comprehensive policy was in place which clearly outlined the reporting process at the practice which was noted by inspectors as good practice.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, Dublin Orthodontics had arrangements in place to ensure the continuity of medical physics expertise at its practice.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, the undertaking had arrangements in place to ensure that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users. The MPE was found to contribute to optimisation, quality assurance and training of staff at the practice. The MPE was also involved in establishing local facility DRLs at the practice.

Judgment: Compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices
Inspectors found that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at Dublin Orthodontics - Swords.
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, as amended. 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	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	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 Dublin Orthodontics - Swords OSV-0007297

Inspection ID: MON-0044641

Date of inspection: 23/10/2024

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, as amended.

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: Updated policies on Quality Assurance (QA) and Quality Control (QC) to explicitly assign tasks to qualified personnel. Documentation revision is completed. Clear lines of authority, responsibility and communication are now in place at all levels of the organisation. We have ensured all practical elements of patient positioning and radiographic exposure are performed exclusively by qualified professionals (dentists and orthodontists). Immediate Action: Effective October 24, 2024, ensure only orthodontists and dentists perform and verify patient positioning. Staff involved (dentists and orthodontists) are already trained in radiation safety and patient positioning, making the adjustments to policies and processes feasible without additional certifications.	
Regulation 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: Since the inspection we have introduced a new system for recording the Justification of medical exposure with a new software-integrated referral form to: 1. Capture justification for every medical exposure, including clear reasons for taking the x-ray and the associated clinical decision. 2. Clearly documents the identification of the referring practitioner (orthodontist or	

dentist) and the practitioner justifying the procedure.
3. Automate and streamlines record-keeping to ensure consistent compliance.
4. Staff Compliance and Training - All orthodontists, dentists, and relevant staff have been trained on how to use the new software feature.

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
To address the concerns raised regarding staff responsibilities for practical aspects of medical radiological procedures, the practice have implemented the following to ensure compliance with Regulation 10:

1. Role Allocation: Only personnel entitled under the regulation (dentists and orthodontists) are responsible for practical aspects of medical radiological procedures, including patient positioning and use of radiological equipment.

2. A Policy Review has been completed and now clearly defines roles and responsibilities, explicitly prohibiting unauthorized staff from handling or using radiological equipment.

Immediate action was taken to communicate to all staff which tasks fall under authorised personnel's responsibilities and which are prohibited for non-authorized staff.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Implementation of the following to comply with regulation 11

Monitor Radiation Doses
- Regularly measure and record the radiation doses administered during procedures using Dose Area Product (DAP).
- Maintain records of typical doses (DAPs – Dose Area Products) for each procedure.

Review and Compare Against DRLs
- Periodically review DAP records and compare them to established DRLs and if typical DAPs consistently exceed DRLs, investigate the cause (e.g., equipment issues, protocol errors, or operator practices). Contact MPE for advice.

Conduct Regular Audits
Schedule routine reviews of focusing on staff adherence to imaging protocols and ALARA principles.
Document all audits and findings.

Optimize Protocols
Adjust imaging protocols to optimize patient safety:
- Use the lowest radiation dose that provides adequate diagnostic quality.
- Adjust exposure parameters (e.g., tube voltage, current, and time) to align with DRLs.
- Conduct image quality audits following reduction of exposure factors
Take Corrective Action
If DAPs exceed DRLs, perform a root-cause analysis to determine the source of the issue:
- Is the equipment malfunctioning or incorrectly calibrated?
- Are staff following the correct protocols?

Take corrective action without delay:
Repair or recalibrate equipment.
Retrain staff on radiation safety and proper imaging techniques.

Document Corrective Actions

Train and Update Staff
Provide ongoing training to staff on:
- DRLs and their importance.
- Radiation safety practices.
- Procedures for reporting and addressing dose/DAP exceedances.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
We will strengthen our clinical audit processes improving the planning, execution, and follow-up of clinical audits and update our 'Clinical Audit Strategy'.

As part of our improved 'Clinical Audit Strategy' we will prioritize and extend the range of topics that are critical to Dublin Orthodontics, including:

• Optimization of radiation doses.
• Patient dosimetry and adherence to diagnostic reference levels (DRLs).
• Justification and documentation of medical exposures.
• Equipment performance and maintenance schedules.

Adjusted Frequency: Audits will be scheduled quarterly beginning in January 2025 rather than semi-annually.

Re-establish Audit Teams and Responsibilities
Assign a multidisciplinary team including:
- Radiation Protection Officer
- Clinical staff (e.g., orthodontists, dentists)
- Administrative staff for record management.
Responsibilities will be clearly defined including roles for conducting audits, analyzing findings, and implementing corrective actions.

Analyze Audit Findings
Identify Gaps: Highlight areas for improvement, such as:
• Overuse of radiation or excessive doses.
• Inadequate training or procedural non-compliance.
• Equipment performance issues.
• Determine Priorities: Rank findings based on risk and impact.

Implement Corrective Actions
• Develop an action plan to address identified gaps, including:
• Updating protocols to optimize patient safety.
• Retraining staff on radiation protection and audit findings.
• Repairing or upgrading equipment as needed.

Document and Report
• Audit Records: Maintain detailed documentation for each audit, including:
• Audit scope, methodology, and results.
• Actions taken to address gaps.
• Follow-up evaluations to confirm improvements.

Foster a Culture of Continuous Improvement
- Engage Staff: Promote a collaborative environment where staff contribute to identifying and addressing gaps.
- Review Trends: Use past audits to identify recurring issues and implement preventive measures.

Monitor and Evaluate the Audit Program
- Periodically review the audit strategy to ensure it remains aligned with our practice's priorities and HIQA 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(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	24/10/2024
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	04/11/2024

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Orange	04/11/2024
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Substantially Compliant	Yellow	04/11/2024
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Substantially Compliant	Yellow	04/11/2024
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical	Not Compliant	Orange	04/11/2024

	exposure, and shall provide such records to the Authority on request.			
Regulation 10(7)	A person shall not carry out practical aspects of a medical radiological procedure unless he or she is a practitioner or a person delegated pursuant to paragraph (4).	Substantially Compliant	Yellow	24/10/2024
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	13/12/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	31/12/2024