



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Ormond Orthodontics - Kylemore Clinic
Undertaking Name:	Huntglade Company Unlimited Company
Address of Ionising Radiation Installation:	Freshford Road, Kilkenny
Type of inspection:	Announced
Date of inspection:	30 June 2021
Medical Radiological Installation Service ID:	OSV-0007037
Fieldwork ID:	MON-0031218

About the medical radiological installation:

Huntglade Company Unlimited Company at Ormond Orthodontics - Kylemore Clinic is based in Kilkenny City and at a satellite practice in Thurles Co. Tipperary. There is a central X-ray room in both practices. In Kilkenny, there is a combined scanner and intra oral unit. The combined scanner can be used to obtain: Orthopantomograms (OPG) which provides panoramic views of the jaw and teeth, Cephalometric (Ceph) radiographs used to provide an image of the side of the face and Cone Beam Computed Tomography (CBCT) used to obtain multiple images from different angles to create a 3D image. The scanner is used for assessment of complex treatments by the orthodontist, prosthodontist, paediatric dentist and periodontist and Oral Surgeon. In the Thurles practice there is an intra oral unit and an OPG machine. All equipment is for diagnostic use only and Ormond Orthodontics - Kylemore Clinic does not take external referrals.

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 30 June 2021	12:00hrs to 13:30hrs	Noelle Neville	Lead
Wednesday 30 June 2021	12:00hrs to 13:30hrs	Kirsten O'Brien	Support

Summary of findings

An inspection of Huntglade Company Unlimited Company at Ormond Orthodontics - Kylemore Clinic was conducted remotely by inspectors on the 30 June 2021 to assess compliance against the regulations.

During the inspection, management described the allocation of responsibilities for the radiation protection of service users at the dental practice. Inspectors were satisfied that effective management and leadership was in place at this dental practice with a clear allocation of responsibilities outlined. The undertaking had listed all dentists working at the dental practice as practitioners within this undertaking and also those who were delegated the practical aspects of medical exposures. Inspectors also noted that a formal mechanism for the discussion of radiation protection had been established through a radiation safety committee (RSC).

The dental practice did not accept referrals for dental imaging from external sources. The referrer and practitioner were the same person and the practitioner took clinical responsibility for medical exposures. The practical aspects of dental procedures were delegated to appropriate individuals and this was clearly documented. Inspectors reviewed evidence of radiation safety training provided to staff noting that dental practitioners involved in conducting CBCT scans had received additional training in this area. A clear commitment to the ongoing radiation safety training of staff involved in medical exposures to ionising radiation at the dental practice was evident.

Written protocols for every type of standard dental radiological procedure were available at the dental practice. In addition, staff demonstrated good knowledge of the rationale for imaging and referral guidelines for dental imaging were available to staff. Inspectors identified Regulation 13(2) as an area for improvement where information related to the exposure did not form part of the report. This finding was accepted and acknowledged by management and a solution to address this issue was proposed during the inspection. Evidence of clinical audit was also reviewed by inspectors and demonstrated a commitment to monitoring and improving practice.

The dental practice had access to a medical physics expert (MPE) who was registered with the Irish College of Physicists in Medicine (ICPM) and arrangements were also in place to ensure the continuity of MPE expertise. The MPE was appropriately involved relative to the level of risk posed by this dental practice. This involvement included quality assurance of equipment, dosimetry, optimisation, diagnostic reference levels (DRLs) and staff training. Inspectors reviewed service records and MPE quality assurance reports demonstrating that equipment was kept under strict surveillance by the undertaking.

Inspectors reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Although no incidents

relating to accidental or unintended exposure had been identified or reported at this dental practice, inspectors were satisfied that systems were adequate to manage an incident or near miss should one occur.

Overall, inspectors were satisfied that the undertaking had robust systems in place to ensure the safe and effective delivery of medical radiological exposures at this dental practice.

Regulation 4: Referrers

From a review of documentation and discussion with management at the practice, inspectors were satisfied that referrals were from staff working within this dental practice, where the referrer and practitioner were the same person. The dental practice did not accept referrals for medical radiological procedures from external sources.

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

There was a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation. Although not a regulatory requirement, an RSC was in place at the dental practice. This committee met twice yearly and discussed issues such as clinical protocols, radiation safety procedures and incident management. The presence of an RSC is seen as a positive additional assurance mechanism for undertakings to strengthen their governance, management and oversight arrangements for medical exposures, especially where undertakings have more than one dental practice.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that practitioners recognised by the Dental Council took clinical responsibility for all medical exposures to ionising radiation. Furthermore, practitioners with responsibility for CBCT imaging had received specific training and evidence of this training was available for review.

Documentation provided showed that the practical aspects of medical radiological procedures were delegated to appropriate individuals. A comprehensive list of tasks and individuals to whom practices were delegated was reviewed by inspectors. In addition, inspectors were satisfied that the optimisation process included the practitioner and the MPE and the justification process for all dental exposures carried out at the practice involved the referrer and practitioner which was the same person at this dental practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that DRLs were established, reviewed and compared to national DRLs for equipment at this dental practice. Documents reviewed in advance of the inspection indicated that some local facility DRLs were slightly above national DRLs. As a result, and following recommendations by the MPE, these DRLs were recently reviewed as required by Regulation 11(6) and adapted to be below national DRLs.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in advance of the inspection. Documentation reviewed showed that appropriate quality assurance and performance testing had been implemented for each piece of medical radiological equipment listed in the inventory including a quality assurance assessment every two years by an MPE. In addition, inspectors found that the scanner unit at the practice had a commissioning report from the equipment vendor and had received an equipment service for preventative and maintenance purposes to ensure that the equipment was in good working order. Inspectors were satisfied that the undertaking kept equipment under strict surveillance with regard to radiation protection.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Staff articulated the radiation incident management process to inspectors during the inspection and a template for recording incidents was available for review. Although no incidents relating to accidental or unintended exposure had been identified or reported at this dental practice, inspectors were satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that a recognised MPE was available to this dental practice and arrangements were in place to ensure the continuity of MPE expertise. Up-to-date professional registration certificates were reviewed in advance of the inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The MPE was involved in dosimetry, optimisation, quality assurance of equipment and provided advice in relation to DRLs. Evidence that the MPE provided in house radiation safety training with specific reference to dental CBCT was also available for review.

Judgment: Compliant

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

Inspectors were satisfied with the documentation reviewed and information provided by staff that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was in line with the level of risk posed at this 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	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 Ormond Orthodontics - Kylemore Clinic OSV-0007037

Inspection ID: MON-0031218

Date of inspection: 30/06/2021

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
Outline how you are going to come into compliance with :	

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