



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Boyne Dental & Implant Clinic
Undertaking Name:	Boyne Dental Ltd
Address of Ionising Radiation Installation:	The Old Courthouse, 4 Ludlow Street, Navan, Meath
Type of inspection:	Announced
Date of inspection:	15 April 2021
Medical Radiological Installation Service ID:	OSV-0006796
Fieldwork ID:	MON-0030647

About the medical radiological installation:

Boyle Dental & Implant Clinic, Navan is a five surgery dental practice established in 2012. In addition to intra-oral radiography, the practice also has a dedicated orthopantomogram (OPG) and cone beam computed tomography (CBCT) imaging room.

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
Thursday 15 April 2021	13:30hrs to 15:30hrs	Kirsten O'Brien	Lead
Thursday 15 April 2021	13:30hrs to 15:30hrs	John Tuffy	Support

Summary of findings

An inspection of Boyne Dental Ltd at Boyne Dental & Implant Clinic was conducted remotely by inspectors on the 15 April 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 practice. Inspectors also noted efforts currently being undertaken to establish a formal mechanism for discussion of radiation protection of patients undergoing medical exposures, such as a radiation safety committee (RSC), by Boyne Dental Ltd across their three practices as an area of good practice. However, as an area for improvement, Boyne Dental Ltd should further elaborate on the information contained in their organisational diagram and policies to ensure that the allocation of responsibilities for the radiation protection of service users at Boyne Dental & Implant Clinic is clearly documented. Furthermore, on the day of inspection, Boyne Dental Ltd had not been found to have notified HIQA of all practices under their remit as undertaking. However these notifications have subsequently been received.

On the day of inspection, inspectors were satisfied that only individuals entitled to act as referrers and practitioners, referred to and took clinical responsibility for dental radiological procedures at the practice. Similarly, inspectors found that Boyne Dental Ltd had mechanisms in place to ensure that only individuals that had completed education and training for that purpose took clinical responsibility for cone beam computed tomography (CBCT) exposures at the practice.

Inspectors found that Boyne Dental Ltd had engaged a recognised medical physics expert (MPE) who was appropriately involved and provided medical physics expertise as required by the regulations. A quality assurance programme had been implemented and maintained with a quality assurance assessment of all dental radiological equipment carried out every two years by an MPE. However, inspectors found that preventative maintenance and servicing of dental radiological equipment had not been carried out at the practice, as per MPE recommendations. Similarly, while a review conducted to ensure that medical exposures are adequately optimised for the protection of patients was seen as a positive indication of compliance with the regulations, Boyne Dental Ltd should ensure that reviews include all relevant parties, such as the equipment manufacturer, where appropriate.

Boyne Dental Ltd was found to have processes in place for the conduct of clinical audits at Boyne Dental & Implant Clinic and previous clinical audits related to dental exposures were reviewed by inspectors. Information was also provided to external referrers relating to the availability and use of selection criteria for dental exposures. However, inspectors found that written protocols had not been established at the practice and this area for improvement was highlighted to management during the inspection.

Overall, inspectors found a good level of compliance at Boyne Dental Ltd, however areas for improvement were identified in order to achieve full compliance with the regulations.

Regulation 4: Referrers

From a review of documentation and speaking with management at the practice, inspectors were 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 found that only persons entitled to act as practitioners took clinical responsibility for dental radiological procedures at Boyne Dental & Implant Clinic.

Judgment: Compliant

Regulation 6: Undertaking

During the inspection management at Boyne Dental Ltd described the allocation of responsibility for the radiation protection of patients and other service users attending the practice. A diagram 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 Boyne Dental & Implant Clinic. For example, details and information about who is considered under the responsibility of the undertaking, Boyle Dental Ltd, for the purpose of dental exposures. Additionally information about which individuals can act as practitioners, refer for dental exposures and or conduct dental radiological procedures, including CBCT imaging, should be included in the practice's documentation.

Inspectors also noted that Boyne Dental Ltd was in the process of setting up a radiation safety committee (RSC) to provide additional assurance of the safe delivery of dental exposures across their three practices. The establishment of a regular forum for discussion of radiation protection matters 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: Substantially Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that all dental exposures took place under the clinical responsibility of a practitioner. Furthermore, Boyne Dental Ltd had put mechanisms in place to ensure that clinical responsibility for CBCT imaging at the practice was only taken by individuals that had completed education and training for that purpose.

Management, which included a practitioner at the Boyne Dental & Implant Clinic, and the MPE communicated to inspectors how a practitioner and the MPE were involved in the optimisation process for all dental exposures. Similarly, the referrer and a practitioner, usually the same person, were involved in the justification process of all dental exposures carried out at the practice. Furthermore, the practical aspects of all dental radiological procedures conducted at the practice are carried out by an individual entitled to act as a practitioner under Regulation 5.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors spoke with management at Boyne Dental Ltd and the MPE and reviewed relevant records and documentation. DRLs were established at Boyne Dental & Implant Clinic which had regard for Irish national DRLs. The practice's DRLs had also recently been reviewed. Inspectors were informed that DRLs were available for use by practitioners when conducting dental exposures.

During the inspection, inspectors also found that a review had been carried out to determine whether the optimisation of protection and safety of patients was adequate where a DRL was found to exceed the national DRL for a CBCT procedure. However, inspectors noted that while the MPE and practitioner were adequately involved in the review, the equipment manufacturer had not been contacted to determine if additional optimisation measures could be implemented to further optimise dental exposures at the practice, while ensuring that image quality was appropriate for its intended diagnostic purpose.

While the implementation, use and regular review of DRLs is seen a positive measure in ensuring compliance with the regulations, reviews to ensure that dental exposures are adequately optimised for the protection of patients should include all appropriate parties.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors found that Boyne Dental Ltd had not established written protocols for standard dental exposures for each type of dental radiological equipment at Boyne Dental & Implant Clinic. Written protocols can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice.

Inspectors also reviewed examples of data collection tools and the results of clinical audits conducted at the practice and were satisfied that processes were in place to facilitate regular clinical audit of dental exposures at Boyne Dental & Implant Clinic. 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.

Additionally, inspectors reviewed documentation which demonstrated that external referrers to Boyne Dental & Implant Clinic for CBCT imaging were informed that they should use selection criteria (referral guidelines) when referring patients to the practice for imaging.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors spoke with the MPE and management at Boyne Dental on the day of inspection. Documentation and records relating to the dental radiological equipment at the practice were also reviewed. Boyne Dental Ltd had implemented a quality assurance programme which included a quality assurance assessment every two years by an MPE. This quality assurance assessment also included an assessment of patient doses.

However, inspectors found that dental radiological equipment at the practice had not received a service 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 the MPE's recommendations and other codes of best practice.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Boyne Dental Ltd had engaged a recognised MPE and inspectors were assured that Boyne Dental Ltd had appropriate access to medical physics expertise as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors spoke with the MPE, management at the clinic and reviewed documentation and records. A recognised MPE was found to act and give specialist advice as appropriate. Inspectors were assured that the MPE took responsibility for dosimetry, gave advice on dental radiological equipment at the practice, and contributed to optimisation, DRLs, quality assurance and training at Boyne Dental & Implant Clinic.

Judgment: Compliant

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

An MPE was found to be appropriately involved for consultation and advice on matters relating to the radiation protection of dental exposures.

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	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially 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 Boyne Dental & Implant Clinic OSV-0006796

Inspection ID: MON-0030647

Date of inspection: 15/04/2021

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
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: BDL allocation of responsibilities for service users S - General Dental Practitioners providing dental services at BDL. M - Qualified GDP or relevant further qualification for CBCT A - All dentists are qualified and IDC registered to work in the undertaking R - All dentists are qualified and IDC registered to work in the undertaking T - Ongoing</p> <p>Forum for discussion on radiation protection S - Will take place during the existing peer review structure. M - Zoom Peer review is taking place In June A - Peer review takes place 3 - 4 times per annum R - All dentist are invited to attend and those that do not will received the presentation by email T - Peer review takes place 3 - 4 times per annum</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: DRL CBCT - Manufacturer Contacted S - machine was purchased through equipment vendor. BDL has contacted Equipment Sales and Service Manager of the equipment vendor in April 21 M - equipment vendor will advise on the possibility of adjusting the DRL on the CBCT once manufacturer have responded</p>	

A - any optimisation adjustments will be made based on the outcome from the manufacturers advice together with any required MPE involvement.
 R - any change will be made to allow for accurate readings at the lowest possible DRL

Regulation 13: Procedures	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:
 Written protocols for each type of dental radiological equipment, as per equipment log. Procedure documents have been created for IOPA, OPG and CBCT to allow someone unfamiliar with the equipment to know how to use it.

Regulation 14: Equipment	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 14: Equipment:
 Equipment: preventative and maintenance service procedures @ BDL

As with Regulation 11 the equipment vendor have been contacted to come and service all radiological equipment. If no date is set by them by the start of June we will re-contact them as a reminder to service all equipment.

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	01/06/2021
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	01/08/2021

	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.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	01/06/2021
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	01/08/2021