



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	River Lee Dental
Undertaking Name:	River Lee Dental
Address of Ionising Radiation Installation:	119 Patrick Street, Cork
Type of inspection:	Announced
Date of inspection:	02 November 2021
Medical Radiological Installation Service ID:	OSV-0008103
Fieldwork ID:	MON-0034180

## About the medical radiological installation:

River Lee Dental provide the following dental radiological procedures:

- Intra oral x-rays to assess, diagnose and conservatively treat dental patients, including bitewing x-rays for assessment of bone and interproximal carie and periapical x-rays to assess bone levels and crown to root ratios caries.
- Orthopantomogram (OPG) x-rays are taken to assess generalised bone levels, tooth distribution, jaw bone irregularities, tempero-mandibular joints and sinus assessments.
- OPGs are also used to assess wisdom teeth position, root involvement with nerves prior to treatment and general suitability for orthodontic treatment.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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 2 November 2021	10:00hrs to 11:35hrs	Noelle Neville	Lead
Tuesday 2 November 2021	10:00hrs to 11:35hrs	Maeve McGarry	Support

## Summary of findings

An inspection of River Lee Dental was carried out by inspectors on 2 November 2021 following the receipt of a declaration of undertaking (NF200) form in September 2021. Inspectors reviewed documentation provided in advance of the inspection and noted that the dental practice commenced in July 2021. Undertakings are required to notify HIQA no later than one month in advance of commencing practices and as a result, inspectors found River Lee Dental to be non-compliant with Regulation 6(1). In addition, inspectors were informed that a Medical Physics Expert (MPE) had not been engaged by the dental practice meaning that not all responsibilities were allocated by the undertaking as required by Regulation 6(3).

The absence of an MPE resulted in a number of non-compliances with regulations including Regulations 6, 10, 11, 14, 19, 20 and 21. Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14. Management informed inspectors that the OPG unit had not had acceptance testing carried out by an MPE, which is required before first use for clinical purposes. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of services users undergoing dental radiological procedures. Management accepted and acknowledged this finding and were in the process of engaging an MPE with a tentative arrangement in place for an MPE visit towards the end of November 2021. While inspectors acknowledge that the dental practice is relatively new and the radiological risk of the dental procedures conducted at the dental practice was relatively low, ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures is maintained.

Following this inspection, River Lee Dental was required to submit an urgent compliance plan to address urgent risks relating to equipment and MPE involvement. The undertaking's response did provide assurance that the risks identified on the day of inspection were adequately addressed following the inspection.

Despite the issues outlined above, inspectors noted areas of good practice and compliance with several regulations, namely, Regulations 4, 5, 8, 13, 16 and 17. River Lee Dental ensured that referrals were from registered dentists and that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at the dental practice. The dental practice also had a policy on justification of medical exposures, which set out the process of justification. Inspectors reviewed a sample of records and spoke with staff and found that justification was conducted by appropriate individuals as defined by Regulation 5. In addition, the record of justification was captured for all procedures carried out at the dental practice.

River Lee Dental had written protocols for each type of standard dental radiological procedure. Inspectors were satisfied that information relating to the medical

exposure formed part of the report of the dental radiological procedure as required by Regulation 13(2) and this information was stored on the digital system used to retain patient notes and images. Management described a plan for clinical audit of image quality which was due to commence in January 2022 once a sufficient sample of data had been acquired at the dental practice which had commenced in July 2021.

Although dental X-rays are seen as very low risk to pregnant service users, River Lee Dental had an established process to determine the pregnancy status of service users where relevant and records of same were seen in a sample of service user records reviewed. In addition, River Lee Dental had a process in place to manage incidents and potential incidents related to dental radiological procedures.

#### Regulation 4: Referrers

From a review of documentation and discussion with management at River Lee Dental, inspectors were satisfied that referrals were from registered dentists.

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

Inspectors found some allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) at River Lee Dental. However, the absence of an MPE meant that not all responsibilities were clearly allocated as required by the regulations, for example, responsibilities under Regulation 20. In addition, inspectors found that there was a delay in notifying HIQA that River Lee Dental was commencing practices as required by Regulation 6(1). All services that conduct medical exposures must notify HIQA that they are conducting medical exposures as required by Regulation 6. Ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures.

Judgment: Not Compliant

### Regulation 8: Justification of medical exposures

Referrals reviewed by inspectors on the day of inspection were available in writing and stated the reason for the request and were accompanied by sufficient medical data. Staff informed inspectors that previous diagnostic information from procedures was also reviewed if available. Information relating to the benefits and risks associated with radiation was available to service users and displayed on posters in the clinical rooms and waiting area.

River Lee Dental had a policy on justification of medical exposures which set out the process of justification. Inspectors reviewed a sample of records and spoke with staff and found that justification was conducted by appropriate individuals as defined by Regulation 5. In addition, the record of justification was captured for all procedures carried out at the 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 at River Lee Dental. Inspectors were satisfied that the optimisation process included the practitioner and the justification process for all dental exposures carried out involved the referrer and practitioner. However, as the dental practice had not engaged the services of an MPE, there was no MPE involvement in optimisation as required under the regulations.

Judgment: Substantially Compliant

### Regulation 11: Diagnostic reference levels

Inspectors were informed that there was one local DRL established for one type of intra-oral medical exposure but not for the other type of X-rays conducted onsite. This local DRL was displayed in the dental practice and was slightly above the national DRL for this procedure. It was noted that a review of this local DRL had not been carried out to determine whether the optimisation of the exposure was adequate as required by Regulation 11(6). In addition, management informed inspectors that local DRLs were not in place for the new OPG unit.

Judgment: Not Compliant

### Regulation 13: Procedures

River Lee Dental had written protocols for each type of standard dental radiological procedure. These protocols can provide assurance that dental procedures are carried out in a safe and consistent manner. Staff articulated knowledge of exposure parameters used when imaging and exposure factors were displayed in the practice.

Inspectors were satisfied that information relating to the medical exposure formed part of the report of the dental radiological procedure as required by Regulation 13(2) and this information was stored on the digital system used to retain patient notes and images.

Staff demonstrated a good knowledge of the rationale for imaging and inspectors were informed that referral guidelines for dental imaging were available to staff at the dental practice.

Management described a plan for clinical audit of image quality which was due to commence in January 2022 once a sufficient sample of data had been acquired at the dental practice which had commenced in July 2021. Clinical audit is an important tool which allows undertakings to identify areas of good practice and areas of improvement to ensure the safe delivery of dental exposures to service users.

Judgment: Compliant

### Regulation 14: Equipment

Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at River Lee Dental.

Inspectors received an inventory of dental radiological equipment in advance of the inspection which listed an intra-oral unit and OPG unit. While management informed inspectors that the OPG unit had been infrequently used, acceptance testing had not been carried out by an MPE before first use for clinical purposes. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of service users undergoing dental radiological procedures. Management acknowledged the need for this to be addressed in the short term, before the equipment is used again clinically, and assured inspectors that MPE commissioning testing would be processed with urgency.

In the absence of an MPE, inspectors found that an appropriate quality assurance programme as required by Regulation 14(2) was not in place. In addition, inspectors

found that while performance testing had just commenced for the intra-oral unit, there was no up-to-date performance testing for the OPG unit due to a lack of testing equipment. Management acknowledged this finding and informed inspectors that they were in communication with the equipment vendor in relation to this issue.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Although dental X-rays are seen as very low risk to pregnant service users, River Lee Dental had an established process to determine the pregnancy status of service users where relevant and records of same were seen in a sample of service user records reviewed.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

Inspectors were informed that River Lee Dental had a process for the management of accidental and unintended exposures and significant events. Staff explained 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 not satisfied that River Lee Dental had put in place the necessary arrangements to ensure the continuity of expertise of an MPE. At the time of inspection, an MPE was not engaged at the dental practice, management acknowledged this finding and informed inspectors that a tentative arrangement was in place with an MPE to conduct an onsite visit towards the end of November 2021.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors were not satisfied that River Lee Dental had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1). Inspectors found that the absence of an MPE resulted in deficits in the areas identified in Regulation 20(2), including optimisation and DRLs, the definition and performance of quality assurance of medical radiological equipment and acceptance testing of medical radiological equipment.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

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

Inspectors were not satisfied that River Lee Dental had arrangements in place to ensure that an MPE was appropriately involved in the dental practice, with the level of involvement in line with the level of risk posed at this dental practice as an MPE had not been engaged at the dental practice at the time of inspection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not 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
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Not Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

# Compliance Plan for River Lee Dental OSV-0008103

Inspection ID: MON-0034180

Date of inspection: 02/11/2021

## 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	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:            An MPE visited the surgery on Monday 15/11/2021 and looked and tested both the intraoral machine and the OPG machine. The OPG machine has still not been in use, and will not be used until reports from this inspection are returned. Ongoing attention will also be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities:            An MPE visited the surgery on 15/11/21 who is now involved in the optimisation as required under the regulations, and this will commence once the report is received back.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:            An MPE visited the surgery on 15/11/21 who looked at both DRLs for both xray machines and these will be displayed and put in place once this report is received back.</p>	

Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:  An MPE visited the surgery on 15/11/21 who will ensure that equipment will be kept under strict surveillance, that an appropriate quality assurance programme will commence, and this will be started once the report is received back. The equipment vendor is also still in the process of providing the equipment to allow for frequent performance testing for both xray machines.</p>	
Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:  An MPE visited the surgery on 15/11/2021 who is now the recognised MPE of the surgery.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:  An MPE visited the surgery on 15/11/21 who is now responsible for optimisation and DRLs, the definition and performance of quality assurance of medical radiological equipment and acceptance testing of medical radiological equipment. This will be displayed and performed once the report is received back.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological	Not Compliant

practices	
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Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:

An MPE visited the surgery on 15/11/21 who is now appropriately involved in the dental practice.

## 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(1)	Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	30/09/2021
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	Not Compliant	Orange	15/11/2021

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Orange	15/11/2021
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	15/11/2021
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	Not Compliant	Orange	15/11/2021

	consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
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	Red	30/11/2021
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	30/11/2021
Regulation 14(3)(a)	An undertaking shall carry out the following testing on its medical radiological equipment, acceptance testing before the first use of the equipment for clinical purposes; and	Not Compliant	Red	30/11/2021
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 maintenance procedure liable to affect the equipment's	Not Compliant	Red	30/11/2021

	performance.			
Regulation 14(4)	A person shall not use medical radiological equipment for clinical purposes unless testing in accordance with paragraph (3)(a) has been carried out.	Not Compliant	Red	30/11/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Not Compliant	Red	30/11/2021
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Red	30/11/2021
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological	Not Compliant	Red	30/11/2021

	practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,			
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Red	30/11/2021
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;	Not Compliant	Red	30/11/2021

	<p>(ii) the definition and performance of quality assurance of the medical radiological equipment;</p> <p>(iii) acceptance testing of medical radiological equipment;</p> <p>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 20(3)	The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise	Not Compliant	Red	30/11/2021

	with the radiation protection adviser.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Red	30/11/2021