



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Lion Medical
Undertaking Name:	Lion Medical
Address of Ionising Radiation Installation:	Unit 8, High Street, Tallaght, Dublin 24
Type of inspection:	Announced
Date of inspection:	26 June 2024
Medical Radiological Installation Service ID:	OSV-0007901
Fieldwork ID:	MON-0043767

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

Lion Medical is a dental health clinic. There are a range of dental treatments provided here including general dentistry, specialist endodontic treatments and orthodontic correctional alignments. Local imaging includes digital intra-oral X-rays, orthopantomograms and CBCT scans.

## 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<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
Wednesday 26 June 2024	10:00hrs to 02:30hrs	Lee O'Hora	Lead

## Summary of findings

An inspection of Lion Medical at Unit 8, High Street, Tallaght was conducted by an inspector on the 26 June 2024. On the day of inspection, the inspector visited all areas where dental medical exposures were conducted and assessed compliance with the regulations relating to the use of intra-oral radiography (X-ray), orthopantomogram (OPG) and cone-beam computed tomography (CBCT) procedures.

The inspector was satisfied that diagnostic reference levels (DRLs) were established, used and reviewed. Records of acceptance and performance testing for radiological equipment at the practice satisfied the inspector that the undertaking had implemented and maintained a quality assurance (QA) programme. Similarly, after speaking with staff and reviewing radiation safety related documentation and records, the inspector was assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided at Lion Medical and satisfied the requirements of the regulations.

After reviewing a number of referral records the inspector noted that there was gaps in the processes used by the undertaking to record and subsequently verify the identity of referrers. The inspector was not satisfied that the undertaking had taken the appropriate measures to ensure that all referrals for medical exposures were accompanied by the necessary information or that all dental exposures were justified in advance. Similarly, the inspector was not assured that the undertaking had systems and processes in place to satisfy themselves that individuals taking clinical responsibility for some aspects of dental exposures were appropriately registered and, where necessary, appropriately trained.

In addition, based on the evidence provided throughout the inspection, the inspector was not satisfied that the undertaking had taken the appropriate steps to ensure that dentists involved in the conduct of CBCT procedures had successfully undertaken training as prescribed by the Dental Council.

As part of this inspection an urgent compliance plan was issued in relation to regulations 8, 10 and 22. The undertaking's response provided information to establish that the risks identified were being addressed by the undertaking.

## Regulation 4: Referrers

The inspector was informed that Lion Medical accept referrals from practitioner dentists only. The staff spoken to on the day had a clear knowledge of the specific dental practices that refer patients for imaging and what type of dental imaging was requested from each practice. All of the referral records reviewed from dentists

working at this practice (internal referrals) had clearly and unambiguously identified the referring dentist as required by the regulations.

However, for external referrals, it was not always clear who the individual referrer requesting the procedure was. For example, on one e-mail referral two referrers were listed and on another referral reviewed no referrer information was supplied. Individual referrals need to clearly and unambiguously identify the referrer and the undertaking must have systems and processes in place to satisfy themselves that these referrers are appropriately qualified.

Judgment: Substantially Compliant

### Regulation 5: Practitioners

Staff spoken with on the day articulated that one radiographer practitioner and six dentist practitioners were operating at Lion Medical. All professional registration was reviewed and the inspector was assured that these staff members satisfied the requirements of Regulation 5.

The inspector was informed that for referrals originating from dentists outside the practice, there was a reliance on these dentists to act as practitioners for the clinical evaluation of the outcome in relation to OPG and CBCT imaging. However, the undertaking did not have any systems or processes in place to ensure that these individuals were appropriately registered as required by Regulation 5.

Judgment: Substantially Compliant

### Regulation 6: Undertaking

The inspector was informed that Lion Medical was the undertaking with overall responsibility for the radiation protection of service users.

While the relevant staff and lines of communication were articulated to the inspector on the day, changes in the service type at Lion Medical had not been communicated to HIQA in a timely manner. These changes were only communicated to HIQA after announcement of this inspection. It is imperative that undertakings ensure that any changes to the undertaking's details including service type changes are made known to HIQA using the prescribed channels as soon as possible.

To ensure the radiation protection of service users, it is imperative that undertakings have a clear, documented and communicated allocation of responsibility for all aspects of radiological exposures. However, the inspector was not satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner. In addition, the required information to allow the

justification of procedures was not consistently available nor was the individual responsible for the justification of these procedures consistently identifiable in the records reviewed on the day of inspection.

Similarly, sufficient evidence was not available to establish that Lion Medical had ensured that individuals involved in CBCT procedures had completed the appropriate training as prescribed by the Dental Council.

Judgment: Not Compliant

### Regulation 8: Justification of medical exposures

The inspector was not satisfied that the undertaking ensured that all individual medical exposures were justified in advance or that the undertaking employed a system to record this justification by a practitioner.

For a number of referrals reviewed no reason for requesting the procedure or sufficient medical data to enable the practitioner to carry out a justification assessment was supplied. Nor was there a system by which practitioner justification for all referrals could be recorded.

It is imperative that undertakings ensure that the appropriate information is sought from referrers to enable a justification assessment by a practitioner before medical exposures are conducted. Once deemed justified by the practitioner there should be a method to record that justification was completed by an identifiable practitioner also.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided assurance that the risk was being addressed.

Judgment: Not Compliant

### Regulation 10: Responsibilities

To ensure compliance with Regulation 10(1) an undertaking must ensure that medical exposures take place under the clinical responsibility of a practitioner. From reviewing the records and speaking with staff the inspector was not satisfied that the undertaking had ensured that all medical exposures took place under the clinical responsibility of a practitioner

As discussed also under Regulation 8, the justification process was not completed for some referrals reviewed on this inspection. For example clinical indications were not always provided as required by the regulations. When clinical indications were

provided, the individual responsible for justification of these procedures was not recorded.

It is imperative that undertakings employ appropriate systems to ensure that all components of clinical responsibility, including evaluation of the outcome, are assigned to a practitioner. For a number of OPG and CBCT images reviewed no clinical evaluation of the outcome was available. The inspector was informed that, in some cases, predominantly external referrals, the evaluation of the outcome was done by the referring dentist. However, the undertaking had no formal agreement in relation to this nor did they have a system to satisfy themselves that the external dentist were appropriately qualified and trained to take this responsibility.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided information that the undertaking was assured that the risk was being addressed.

Judgment: Not Compliant

### Regulation 11: Diagnostic reference levels

The inspector reviewed documentation and records pertaining to DRLs and spoke with staff. Lion Medical had established DRLs and had compared these local facility DRLs to national DRLs as required by the regulations.

The inspector also visited the clinical area and observed multiple examples of local facility DRLs displayed. Based on the evidence reviewed, the undertaking was found to be compliant with this regulation.

Judgment: Compliant

### Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. All records reviewed detailed that all testing was up to date. The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant



## Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the practice were described to the inspector by staff and all evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of medical physics expertise.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the appropriate professional registration certificates which were up to date.

From reviewing the documentation and speaking with staff at the practice, the inspector was satisfied that arrangements were in place to ensure that the MPE took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of DRLs, the definition of QA programmes, the delivery of radiology equipment acceptance testing and the training of practitioners.

The inspector was assured that the involvement and contribution of MPEs was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service.

Judgment: Compliant

## Regulation 22: Education, information and training in field of medical exposure

Radiation safety training, not specific to CBCT, was available for dentists operating at Lion Medical. This training was largely focused on regulatory requirements and

delivered by Lion Medical's MPE, and this was seen as a good use of medical physics resources.

On the day of inspection, inspectors were informed that only two of the dentists from within the practice were involved in the referral and evaluation of CBCT procedures. Some records of training in CT were supplied for these two dentists over the course of the inspection, however, the documentation supplied did not satisfy the relevant training requirements as prescribed by the Dental Council for CBCT specifically.

In addition, the inspector was informed that dentists from outside the practice also referred patients to Lion Medical for CBCT imaging, for which, unreported images were returned to these referrers. However, no training records for these external dentists were available on the day of inspection. Therefore the inspector found that Lion Medical had not ensured that staff involved in the evaluation of the outcome of CBCT procedures had successfully undertaken or completed training as prescribed by the Dental Council.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided information that the undertaking was assured that the risk was being 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, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
<b>Summary of findings</b>	
Regulation 4: Referrers	Substantially Compliant
Regulation 5: Practitioners	Substantially Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	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
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

# Compliance Plan for Lion Medical OSV-0007901

Inspection ID: MON-0043767

Date of inspection: 26/06/2024

## 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 4: Referrers	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 4: Referrers: External referrers, have been informed immediately post inspection date, of the required regulations for compliance. They were advised verbally, and in written format of the importance of clear information of patient, required x-ray, sufficient clinical indication, referring practitioners details.</p> <p>A template of referral letter has been supplied to each external referrer.</p>	
Regulation 5: Practitioners	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 5: Practitioners: Immediately after inspection date, service level agreements have been created for each referring clinic. It clearly states the referring clinicians, their IDC number, and the doctors taking responsibility of image evaluation where OPG's are concerned. In relation to CBCT scanning, the SLA states the referring doctors, IDC numbers, whether Level 1 CBCT centred training is acquired, in order to be able to refer. A radiologist's report is then created and sent back to the referring dentist. There are no referring dentists with Level 2 CBCT centred training at the moment.</p>	
Regulation 6: Undertaking	Not Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:  
The undertaking intends to be fully compliant and notify HIQA in advance if any other changes would be done in the service type of Lion Medical.

Similar to the answer under Regulation 5, SLA have been established and signed by each referring clinic, with only one outstanding clinic.

We expect full compliance by the end of September, as many dentists have been on annual leave during August.

When it comes to justification processes, it is fully compliant since the inspection date. Internal referrers record justification in writing, on electronic patient records. Where it comes to external referrals, justification is recorded on the referral letter and uploaded on the electronic patient record.

Regulation 8: Justification of medical exposures

Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:

As already mentioned in the answers under Regulation 6, all individual medical exposures were justified in written format on the patient electronic record, for both internal and external referrals. It has been implemented immediately since inspection date.

Similar to answers under Regulation 4, all referrers were advised verbally, and in written format of the importance of clear information of patient, required x-ray, sufficient clinical indication, referring practitioners details. Where not enough clinical information was supplied, it was communicated back to the referrer for adjustments prior to booking.

In aid to the dentists a template of referral letter has been supplied to each external referrer.

Regulation 10: Responsibilities

Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:  
Similar to the answers under Regulation 5 and 6. Service Level Agreement have been established in written format between the clinic and internal/ external referrers. It clearly states the referring dentists, IDC registration number, responsibility of image evaluation where applicable. In cases with CBCT referrals, there is no dentists with existing

adequate Level 2 CBCT centred training, hence a radiologist is engaged to supply them with a comprehensive medical report.

Each qualified dentists with Level 1 training had supplied certificate evidence of adequate CBCT centred training in order to refer for CBCT scans.

Currently there are two dentists from one external clinic that have a timeframe until the end of September to give evidence of Level 1 CBCT centred training, which would be part of a specific SLA agreement.

Regulation 22: Education, information and training in field of medical exposure	Not Compliant
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Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure:

The two dentists in Lion Medical that refer for CBCT scans, have Level 1 CBCT centred training supplied few days post inspection date.

External referrers have required Level 1 training, with certification evidence, and a Service Level Agreement establishing that clinical evaluation is not performed by them. A radiologist's report is externally sourced and supplied to each referrer with the CBCT images.

## 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 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Substantially Compliant	Yellow	28/06/2024
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Substantially Compliant	Yellow	28/06/2024
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of	Not Compliant	Orange	30/09/2024



	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.			
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 specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Red	28/06/2024
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	Red	28/06/2024
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states	Not Compliant	Red	28/06/2024

	the reason for requesting the particular procedure, and			
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Red	28/06/2024
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Red	30/09/2024
Regulation 22(1)(a)	Subject to paragraph (2), an undertaking shall ensure that practitioners have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation protection, in accordance with the provisions of this Regulation.	Not Compliant	Red	30/09/2024
Regulation 22(3)	Subject to paragraph (4), the persons referred to	Not Compliant	Red	30/09/2024

	<p>in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection—</p> <p>(a) prescribed by the Dental Council,</p> <p>(b) prescribed by the Irish College of Physicists in Medicine,</p> <p>(c) prescribed by the Nursing and Midwifery Board of Ireland,</p> <p>(d) prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, or</p> <p>(e) approved by the Radiographers Registration Board under Part 5 of the Health and Social Care Professionals Act 2005, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and</p>			
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	Training of Medical Professionals in the European Union (Radiation Protection No. 175).			
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