



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Green Dental
Undertaking Name:	Green Dental
Address of Ionising Radiation Installation:	Unit 122C/Unit 123, Middle Floor, Stephen's Green Shopping Centre, Dublin 2
Type of inspection:	Unannounced
Date of inspection:	22 May 2023
Medical Radiological Installation Service ID:	OSV-0008527
Fieldwork ID:	MON-0040191

## About the medical radiological installation:

There are three X-Ray equipment in Green Dental, two Intra-Oral X-Ray and one Orthopantomogram X-Ray.

Our patients undergo a medical exposure of ionising radiation if the dentists need them for consultation, and dental planning and 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
Monday 22 May 2023	10:35hrs to 14:30hrs	Margaret Keaveney	Lead

## Summary of findings

An unannounced inspection of Green Dental was completed by the inspector on 22 May 2023, following receipt of information that medical exposures of ionising radiation were being conducted in this service without having declared to HIQA as required by Regulation 6 (2). During the inspection, the inspector established that medical exposures of ionising radiation were being completed in this service, that the management team had not declared to HIQA and therefore were not in compliance with Regulation 6 (2): Undertaking.

The inspector also saw that the governance structures in Green Dental were not well defined or documented. This poor allocation of roles and responsibilities in the service contributed to a significant number of non-compliances with the regulations, as discussed throughout this report. Clearly defined governance and management arrangements are necessary to ensure that service users receive safe and effective care, in relation to medical exposures to ionising radiation.

On the day of inspection, the inspector visited three X-ray rooms in the service and saw that the service provided medical exposures of ionising radiation to service users by means of two intra-oral radiography units and one orthopantomogram (OPG) unit.

Throughout the day of the inspection, the inspector met with a principal dentist who was identified as the radiation protection officer in the service. However, this dentist was unable to clearly describe their specific responsibilities, and the responsibilities of other key personnel in the service, with regard to the radiation protection of services users. Effective radiation protection practices include the clear allocation and documentation of roles and responsibilities to appropriate individuals. This is to ensure that each person working in the service is aware of their individual and collective responsibilities for the radiation protection of service users.

The inspector reviewed professional certificate documentation which verified that all dentists working in the service were appropriately registered. The inspector was satisfied that only an individual entitled to act as a practitioner took clinical responsibility for completing medical exposures of ionising radiation at the practice, and that the referrer and the practitioner were the same individual for medical exposures within the practice. However, a review of service user records showed that these practitioners had not fully carried out their clinical responsibilities with regard to completing medical exposures of ionising radiation for service users. For example, the review of these records showed that justification of exposures in writing, dose optimisation, the clinical evaluation of the exposure outcome and providing information to service users on the benefits and risks of ionising radiation to service users had not been completed by practitioners. The inspector also noted gaps in the oversight of documentation around justification.

On the day of inspection, the inspector saw that recognised medical physics expert

(MPE) had been engaged by the management team of Green Dental to complete commissioning testing on radiological equipment installed in the service in 2018 and 2013. However, the inspector noted that in the period between 2018 and 2023 a MPE had not been engaged by the service to consult with and advise on the radiation protection of service users. This gap in MPE services resulted in poor compliance with the regulations with regard to the use of local diagnostic reference levels (DRLs), dose optimisation and the surveillance of the radiological equipment.

From a review of documentation, the inspector saw that although the MPE had established DRLs for all radiological equipment in use in the service, the management team had not taken the actions recommended by the MPE to ensure that the DRLs for the two intra-oral units were comparable to national DRLs and that the dose to the service user during a medical exposure was optimised. The inspector also observed that in two clinical areas, the DRLs were not available to practitioners to refer to prior to completing a medical exposure of ionising radiation.

Although a number of non-compliances with the regulations were identified during the inspection, the inspector was satisfied that there was no immediate risk to service users. However, substantial action is required by the undertaking to ensure that regulatory requirements are met, as are discussed throughout this report.

#### Regulation 4: Referrers

From speaking with staff and a review of professional registration records, the inspector was satisfied that only appropriately trained and recognised persons referred individuals for medical radiological procedures in Green Dental.

Judgment: Compliant

#### Regulation 5: Practitioners

From speaking with staff and a review of professional registration records, the inspector was satisfied that only persons, as defined in the regulation, took clinical responsibility for individual medical exposures.

Judgment: Compliant

#### Regulation 6: Undertaking

On the day of the inspection, the inspector spoke with the management team at Green Dental and established that the undertaking had not declared to HIQA but

was providing medical exposures of ionising radiation to individuals. The regulations require that an undertaking declare to HIQA no later than one month prior to commencing such practices, to ensure that the undertaking is providing safe and effective care to individuals in line with the regulations. The inspector requested that the management team immediately submit the declaration. The declaration was received and processed following the inspection.

From speaking with the management team on the day of the inspection, the inspector was not assured that there was a clear allocation of responsibilities for the protection of service users in Green Dental. The inspector also requested documentation, such as local procedures, detailing the clear allocation of collective and individual responsibilities, and was informed that none was available. The undertaking is responsible for all medical exposures of ionising radiation carried out on individuals by practitioners and others engaged by it. It is also responsible for compliance with the regulations, by all such persons. Documentation that clearly allocate person's roles and responsibilities in the service, and the governance arrangements of the service, are necessary to support compliance with the regulations, and staff working within the service should be aware of their roles and responsibilities.

Judgment: Not Compliant

### Regulation 8: Justification of medical exposures

The inspector reviewed four service user treatment and imaging records, and was not assured that the undertaking had the appropriate justification practices in place to ensure that each medical exposure was justified in advance, and that each justification was recorded by the practitioner. For example, in three of the four records reviewed the practitioner had not clearly state the reason for the particular procedure, or were accompanied by sufficient medical data to carry out a justification assessment.

The inspector also observed that the management team had not documented the justification process. Therefore, there was no clear guidance or support for practitioners to ensure that they understood their responsibility to justify all medical exposures in advance of carrying them out, and to also ensure that service users only received an exposure of ionising radiation that provided them with a net benefit. The inspector also observed that there was no evidence that information on the risks and benefits of exposures had been given to service users. The management team stated that this was provided during the treatment consent procedure, however the inspector observed that the consent form did not contain any information on the risks and benefits of exposures of ionising radiation.

Judgment: Not Compliant

## Regulation 9: Optimisation

From a review of documentation and discussions with staff, the inspector was not assured that the management team in Green Dental had appropriate processes in place to ensure that doses to service users due to medical exposures were kept as low as reasonably possible. For example, staff spoken with were not aware of their roles and responsibilities in dose optimisation, they did not have a robust QA programme in place for radiological equipment, and they had no system in place to audit and ensure consistency in the practical aspects of completing exposures.

Judgment: Not Compliant

## Regulation 10: Responsibilities

The inspector was informed that all medical exposures of ionising radiation took place under the clinical responsibility of a practitioner, in accordance with Regulation 5. The management team at Green Dental also informed the inspector that only registered dentists carried out the practical aspects of dental radiological procedures. From a review of service user records, the inspector was not assured that persons, entitled to act as both the referrer and the practitioner for medical exposures, were involved in the justification process, when completed, for radiological procedures in Green Dental.

However, from a review of equipment records, the inspector noted that the undertaking had not implemented MPE recommendations on the optimisation of exposures in 2018 and in 2023. For example, the lowering of exposure times to ensure that the dose received by service users was as low as achievable. Furthermore, the inspector was not assured that practitioners were involved in the optimisation process for all dental exposures carried out at Dublin Green Dental. For example, in two equipment areas the dentists did not have local DRLs to refer to, to ensure that they were comparable to national DRLs.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

From a review of documentation, the inspector observed that a MPE had established local DRLs for the radiological equipment in use in the service, during commissioning and quality assurance testing in 2018 and 2023. However, the inspector was informed that the management team did not have arrangements in place to ensure that these local DRLs were regularly reviewed or that they were in use by practitioners working in the service. For example, the management team did not



have documented guidance in place to review DRLs. Also the inspector observed that the DRLs were not accessible to practitioners in two areas where procedures were carried out, and from discussions with staff the inspector was not assured that they were aware of their responsibilities to use DRLs as good practice in the radiation protection of service users.

The inspector also noted that the management team had not actioned optimisation recommendations from the MPE to ensure that the DRLs established were comparable to national DRLs. For example, a recommendation to discontinue a practice that resulted in DRLs higher than the national DRLs had not been communicated to practitioners in the service. Also the management team had not made available to practitioners optimised exposure guidance for one piece of equipment, as recommended by the MPE, to ensure that doses received by service users were comparable or below national levels. These recommendations had been categorised as critical by the MPE and made available to the management team one month prior to the inspection.

Judgment: Not Compliant

### Regulation 14: Equipment

On the day of the inspection, the inspector spoke with the MPE and the management team at Green Dental, and reviewed documentation pertaining to the radiological equipment in the service. Although commissioning testing had been completed on the three pieces of radiological equipment in use, overall, the inspector was not satisfied that the radiological equipment at Green Dental was kept under strict surveillance, with regard to radiation protection.

The inspector noted that although a MPE had completed commissioning testing on two pieces of equipment in 2018, a subsequent QA review had not been performed until 2023. Furthermore, a dose issue identified in 2018 had not been addressed by the management team on the day of the inspection. Also the QA performed by a MPE in April 2023 had identified a number of issues that required urgent action, but on the day of the inspection the inspector was informed that no person in Green Dental had yet been assigned responsibility for completing these actions.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

The inspector reviewed documentation and saw that although a MPE had been involved in the commissioning of radiological equipment in the service in 2018, they had not been engaged by the undertaking again until 2023. The involvement of a

MPE in a service provides assurance to service users about the quality of services being provided.

Judgment: Substantially Compliant

### Regulation 20: Responsibilities of medical physics experts

On the day of the inspection, the inspector requested evidence of the involvement of a MPE in the service. The management team provided the inspector with records that evidenced the MPE's had completed acceptance and quality assurance testing on medical radiological equipment in the service. There was also evidence that they had provided consultation and advice on radiation protection in the service in 2018 and 2023. The MPE had also contributed to optimisation of radiation protection of service users, which included establishing DRLs for a number of procedures.

Judgment: Compliant

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

Following a review of documentation and discussions with the management team, the inspector was not assured that the involvement of the MPE in the radiological practices in Green Dental was commensurate with the risk involved for service users. As detailed previously in this report, the management team of Green Dental had not regularly engaged the input of a MPE, to ensure that they met the requirements of the regulations.

Judgment: Substantially 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	Not Compliant
Regulation 9: Optimisation	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

# Compliance Plan for Green Dental OSV-0008527

Inspection ID: MON-0040191

Date of inspection: 22/05/2023

## 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:            A NF200 was submitted to HIQA on 24/05/2023.            A review of the internal governance structure at Green Dental Ltd was carried out by the undertaking. The roles and responsibilities as per the regulations are set out in the updated practice radiation safety procedures and local rules.            The updated radiation safety procedures are available to all practitioners and henceforth will form part of new practitioner induction training.            The undertaking has engaged the MPE in a service level contract for a 2-year period to support and advise the undertaking’s responsibility to comply with the requirements of the regulations.</p>	
Regulation 8: Justification of medical exposures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:            Green Dental has updated and circulated its practice radiation safety procedures to practitioners.            Commencing July 2023 Green Dental will implement a practice policy to ensure that documentation on justification for dental exposures is recorded in each patient’s record in advance of an exposure and for each type of radiograph prescribed. Patient information posters will be placed in a number of public and clinical areas in the practice. A process of clinical audit will commence to ensure that individual practitioners are adhering strictly to the practice policy on justification.</p>	

Regulation 9: Optimisation	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 9: Optimisation:  The advice of the MPE in relation to a routine Quality Assurance (QA) program for intra-oral and OPG x-ray systems is being implemented. The MPE has been engaged for on-going support through a 2-year service level agreement. The advice of the MPE on suitable exposure parameters for each imaging system has been received and acted upon. A process of clinical audit will commence to ensure that individual practitioners are strictly adhering to the practice policy on optimisation as set out in the radiation safety procedures.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities:  The practice radiation safety procedures state that all medical exposures take place under the clinical responsibility of a practitioner. The radiation safety procedures require the practitioner to justify and optimise individual exposures. The radiation safety procedures are available to all practitioners and henceforth will form part of new practitioner induction training. A process of clinical audit will commence to ensure that individual practitioners are adhering strictly to their responsibilities.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:  The advice of the MPE has been communicated to all dental practitioners. Tables of exposure parameters, as recommended by the MPE, along with the Local DRL for each x-ray unit have been completed and are on display beside the x-units.  Local Rules have been made available to all dental practitioners. All dental practitioners have signed the Local Rules. The practice radiation safety procedures direct practitioners to record the exposure parameters for each exposure in the patient's chart. A process of clinical audit and image quality analysis will commence to ensure that individual practitioners are adhering strictly to the practice policy on prescribing and documenting exposure parameters.</p>	

Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:  The service level agreement with the MPE provides for a biennial QA programme, along with a programme of acceptance testing as appropriate. A qualified service engineer visited the practice on 30/06/2023 to carry out routine servicing on all x-ray units as per manufacturers' instructions. The radiation safety procedures set out an ongoing in-house programme of quality controls to be carried out and documented by a designated practitioner at least every quarter. The undertaking will ensure this programme of quality assurance and regular performance testing is implemented.</p>	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:  A 2-year Service Level Agreement has been entered into with the MPE for ongoing support and advice from 30 June 2023 to 30 June 2025. It is the intention of management to extend this contract at the end of the contract period. The Service Level Agreement ensures that the MPE is available to the undertaking, radiation protection officer, and practitioners for consultation and advice on matters relating to the radiation protection of patients at Green Dental.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:  A 2-year Service Level Agreement has been entered into with the MPE for ongoing support and advice from 30 June 2023 to 30 June 2025. It is the intention of management to extend this contract at the end of the contract period. The service level agreement ensures that the MPE is available to the undertaking, radiation protection</p>	

officer, and practitioners for consultation, advice and when relevant in-house training. The undertaking shall ensure that the MPE is involved appropriate to the radiation risk in the 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(2)	An undertaking which, on the commencement of these Regulations, is carrying out practices shall notify the Authority, no later than 3 months after the commencement of these Regulations, of such activity, in such form and manner as may be prescribed by the Authority, and may continue such activity pending said notification.	Not Compliant	Orange	24/05/2023
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	Substantially Compliant	Yellow	03/07/2023

	<p>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.</p>			
Regulation 8(8)	<p>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.</p>	Substantially Compliant	Yellow	11/08/2023
Regulation 8(10)(b)	<p>A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and</p>	Substantially Compliant	Yellow	11/08/2023
Regulation 8(10)(c)	<p>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</p>	Substantially Compliant	Yellow	11/08/2023

	justification assessment in accordance with paragraph (1).			
Regulation 9(1)	An undertaking shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.	Not Compliant	Orange	11/08/2023
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Substantially Compliant	Yellow	11/08/2023
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	11/08/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are	Not Compliant	Orange	11/08/2023

	established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Orange	11/08/2023
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	11/08/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological	Not Compliant	Orange	11/08/2023

	equipment in use by it is kept under strict surveillance regarding radiation protection.			
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.	Substantially Compliant	Yellow	30/06/2023
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.	Substantially Compliant	Yellow	11/08/2023