



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Gracefield Dental
Undertaking Name:	Dr Jerome P Sullivan
Address of Ionising Radiation Installation:	Kilmalogue Cross House, Portarlinton, Laois
Type of inspection:	Announced
Date of inspection:	17 November 2020
Medical Radiological Installation Service ID:	OSV-0006929
Fieldwork ID:	MON-0028905

## About the medical radiological installation:

Gracefield Dental is a dental practice that provides both general and specialised treatments for patients. There are three dental surgery rooms, each with its own intra-oral X-ray unit for dental exposures, including:

- bite-wing dental X-rays, used to show the crowns of the upper and lower teeth simultaneously
- periapical exposures, which show the entire crown and root of the teeth and is used to provide information about the teeth and surrounding bone.

There is also a dedicated X-ray room where a combined scanner is housed. This scanner allows both cone beam computer tomography scans (CBCT) and orthopantomographs (OPT) to be acquired. This scanner captures both two and three dimensional images and is used to plan more complex treatments that may involve implants, wisdom teeth, difficult extractions, full mouth rehabilitations and periodontal problems. All X-ray equipment is for diagnostic use only and Gracefield Dental do not take radiographic referrals from other practices.

## 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 17 November 2020	13:00hrs to 15:00hrs	Agnella Craig	Lead

## Summary of findings

Effective management and leadership was evident in this dental practice with a clear allocation of responsibilities outlined to the inspector. In a document provided to the inspector in advance of the inspection, the undertaking had listed all dentists working in this practice as practitioners within this undertaking.

Based on the evidence reviewed, and further discussions with staff on the day of inspection, it was clear that the undertaking had oversight arrangements in place to ensure that those carrying out medial radiological procedures within this facility comply with the regulations. This included conducting clinical audits on image quality, following the facility's protocols and reporting any issues with equipment to the undertaking.

This dental practice did not accept referrals for dental imaging from external sources. The referrer and the practitioner were the same person, and this practitioner took clinical responsibility. One dental practitioner took responsibility for conducting CBCT scans, and this individual had received additional training in using the CBCT scanner.

The dental practice had access to a medical physics expert (MPE) who was registered with the Irish College of Physicists in Medicine (ICPM) and this MPE was appropriately involved relative to the level of risk typically posed by a dental service of this kind. This included involvement in dosimetry, optimisation and reviewing diagnostic reference levels (DRLs). Evidence that the undertaking had acted on the recommendations of the MPE was clear, however, the undertaking may need to consider implementing the use of rectangular collimation at this practice. Consideration should also be given to having access to appropriate referral guidelines for best practice and documenting information relating to patient exposure on the patients record for radiological procedures performed in this facility.

The undertaking had used the self-assessment questionnaire, submitted to HIOA in 2019, as a gap analysis and had acted on the gaps identified in this assessment. This included implementing clinical audits and recording information on the number of procedures per year that the facility carries out. This information was recorded manually for patients receiving OPT and CBCT scans since January 2020. A system to identify, record and investigate potential and actual accidental and unintended exposures, should they occur, had also been implemented.

Overall, the inspector was assured that this undertaking had robust systems in place to ensure the safe and effective delivery of medical radiological exposures for patients attending this practice.

#### Regulation 4: Referrers

All referrals in Gracefield Dental are from the staff working within this dental practice, where the referrer and practitioner are the same person. External referrals for medical radiological procedures such as CBCT scans are not accepted from external sources.

Referrals for medical radiological procedures reviewed on the day of inspection were only accepted from those entitled to refer an individual for a medical exposure as per the regulations.

Judgment: Compliant

#### Regulation 5: Practitioners

From the documents provided in advance of inspection and the records of medical exposures reviewed on the day of inspection, the inspector was satisfied that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures in this dental practice.

Judgment: Compliant

#### Regulation 6: Undertaking

A clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation was evident in the documents reviewed in advance of inspection. Further evidence to support this was found when speaking with other staff available on the day of inspection, in addition to the undertaking, who described how responsibility for those working within this practice is managed. This includes reviewing audits undertaken by the dentists in the practice, organising quality assurance on equipment and following up on any identified issues.

Judgment: Compliant

#### Regulation 8: Justification of medical exposures

The process of consent for medical exposures and how justification was documented in the patients' clinical notes was explained to the inspector by one of the practitioners in this dental practice. In all instances, the referrer and the practitioner

are the same person in this facility. Reports reviewed by the inspector on the day of inspection showed that referrals were documented, included the reason for the exposure and sufficient data was provided to identify that exposures were justified.

In addition, the record of a patient who had received previous imaging in another dental practice was reviewed and evidence that this patient's previous medical imaging was obtained was available. Obtaining previous imaging from other dental practices is a good example of how this practitioner ensures appropriate justification is considered before patients undergo medical exposures in this practice.

Judgment: Compliant

### Regulation 9: Optimisation

From the evidence reviewed before inspection and gathered on-site, it was clear that the undertaking was working towards ensuring doses are kept as low as reasonably achievable. For example, recommendations from the MPE in relation to the servicing of equipment had been carried out and the engineer's reports were made available to the inspector. However, a recommendation from the MPE on the importance of using rectangular collimation had yet to be implemented. The undertaking had considered the use of this collimation as a means to further reduce dose, but gave a rationale to the inspector on the day as to why this had not been implemented.

Based on the international evidence available on the use of this type of collimation, it is important that this practice revisits the MPE's recommendation in relation to the use of rectangular collimation as an ancillary piece of equipment which can be used to further ensure the dose to patients is kept as low as reasonably achievable, while providing good quality useful images.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

From the documentation reviewed and discussions with staff, the inspector was assured that practitioners who were recognised by the Dental Council took clinical responsibility for all exposures to ionising radiation. Although the practitioner was assisted by the dental surgery assistant, the practical aspects of medical radiological procedures were not delegated to other individuals in this practice at the time of inspection.

The inspector was informed that the practitioner with responsibility for the CBCT scanner had received specific training and the certificate of this training was

available for review. The inspector was assured that the optimisation process included the practitioners and the MPE.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

Documentation reviewed in advance of this inspection confirmed that the undertaking had established and recently reviewed DRLs in this practice although DRLs were not displayed in the clinical area on the day of inspection. The undertaking and staff acknowledged the advantage of displaying DRLs in the clinical area to serve as a prompt in ensuring each patient exposure is optimised.

Documents reviewed by the inspector prior to inspection indicated that the local facility's DRLs for procedures in two X-ray rooms were marginally above the national average, however, the recommendations from the MPE in relation to equipment had been carried out to remedy this issue. The engineer's reports were made available to the inspector and supported that the necessary changes had been implemented.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols for every type of standard dental radiological procedure were available in advance of inspection and the inspector noted that these protocols were displayed prominently in the clinical area to act as a visual reminder to the practitioner.

From reviewing previous patients' reports, information relating to exposure was part of the report for patients who received OPT and CBCT scans, but this information did not form part of the report for patients undergoing other types of imaging. Staff informed the inspector that this information is currently not recorded for those receiving periapical imaging.

Staff demonstrated a good knowledge of the rationale for imaging but evidence of the availability of referral guidelines for dental imaging was not found on inspection. Staff acknowledged that guidelines are not used in this practice but recognised the advantage of having access to national and or international guidelines.

The inspector was informed by staff that audits of image quality had commenced since this was an area identified as a gap when previously completing the self-assessment questionnaire. The inspector reviewed records of the image quality audits and found records for all practitioners working in this dental practice. At the time of inspection, there was no evidence of follow up actions in relation to these

audits, however staff explained the processes that would be followed if issues were ongoing or significant issues were identified. This included review of the audits by the undertaking and further training for practitioners if necessary.

Judgment: Substantially Compliant

### Regulation 14: Equipment

The inspector was provided with an up-to-date inventory of medical radiological equipment in advance of this inspection. The inspector reviewed documentation which showed that appropriate quality assurance and performance testing had been implemented for each piece of medical radiological equipment listed in this inventory. The quality assurance reports identified that a number of recommendations were made by the MPE. Evidence that these recommendations had been addressed by the undertaking was also available to the inspector.

From the reports provided and the follow up actions which were completed, it was evident that the undertaking kept the equipment under strict surveillance regarding radiation protection.

Judgment: Compliant

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

The *X-ray Incidents and Accidents Management policy*, reviewed in advance of this inspection, clearly identified the types of incidents that should be reported and to whom. Details on how radiation incidents should be managed was also included. In addition, specific guidelines explaining possible doses for radiation incidents in the dental setting were also available.

The *Dental Radiography Incident Report Form*, a template for recording incidents, was also available for review.

Although no incidents relating to accidental or unintended exposure had been identified or reported by this practice, the inspector had no concerns because of the available evidence and the nature of this setting.

Judgment: Compliant

## Regulation 18: Estimates of population doses

The undertaking was found to be compliant with Regulation 18; a regulation previously identified by this undertaking as an issue in the self- assessment questionnaire.

Estimates of the annual number of patients undergoing medical exposures, which was differentiated for distinct types of medical radiological procedures in this dental facility, was provided to the inspector in advance of this inspection.

In addition, since January 2020 the undertaking has manually recorded the dose area product (DAP) for all patients undergoing OPT and CBCT scans. DAP is a measurement commonly used in diagnostic radiography to represent the dose a patient receives during an X-ray procedure. The undertaking's proactive approach in recording this figure is a good example of how this undertaking has acted on gaps identified in the self-assessment questionnaire.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

The inspector was assured that a recognised MPE was available to this undertaking and on the day of inspection no concerns were identified in relation to the continuity of the service provided by the MPE.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Involvement of the MPE in dosimetry, quality assurance and acceptance testing of radiological equipment was evident in the documentation reviewed in advance of inspection. Advice on DRLs was also provided by the MPE. Evidence that the MPE provides training on radiation protection was also available for review and all practitioners in this facility had recently completed radiation protection training which was provided by the MPE.

Judgment: Compliant

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

The inspector was assured, by the documentation reviewed and the information provided by staff, that the undertaking has arrangements in place to ensure the level of involvement of the MPE is in line with the level of risk posed in this dental practice.

Judgment: Compliant

## Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 18: Estimates of population doses	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 Gracefield Dental OSV-0006929

Inspection ID: MON-0028905

Date of inspection: 17/11/2020

## 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 9: Optimisation	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 9: Optimisation: We are currently trialing different rectangular collimation systems to identify the optimal way to facilitate the best image quality for the lowest radiation exposure dose to the patient. Most critical is identifying a system which does not increase the incidence of mistakenly cropping images so that the relevant section of the image is not captured. One such example would be cutting off the apex of a root when taking a diagnostic periapical for RCT. Avoiding second exposures and the risk of doubling the radiation load is clearly a key consideration. To that end, we understand that optimizing the DAP with rectangular collimation involves not only the selection of a suitable system that is practical but also the correct technique in the deployment of that system. Thus far we have trialed two systems; the first- which although bulky have alignment templates on the guide rings. The second system has the specific rectangular collimation inserts. So far we have all found the second system easier to use with less incidence of cropping problems. Unless a superior rectangular collimation system is made known to me, we at Gracefield dental will be committing to the second system at the start of the New Year.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: All intra-oral devices are regularly serviced and tested to ensure that all intra-oral exposures are optimized in terms of DAP to the patient versus image quality, and that the DAP also falls within the radiation level of the accepted standard radiological dosage for such an exposure. The reason for the exposure, the image quality of every intraoral radiograph and confirmation that the DAP falls within the standard radiological dosage is now recorded in the patient's record for every such exposure.</p>	

Regulation 13 (3)

I as the undertaking, now recognise the importance of following national and international guidelines in relation to all radiological exposures.

To this end I have referenced:

1. European Guidelines on Cone Beam CT for Dental and Maxillofacial Radiology.
2. Radiological protection in Dental Radiology.
3. Faculty of General Dental Practice selection Criteria for Dental Radiology.

This information is available to referrers within 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 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.	Substantially Compliant	Yellow	31/01/2021
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms	Substantially Compliant	Yellow	31/12/2020

	part of the report of the medical radiological procedure.			
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	31/12/2020