



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	3Dental (Dublin)
Undertaking Name:	3Dental
Address of Ionising Radiation Installation:	Red Cow House, Naas Road, Dublin 22
Type of inspection:	Announced
Date of inspection:	08 December 2020
Medical Radiological Installation Service ID:	OSV-0005977
Fieldwork ID:	MON-0030743

## About the medical radiological installation:

3Dental is a multi-disciplinary dental practice located in Dublin 22 providing both general and specialised dental care directly to the public and also on a referral basis. 3Dental opened in 2016 and expanded in 2018 and 2020. The practice has 11 surgeries, the latest one added in November 2020, and a cone beam computed tomography (CBCT) room. The opening hours are 08:00 to 20:00, Monday to Friday and 09:00 to 17:00 on Saturday. There are a total of 21 dentists working both full-time and part-time. The practice carries out approximately 12,000 patient appointments annually. Most patients attend 3Dental looking for solutions to complex dental problems. The practice is based around the three core specialties of Implantology, Cosmetic Dentistry, and Orthodontics. The other specialities covered include Oral Surgery and Endodontics. Many of 3Dental's more complex treatments involve the use of CBCT imaging such as; implant planning, bone grafts, surgical removal or exposure of impacted teeth, complex endodontic treatments and orthodontic treatment planning.

## 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 8 December 2020	12:00hrs to 14:30hrs	Kirsten O'Brien	Lead
Tuesday 8 December 2020	12:00hrs to 14:30hrs	Agnella Craig	Support

## Summary of findings

On the day of inspection, inspectors found that clear lines of oversight and management were in place at 3Dental. All associate dentists working at the practice were under the overall governance structure of 3Dental. Records reviewed by inspectors demonstrated that all persons involved in dental exposures at the dental practice had read 3Dental's *Code of Practice Radiation Protection* and agreed to conduct dental radiological procedures as per local policy.

Records of dental radiological procedures were reviewed by inspectors who also spoke with staff on-site. All dental radiological procedures were conducted under the clinical responsibility of a dentist, registered with the dental council, as per the regulations. A medical physics expert was available for advice and consultation as appropriate and was involved in the optimisation of all procedures in conjunction with practitioners. 3Dental had also established local facility diagnostic reference levels (DRLs) which were used and reviewed.

Referrals for cone beam computed tomography (CBCT) reviewed on-site were found to be in writing and stated the reason for the procedure. However, some referrals reviewed for intra-oral X-rays did not clearly state the reason for requesting the procedure in the patients' notes. While there was sufficient medical data accompanying all referrals reviewed by inspectors, 3Dental must ensure that all referrals are clearly written and state the reason for requesting the particular dental radiological procedures to ensure full compliance with the regulations. Additionally, information about the radiation dose must be included on the report of the procedure. These findings were acknowledged by management on the day.

3Dental had arrangements in place to ensure the continuity of medical physics expertise at the practice. Additionally, records of quality assurance and acceptance testing of radiological equipment demonstrated that equipment at the practice was kept under strict surveillance regarding radiation protection. A comprehensive clinical audit carried out was also noted by inspectors as an example of good practice.

Inspectors found that education and training records of practitioners taking clinical responsibility for CBCT procedures were not available on the day of inspection. 3Dental must ensure that all persons acting as practitioners for CBCT imaging have successfully completed training, as prescribed by the Dental Council, and records of this training are maintained. Despite this finding, the engagement of the radiation protection officer with the CBCT equipment application specialist, and the provision of in-house training to staff by the medical physics expert, were noted as positive interim measures.

Overall, notwithstanding the specific areas requiring attention, inspectors were satisfied that 3Dental had taken a proactive and meaningful approach to ensuring

the radiation protection of patients at the practice.

#### Regulation 4: Referrers

All referrals reviewed on-site by inspectors were from referrers as defined in the regulations.

Judgment: Compliant

#### Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

#### Regulation 6: Undertaking

A clear allocation of responsibility for the radiation protection of patients was in place at 3Dental. Inspectors reviewed documentation provided and spoke with staff and a representative from the undertaking who clearly communicated the management and oversight structure in place for dental exposures to ionising radiation at the practice.

All associate dentists at the practice signed a *Statement of understand - Code of Practice Radiation Protection* which was seen as a positive measure to ensure that all persons involved in the conduct of dental exposures at the practice were aware of, and agreed, to conduct exposures in accordance to 3Dental's policies.

Judgment: Compliant

#### Regulation 8: Justification of medical exposures

On the day of inspection, posters were present in the waiting room and dedicated X-ray/CBCT room to provide information relating to the risks and benefits associated with dental exposures to patients. A sample of records of dental radiological procedures were reviewed during the on-site inspection. Staff spoken with communicated that previous imaging was sought where it would prevent an

unnecessary exposure and a specific example of this was identified by inspectors during the review of records on-site.

Inspectors found that a dentist, registered with the Dental Council, took clinical responsibility for justifying all individual procedures. However, while referrals were found to be accompanied by sufficient medical data in the patients' notes to allow the practitioner to justify the procedure, inspectors found that referrals for some intra-oral exposures were not always clearly documented and sometimes did not state the reason for requesting a particular procedure. This finding had been previously identified by 3Dental in an audit and was acknowledged by management as an area for improvement on the day of inspection.

Judgment: Substantially Compliant

### Regulation 9: Optimisation

Inspectors found that the undertaking had taken a proactive approach to ensuring that all procedures carried out at the practice were optimised. A medical physics expert carried out quality assurance at the practice and findings and recommendations generated were acknowledged and acted on by 3Dental. Patient doses were assessed through the use of DRLs and corrective actions were taken to ensure that all doses were kept as low as reasonably achievable at the practice. Inspectors were also informed that those conducting the exposures reviewed the set exposure factors prior to obtaining an image to confirm that these were correct.

Inspectors noted that an application specialist had been contacted to advise on further optimisation of the CBCT procedures at 3Dental(Dublin) and this was identified as an example of good practice.

Judgment: Compliant

### Regulation 10: Responsibilities

Inspectors found that all medical exposures took place under the clinical responsibility of a practitioner, as per Regulation 5. Staff spoken with communicated how practitioners and a medical physics expert were involved in the optimisation process for all medical exposures, such as the assessment and optimisation of patient doses through the establishment, use and review of DRLs.

Additionally, only practitioners carried out the practical aspects of dental radiological procedures. Similarly, records reviewed on inspection, demonstrated that persons entitled to act as both the referrer and the practitioner for individual dental exposures were involved in the justification process for each dental radiological

procedure.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs had been established for individual radiological equipment at 3Dental (Dublin). Inspectors were informed that DRLs were used by those conducting the practical aspects of exposures and reviewed regularly. Where individual facility DRLs were found to exceed the national DRLs, a review to ensure appropriate corrective actions was undertaken by the radiation protection officer at the practice.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols were in place for dental radiological procedures for each type of equipment. These were available in dental rooms at the point of care in the practice. Referral criteria (selection criteria) was available to referrers in each individual room at the practice. Staff spoken with demonstrated that they were aware of the availability of these guidelines and their uses. However, inspectors found that information relating to patient exposure did not form part of the report of the dental radiological procedure.

Inspectors found that a clinical audit of radiographic practices had been carried out at the practice and a comprehensive report had been compiled. The actions identified in the audit had been followed up on and inspectors were informed that a follow-up audit was scheduled to re-evaluate going forward. This was seen as an example of good practice and provided the undertaking with an opportunity to identify and act on areas for continuous improvement.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Records reviewed demonstrated that dental radiological equipment at 3Dental (Dublin) was kept under strict surveillance regarding radiation protection. An appropriate quality assurance programme was defined and carried out by a registered medical physics expert, and acceptance testing was carried out before the first clinical use of equipment.



The CBCT unit had a feature which informed the practitioner of the relevant parameters for assessing patient doses and this information was transferred to the record of the examination. Additionally, the undertaking had an up-to-date inventory of dental radiological equipment and provided this to HIQA on request prior to the inspection.

Judgment: Compliant

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

A policy which outlined how to report accidental and unintended exposures and significant events at the 3Dental was reviewed by inspectors who also spoke with staff on the day. Inspectors were satisfied that 3Dental had an appropriate system in place to record events involving or potentially involving accidental or unintended exposures to ionising radiation, in addition to a process to ensure that HIQA is notified of any significant event, if required.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The undertaking had arrangements in place to ensure the continuity of medical physics expertise at 3Dental (Dublin). For example, 3Dental had a contract in place with a registered medical physics expert to provide medical physics services at the practice.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

A medical physics expert was found to act and give specialist advice, as appropriate. Medical physics expert involvement at 3Dental included contribution to optimisation of the radiation protection of patient, through the establishment and review of DRLs, the provision of advice on medical radiological equipment, and the definition and performance of quality assurance of medical radiological equipment. Records reviewed demonstrated that acceptance testing had been carried out by the medical physics expert when new medical radiological equipment had been installed and before first clinical use. Similarly, inspectors were informed that the medical physics expert provided training to practitioners in relevant aspects of radiation protection.

Judgment: Compliant

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

Inspectors found that 3Dental had ensured that a medical physics expert was appropriately involved at 3Dental practice Dublin to provide consultation and advice as required by the regulations.

Judgment: Compliant

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

On the day of inspection, inspectors were informed that the radiation protection officer had completed post-graduate education, which incorporated some training in the use of CBCT radiological procedures. Additionally, inspectors were informed that 3Dental and the MPE had provided in-house training for dentists that conducted CBCT radiological procedures.

However, records evidencing the successful completion of training by practitioners in CBCT, as prescribed by the Dental Council, were not available for review by inspectors. In order to be compliant with Regulation 22, 3Dental must ensure that practitioners who take clinical responsibility for CBCT have completed training, as prescribed by the Dental Council, and successful completion of such training must be documented and recorded.

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	Compliant
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 9: Optimisation	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 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 3Dental (Dublin) OSV-0005977

Inspection ID: MON-0030743

Date of inspection: 08/12/2020

## 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 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>Following the radiographic audit carried out in Nov 2020, individual dentists who had not adequately justified radiographs in their notes were advised of the correct procedure and instructed to justify each exposure in their notes. They have been reminded of this on several occasions since, and the radiographic audit is due to be repeated in May 2021, and individual dentist compliance rates will be scrutinised.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>All of the dentists have been informed that information relating to individual exposures are to be recorded in the patient notes. Compliance with this will be evaluated during the repeat audit in May. 2021</p>	
Regulation 22: Education, information and training in field of medical exposure	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 22: Education,</p>	

information and training in field of medical exposure:

There is just one CBCT training course in Ireland, which is run by the RCSI and was last held in 2019. They have no plans to hold in again in the current climate with the threat of Covid. There are CBCT courses in the UK which fulfil the criteria of the UK General Dental Council, which are similar to the Irish Dental Council guidelines for CBCT.

In the interim, Dr X has enrolled in an online CBCT course in the UK on the next available date, which is 26/06/21. The course fulfils the requirements of the current HPA guidelines and the BSDMFR curriculum in relation to the IR(ME)R referrer and IR(ME)R operator (reporting).

This includes 7 hours verifiable CPD using online modules and 6 hours verifiable CPD using virtual hands-on reporting session with a maxillofacial radiologist.

This course addresses the theoretical elements of CBCT and includes an extensive hands-on reporting aspect, covering the following topics:

- Radiation Physics in relation to CBCT Equipment
- Radiation Protection in relation to CBCT examinations
- Apparatus and equipment
- CBCT image acquisition and processing
- Principles of CBCT imaging
- Principles and practice of interpretation of dento-alveolar 3D CBCT images
- An update on radiological anatomy of teeth and jaws relevant to CBCT
- An update on dental and maxillofacial pathology
- Radiological interpretation of dental and maxillofacial diseases

Within a month of taking the course Dr X will hold an in house training session with the practitioners who take CBCTs in the practice covering the areas outlined above as an interim measure until there is a course in Ireland on dental CBCT which the others can attend.

## 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 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Substantially Compliant	Yellow	31/05/2021
Regulation 8(10)(b)	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	Substantially Compliant	Yellow	31/05/2021
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	31/05/2021
Regulation 13(2)	An undertaking	Not Compliant		31/05/2021

	shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.		Orange	
Regulation 22(3)	Subject to paragraph (4), the persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection— (a) prescribed by the Dental Council, (b) prescribed by the Irish College of Physicists in Medicine, (c) prescribed by the Nursing and Midwifery Board of Ireland, (d) prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, or (e) approved by the Radiographers Registration Board under Part 5 of the	Not Compliant	Orange	31/07/2021



	Health and Social Care Professionals Act 2005, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).			
Regulation 22(5)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the exposure, and shall provide such records to the Authority on request.	Not Compliant	Orange	31/07/2021