



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dental Tech
Undertaking Name:	Dental Tech
Address of Ionising Radiation Installation:	Whitehall House, Whitehall Close, Terenure, Dublin 6w
Type of inspection:	Announced
Date of inspection:	13 January 2022
Medical Radiological Installation Service ID:	OSV-0006299
Fieldwork ID:	MON-0034871

## About the medical radiological installation:

Dental Tech uses oral X-ray for taking periapical X-rays for dental patients requiring treatment including but not limited to root canal treatments and extractions.

## 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
Thursday 13 January 2022	12:00hrs to 13:10hrs	Noelle Neville	Lead
Thursday 13 January 2022	12:00hrs to 13:10hrs	Kay Sugrue	Support

## Summary of findings

An inspection of Dental Tech was carried out remotely by inspectors on 13 January 2022. Due to the manner in which this inspection was conducted, the focus was limited to the assessment of compliance with the regulations outlined in this report. The inspection was initiated as a result of the non-return of a regulatory dental self-assessment questionnaire that had been issued to the undertaking. Management informed inspectors that the designated manager of the dental practice had changed and updated contact details had not been provided to HIQA. As a result, the dental self-assessment questionnaire was overlooked and up-to-date information was subsequently provided to HIQA following the inspection.

Inspectors were informed that while the dental practice had a Medical Physics Expert (MPE), the MPE had not been engaged by the dental practice since the commencement of the regulations in 2019, meaning that not all responsibilities were allocated by the undertaking as required by Regulation 6(3).

The absence of engagement of an MPE resulted in a number of non-compliances with the regulations including Regulations 6, 11, 14, 19, 20 and 21. Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14. Management acknowledged this finding and informed inspectors that an arrangement was in place with an MPE to conduct an onsite visit in the days following the inspection. While inspectors acknowledge that the radiological risk of the dental procedures conducted at the dental practice was relatively low, ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures is maintained.

Despite the issues outlined above, inspectors noted compliance with Regulations 4 and 5. Dental Tech ensured that referrals were from registered dentists and that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at the dental practice.

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

## Regulation 4: Referrers

From discussions with management and staff at Dental Tech, inspectors were

satisfied that referrals were from registered dentists.
Judgment: Compliant
<b>Regulation 5: Practitioners</b>
Inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at this dental practice.
Judgment: Compliant
<b>Regulation 6: Undertaking</b>
Inspectors found some allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) at Dental Tech. However, the absence of engagement of an MPE at the practice since the commencement of the regulations in 2019 meant that not all responsibilities were clearly allocated as required by the regulations, for example, responsibilities under Regulation 20. Inspectors determined that the clear allocation of responsibilities needed to be strengthened to include the role of the MPE.
Judgment: Not Compliant
<b>Regulation 11: Diagnostic reference levels</b>
Inspectors were not satisfied from discussions with management and staff that there was an awareness of diagnostic reference levels (DRLs) or that they had been established, regularly reviewed and used at Dental Tech.
Judgment: Not Compliant
<b>Regulation 14: Equipment</b>
Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Dental Tech.
Inspectors received an inventory of dental radiological equipment in advance of the inspection which listed a fixed intra-oral unit and a handheld intra-oral unit. In the

absence of MPE engagement at the dental practice since the commencement of the regulations in 2019, inspectors found that an appropriate quality assurance programme as required by Regulation 14(2) was not in place. While management provided some service records for the handheld intra-oral unit, inspectors were not satisfied that performance testing was carried out on the two intra-oral units on a regular basis as required under Regulation 14(3). Management acknowledged and accepted this finding and informed inspectors that an MPE was due onsite in the days following the inspection.

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

Judgment: Not Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were not satisfied that Dental Tech had put in place the necessary arrangements to ensure the continuity of expertise of an MPE. At the time of the inspection, an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019. Management acknowledged this finding and informed inspectors that an arrangement was in place with an MPE to conduct an onsite visit in the days following the inspection.

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

Judgment: Not Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors were not satisfied that Dental Tech had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1). Inspectors found that the absence of engagement of an MPE since the commencement of the regulations in 2019 resulted in deficits in the areas identified in Regulation 20(2), including optimisation, DRLs and the definition and performance of quality assurance of medical radiological equipment.

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

Judgment: Not Compliant

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

Inspectors were not satisfied that Dental Tech had arrangements in place to ensure that an MPE was appropriately involved in the dental practice as an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019.

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

Judgment: Not Compliant



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

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

Regulation Title	Judgment
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

# Compliance Plan for Dental Tech OSV-0006299

Inspection ID: MON-0034871

Date of inspection: 13/01/2022

## Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance or where the non-compliance poses a significant risk to the safety, health and welfare of service users will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

## Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:            An MPE has been engaged on a continual basis and shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure. The MPE visited the facility and completed QA testing 18th January 2022. Reports were received on 21 January 2022; advice following the QA visit has been reviewed and actioned accordingly by the undertaking in conjunction with the practitioner.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:            MPE advice on optimisation was received and acted upon. QA testing was completed 18th January 2022            Local DRLs have been established in consultation with the MPE (i.e. Radiation Dose at Cone tip for an Adult Maxillary Molar in mGy).</p> <p>The local DRLs are on display adjacent to the x-ray units.            Diagnostic Reference Levels will be reviewed every 2 years by the MPE, in collaboration with the practitioner taking into consideration HIQA Guidance and National DRLs (guidance documentation available to relevant persons).</p> <p>An in-house audit cycle of records has been established to support monitoring this.</p>	

Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: The MPE is engaged on a continual basis advice and to carry out biennial assessment of equipment, or sooner as may be appropriate, going forward.</p> <p>QA testing was completed by RPA and MPE on the 18th January 2022. The MPE's written advice was received and has been acted upon.</p> <p>The MPE will assess equipment every 2 years or more frequently if required and advise on equipment. The x-ray units will be maintained in serviceable condition and removed from clinical use for service or physics assessment if there is any question as to the safety of the unit</p> <p>A visual check of x-ray equipment will be conducted and recorded on a regular basis by the practitioner.</p>	
Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: An MPE has been engaged by the undertaking on continual basis for consultation and advice. The MPE is an ICPM registered MPE.</p> <p>QA testing completed 18th January 2022 and the reports have been issued to the undertaking.</p> <p>The appointed MPE has the support of additional MPEs in the event of their absence, to ensure continuity of support to our practice.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities	

of medical physics experts:

An MPE was engaged on continual basis for advice. The MPE also acts as RPA service.

QA testing completed 18th January 2022. Reports received 21st January 2022

MPE advice received on and acted upon in relation to:

- Definition, and performance of appropriate quality assurance of dental radiological equipment
- Optimisation
- Local DRLs
- Incident management

MPE advice on optimisation received and acted upon. Local DRLs established and in place. MPE assessments will be carried out every 2 years or more frequently if required.

Dental Tech has no plans for additional equipment installations, but the MPE would be available for assessment if new equipment were planned. No accidental or unintended exposures occurred but MPE would give advice in the event it occurred. HIQA guidance document will be followed in the event of such exposure.

Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
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Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:

An MPE has been engaged on a continual basis for advice. QA testing completed 18th January 2022, reports were received on 21st January 2022 and have been acted upon

## 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(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	21/01/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	21/01/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	11/02/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	11/02/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Not Compliant	Red	11/02/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom	Not Compliant	Red	11/02/2022

	it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Red	11/02/2022
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Red	11/02/2022
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological	Not Compliant	Red	11/02/2022



	practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design;	Not Compliant	Red	11/02/2022

	(v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 20(3)	The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise with the radiation protection adviser.	Not Compliant	Red	11/02/2022
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Red	11/02/2022

