

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	3Dental Galway
Undertaking Name:	3Dental
Address of Ionising Radiation Installation:	28 Briarhill Business Park, Galway, Galway
Type of inspection:	Announced
Date of inspection:	22 July 2026
Medical Radiological Installation Service ID:	OSV-0009438
Fieldwork ID:	MON-0050707

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

3Dental is a multidisciplinary dental practice located in Galway providing both general and specialised dental care directly to the public, and also on a referral basis. Opened in 2022, the practice has 7 surgeries. The opening hours are 8am-8pm Monday-Friday and 9am-5pm on Saturday. There are a total of 15 dentists working both full time and part time, and the practice carries out approximately 25,000 patient appointments annually. 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 our more complex treatments require the use of CBCT such as: Implant planning, Bone grafts, Surgical removal or exposure of impacted teeth, Complex endodontic treatments, 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, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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

¹ 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.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 22 July 2026	10:00hrs to 15:00hrs	Lee O'Hora	Lead

Summary of findings

An inspection of the undertaking 3Dental at 3Dental Galway to assess compliance with the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended, was carried out on 22 July 2026. As part of this inspection, the inspector spoke to management and staff, reviewed imaging records and radiation safety documentation including training records and visited all areas within the practice where ionising radiation was used as part of service delivery.

While the inspector was satisfied that the undertaking had met the requirements of the regulations in Regulations 4, 5, 8, 10, 14, 19, 20 and 21, other areas were highlighted as needing further work to meet compliance and these areas are discussed further under Regulations 6, 11 and 13. Based on the evidence provided throughout the inspection, the inspector was not satisfied that the undertaking had taken the appropriate steps to ensure that all dentists involved in the conduct of cone beam computed tomography (CBCT) procedures had successfully completed full training as prescribed by the Dental Council and required under Regulation 22. This was a significant non compliance with current regulatory requirements and an urgent compliance plan was issued to 3Dental in relation to Regulation 22. The undertaking's response provided assurance to establish that the non compliance identified was being addressed by the undertaking as a matter of urgency. All non compliances identified will be followed up by HIQA as part of regulatory follow up.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for dental radiological procedures and by speaking with staff, the inspector was satisfied that 3Dental Galway only accepted referrals from appropriately recognised referrers, namely dentists.

Judgment: Compliant

Regulation 5: Practitioners

Similarly, following record review and staff communication, the inspector was satisfied that systems were in place to ensure that only appropriately qualified

individuals, as defined by the Regulations, took clinical responsibility for all dental exposures.

Judgment: Compliant

Regulation 6: Undertaking

The inspector was informed that 3Dental Galway opened in March 2022. However, HIQA was not informed of the commencement of this practice in the time frame required. All undertakings must notify HIQA, no later than one month before commencing practices, in a manner detailed in the HIQA guidance document *Providers (undertakings) of medical exposure to ionising radiation information handbook*.

Regulation 6 also requires that undertakings provide 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 provide evidence of such allocation. While the structures and communication pathways used by 3Dental Galway were articulated to the inspector and documented in organograms supplied as part of this inspection, some areas required the attention of the undertaking to ensure the clear allocation of responsibility in relation to the radiation protection of service users. One such area related to Diagnostic Reference Levels (DRLs). The inspector reviewed documentation and spoke with staff members in relation to 3Dental Galway's use of DRLs. The allocation of responsibility was insufficient to ensure that appropriate corrective actions were taken without undue delay when typical doses are found to consistently exceed the relevant diagnostic reference level. As a result, the inspector found that recommendations made by the medical physicist in April of 2025 were not acted on. The associated related non compliance is discussed further under Regulation 11.

Finally, the inspector was not assured that the undertaking has systems and processes in place to ensure that the relevant practitioners had successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection, specific to CBCT, as prescribed by the Dental Council. This is discussed further under Regulation 22 and the undertaking was required to submit an urgent compliance plan to address an urgent risk under Regulation 22.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of imaging records on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure that all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. In line with Regulation 8, all referrals reviewed by the inspector were available in writing, stated the reasons for the requests and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector reviewed radiation safety procedure documentation, a sample of referrals for dental radiological procedures and spoke with staff and was satisfied that all medical exposures at 3Dental Galway took place under the clinical responsibility of a practitioner. The inspector was also assured that the optimisation process involved the practitioner and the MPE and that the justification process for individual dental exposures involved the practitioner and the referrer.

Additionally, the inspector observed and was informed that practical aspects of dental radiological procedures were only carried out at this facility by dentist practitioners and dental nurses as per the regulations. The inspector was informed that dental nurses were only involved in the practical aspects of orthopantomogram (OPG) procedures. Documentation supplied to HIQA satisfied the inspector that the delegation of responsibility for the practical aspects of dental procedures to dental nurses had been formally recorded as required by the regulations. The associated professional registration and records of training in radiation safety prescribed by the Dental Council were reviewed, satisfying regulatory requirements in relation to the delegation of practical aspects of dental exposures to dental nurses at 3Dental Galway.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Regulation 11 requires that undertakings ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate and retains a record of all associated reviews and corrective actions taken. Following a review of DRL documentation, the inspector was satisfied that DRLs have been established, were compared to national levels, and were displayed in the clinical areas of this practice. However, the inspector was not satisfied that the undertaking had the appropriate systems and processes in place to ensure that when DRLs exceed national levels, the appropriate reviews and corrective actions

were completed. For example, recommendations made by the medical physicist in April of 2025 in relation to a facility DRL which exceeded that of the national DRL had not been actioned by the time of the inspection. As a result, no records of associated reviews or corrective actions were available on the day of inspection.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for all standard dental radiological procedures at 3Dental Galway.

The inspector reviewed information relating to clinical audit in documents supplied and by speaking with staff. The inspector noted that the audit process had been recently commenced by the undertaking and an example of a recently completed regulatory compliance audit was reviewed by the inspector on site. However, the requirement for audit has been nationally mandated since the publication of HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* in November 2023. Therefore, more work is required to ensure the approach to clinical audit is systematic, formally documented, communicated to staff, and in accordance with national procedures established by HIQA.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory which was verified on site. From the evidence available, the inspector was satisfied that all dental radiological equipment was kept under strict surveillance by the undertaking. The process to ensure this included the implementation and maintenance of a quality assurance (QA) programme.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that arrangements in place secured the continuity of medical physics involvement and contribution at 3Dental Galway.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector was satisfied that the undertaking engaged persons with up-to-date voluntary professional certification with the Irish College of Physicists in Medicine (ICPM). In the absence of a statutory Register of Medical Physics Experts, as per Regulation 19, this ensured that the undertaking had engaged medical physicists with appropriate knowledge, skills and competencies to act or give specialist advice in relation to dental radiological practices.

The inspector saw evidence that medical physicists took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of DRLs, the definition of QA programmes and the delivery of radiology equipment acceptance testing.

Judgment: Compliant

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

From the evidence gathered during the course of this inspection, the inspector was satisfied that the level of medical physicists involvement was appropriate and proportionate to the radiological risk associated with medical radiological practices at 3Dental Galway.

Judgment: Compliant

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

On the day of inspection, the inspector was informed that only four dentists working at the practice were involved in the referral, justification, practical aspects and evaluation of CBCT procedures. Some records of training in CBCT were supplied for these four dentists, however, the documentation supplied did not fully satisfy the relevant training requirements as prescribed by the Dental Council for CBCT.

An urgent compliance plan was issued in relation to this non compliance. The undertaking's response provided information to establish that the risks identified were being addressed by the undertaking as a matter of urgency.

Judgment: Not Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

Compliance Plan for 3Dental Galway OSV-0009438

Inspection ID: MON-0050707

Date of inspection: 22/07/2026

Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Since the inspection on 22 July 2026, 3Dental has undertaken an immediate review of all clinicians who prescribe, justify or undertake CBCT examinations across the organisation. The inspection highlighted that, while clinicians had undertaken CBCT education, we could not demonstrate through our governance systems that all clinicians undertaking CBCT had completed training meeting the current Dental Council requirements. This issue has been treated as an organisational priority. As an immediate risk mitigation measure, we have reviewed our existing CBCT governance documentation and revised both our CBCT Selection Protocol and our Diagnostic Reference Levels (DRLs). These documents have been updated to provide clearer guidance to clinicians regarding justification, field of view (FOV) selection and optimisation, and were issued immediately to all clinicians undertaking CBCT examinations. The revised protocol reinforces that CBCT examinations may only be undertaken following clinical examination, review of existing imaging, individual justification by the practitioner, selection of the smallest appropriate field of view and full evaluation of the acquired volume. In parallel with these immediate governance improvements, we have commenced arrangements to ensure all relevant clinicians complete CBCT training that satisfies the current Dental Council requirements. 3Dental has arranged a dedicated CBCT training programme for our clinicians, which will be delivered by a suitably qualified provider of Dental Council approved CBCT training. Our intention is to provide Level 1 and Level 2 training for all clinicians undertaking CBCT examinations across all practice locations. This approach will ensure that training is delivered consistently, and that documentary evidence of completion can be maintained centrally.	

Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: We have reviewed our local Diagnostic Reference Levels. A revised DRL document has been produced which adopts the 4×4 cm volume ($223 \text{ mGy}\cdot\text{cm}^2$) as the default protocol for single implant assessment where clinically appropriate, recognising that this is below the current national adult dental CBCT DRL of $265 \text{ mGy}\cdot\text{cm}^2$. Separate local DRLs have also been established for single-arch and dual-arch imaging to support optimisation of patient dose.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Clinical audits will be conducted every six months by the Practice Manager and Principal Dentist at 3Dental Galway. These audits will take place in January and July each year, with ongoing monitoring and review conducted throughout the year to ensure continued compliance with clinical standards, policies and regulatory requirements. Any findings identified through the audit process will be documented, reviewed and addressed promptly, with appropriate corrective actions implemented where required. Progress against any identified actions will be monitored throughout the year to ensure continuous improvement and sustained compliance.	
Regulation 22: Education, information and training in field of medical exposure	Not Compliant
Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure: We are establishing a central register of CBCT training records for all clinicians undertaking CBCT examinations. This register will record completed training, dates of completion and supporting certification and will form part of the undertaking's ongoing	

governance arrangements to ensure compliance with Regulation 22.

Pending completion of the Dental Council compliant training programme, we will continue to review clinician training records and monitor compliance with its revised CBCT protocols. Once the training programme has been completed, the central register will be updated and maintained as part of our ongoing radiation governance processes.

We believe that these actions significantly reduce the identified risk while establishing a robust governance framework to achieve full compliance with Regulation 22(3) within the timeframe specified by HIQA.

Level 1 CBCT training will be conducted at the 3Dental Head Office on Monday 14th September 2026.

Level 2 CBCT training will subsequently be held at the 3Dental Head Office on Friday 16th October 2026.

Both training sessions have been arranged to ensure that relevant clinicians complete the required CBCT training within the stipulated timeframe and in accordance with current Dental Council requirements.

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(1)	Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	08/09/2026
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	Substantially Compliant	Yellow	12/10/2026

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 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	08/09/2026
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	08/09/2026
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with	Substantially Compliant	Yellow	08/09/2026

	national procedures established by the Authority.			
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 Health and Social Care Professionals Act 2005, as appropriate,	Not Compliant	Red	23/10/2026

	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).			
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