



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Virginia Dental Care & Implants
Undertaking Name:	Michael Hannick
Address of Ionising Radiation Installation:	Main Street, Virginia, Cavan
Type of inspection:	Announced
Date of inspection:	13 October 2022
Medical Radiological Installation Service ID:	OSV-0008324
Fieldwork ID:	MON-0037661

About the medical radiological installation:

Virginia Dental Care & Implants is a new dental practice on Main Street Virginia which opened its doors on September 5th 2022, with the aim of providing private and public dentistry to the community. The practice has 3 operational surgeries with two Intraoral wall mounted X-Ray. Cone beam computed tomography technology is also offered where required to assess vital structures and bone quantity prior to implant placement.

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 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
Thursday 13 October 2022	12:30hrs to 14:00hrs	Lee O'Hora	Lead

Summary of findings

An on-site inspection of the undertaking Michael Hannick operating at Virginia Dental Care & Implants was completed on 13 October 2022.

The inspector found effective management arrangements at Virginia Dental Care & Implants with a clear allocation of responsibility for the protection of service users undergoing dental radiological exposures. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspector on the day of inspection.

The inspector was assured that processes were in place to ensure the safe conduct of dental radiological procedures by the undertaking. The inspector was satisfied that the dentist operating at the practice acted as the referrer and the practitioner, and took clinical responsibility for all dental radiological procedures. The practical aspects of dental radiological procedures were not delegated to any other individuals at the time of inspection.

The inspector was confident that the undertaking ensured that diagnostic reference levels (DRLs) were established, reviewed and used. Written protocols for every type of standard dental radiological procedure were available and the inspector was satisfied that information relating to patient exposure formed part of the report of dental radiological procedures.

Medical physics expert (MPE) continuity of expertise and involvement was well documented and articulated to the inspector. One area noted for improvement was that evidence of training in the use of cone beam computed tomography (CBCT) equipment, as prescribed by the Dental Council, was not available and this should be addressed by the undertaking as a matter of urgency.

Overall, while the instance of non-compliance found on inspection is an area for improvement, the inspector found that the undertaking demonstrated good levels of compliance with the other regulations considered on the day of inspection.

Regulation 4: Referrers

Following review of documentation and speaking with staff, the inspector was satisfied that all referrals for dental radiological procedures originated within the practice from the registered dentist. Up-to-date professional registration information was supplied to the inspector and satisfied relevant regulatory requirements.

Judgment: Compliant

Regulation 5: Practitioners

The inspector reviewed the professional registration details of the practitioner operating at Virginia Dental Care & Implants. All professional registration information was up to date and satisfied relevant regulatory requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector was informed that the dentist operating at the practice was both the referrer and practitioner for all dental radiological procedures carried out on site. This was confirmed by reviewing a sample of patient records which also assured the inspector that all dental exposures were justified in advance. Furthermore, the referral records reviewed on the day stated the reason for the dental X-ray as well as providing sufficient medical data for the procedure. Staff spoken with on the day demonstrated clearly their ability to communicate the benefits and risks of dental X-ray procedures to patients when required to do so.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied following review of documentation and speaking with staff that all dental exposures took place under the clinical responsibility of the dentist operating at the practice and the MPE was involved in the optimisation process with the dentist. The inspector was informed that practical aspects of dental radiological procedures were not delegated to other individuals at the time of

inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Records of MPE performance testing supplied to the inspector as part of the inspection process detailed that diagnostic reference levels (DRLs) were established in September 2022 during equipment acceptance testing. The associated MPE QA report included recommendations for the undertaking to further investigate where local facility DRLs exceeded the national levels through initial manufacturer service engineer communication. Evidence of service engineer communication was shown to the inspector on the day of inspection who was assured that the appropriate investigations were underway. It is imperative that all subsequent corrective actions deemed relevant by the undertaking, service engineer and MPE are taken without undue delay.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard dental procedure were supplied to the inspector in the form of bespoke *Step by Step* guides developed by the undertaking.

After a review of a sample of imaging reports the inspector was assured that the undertaking had implemented a system to routinely include information relating to patient exposure on the report of the medical radiological procedure.

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that all dental radiological equipment was kept under strict surveillance. Records of MPE commissioning testing and performance testing were reviewed by the inspector and satisfied regulatory requirements. A full radiological equipment inventory was supplied in advance of the inspection and this was verified on site by the inspector.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Local documentation reviewed by the inspector clearly categorised radiation incidents, detailed the process for the management of such incidents and included sample dental radiography incident report forms. Staff articulated the radiation incident management process to inspectors during the course of the inspection. At the time of inspection, no incidents or near misses had been recorded however the inspector was satisfied that this was due to the nature of the patient pathway and there were no concerns in relation to an absence of reporting.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was assured that the necessary arrangements were in place to ensure continuity of expertise of the MPE at Virginia Dental Care & Implants.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records of MPE contributions to equipment QA, equipment acceptance testing and DRL establishment were reviewed by the inspector. MPE registration details were supplied and these were up to date. After document review and staff communication, the inspector was satisfied that the responsibilities and contributions of the MPE satisfied regulatory requirements in relation to Regulation 20.

Judgment: Compliant

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

Following document review and speaking with staff, the inspector was satisfied that the involvement of the MPE was appropriate for the level of risk associated with the service provided by Michael Hannick at Virginia Dental Care & Implants.

Judgment: Compliant

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

On the day of inspection, evidence of training completed by the practitioner in the use of cone beam computed CBCT, as prescribed by the Dental Council, was not available for review. The inspector was informed that this training was not complete. The undertaking 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. This should be addressed as a matter of urgency to ensure compliance with the training requirements of Regulation 22.

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
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	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 Virginia Dental Care & Implants OSV-0008324

Inspection ID: MON-0037661

Date of inspection: 13/10/2022

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 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: The undertaking has since partaken and completed CBCT training Level 1 (Core). Level 2 training has been scheduled and will completed on the 2 February 2023 (Dental CBCT Justification and image interpretation).	

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 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	Not Compliant	Orange	02/02/2023

	<p>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, 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).</p>			
Regulation 22(5)	<p>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.</p>	Not Compliant	Orange	02/02/2023