



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Touchstone Dentistry
Undertaking Name:	RS Dentistry Limited
Address of Ionising Radiation Installation:	First Floor, Riverside Primary Care Centre, Mulhuddart, Dublin 15
Type of inspection:	Announced
Date of inspection:	12 November 2021
Medical Radiological Installation Service ID:	OSV-0006618
Fieldwork ID:	MON-0034640

About the medical radiological installation:

Touchstone Dentistry provides a range of general dental and cosmetic treatments in Mullhuddart, Dublin 15.

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
Friday 12 November 2021	12:00hrs to 13:30hrs	Kirsten O'Brien	Lead

Summary of findings

On the day of inspection, the allocation of responsibility for the radiation protection of service users was clearly communicated by management at Touchstone Dentistry. The inspector was satisfied that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice. A recognised medical physics expert (MPE) was also appropriately involved and provided medical physics expertise as required by the regulations.

All dental radiological procedures were conducted under the clinical responsibility of a dentist, registered with the Dental Council, as per the regulations. The process for referral and justification in advance by a practitioner was communicated to the inspector. From the records of referrals reviewed on the day, the inspector was satisfied that while a record of the referral for dental exposures with sufficient clinical information was included in patients' notes, a more defined mechanism for recording written referrals should be considered to provide comprehensive evidence of compliance with the regulations.

The undertaking is required to have written protocols available for each type of standard procedure for each type of equipment, however while documentation reviewed contained information on the conduct of exposures generally, protocols should be updated to include additional details about how each type of dental radiological procedure at the practice is conducted. Having written protocols in place helps ensure that procedures and radiation doses received by the service user are appropriate and standardised. Furthermore, information relating to the dental exposure was also not included in the report of the dental exposure as part of the patients' notes.

The inspector was satisfied that diagnostic reference levels (DRLs) had been established at Touchstone Dentistry. The inspector also found that preventative maintenance and servicing of dental radiological equipment had been recently carried out at the practice. However, quality assurance (QA) testing which is carried out every two years by an MPE was overdue on the day of inspection. This finding had been identified prior to the inspection and the inspector reviewed records and correspondence that provided an assurance that RS Dentistry Limited had already taken action to come into compliance with this requirement of the regulations. Additionally, the inspector found that acceptance testing had not been completed prior to clinical use on one piece of dental radiological equipment. These findings were accepted by the designated manager on the day of inspection and an assurance was provided to the inspector that the equipment would not be used to conduct dental radiological procedures until such time as a QA review has been conducted by a registered MPE.

The undertaking was requested to submit an urgent compliance plan under Regulation 14 to address the risks identified. The undertaking's response did provide

assurance that the risks identified was adequately addressed.

Regulation 4: Referrers

From a review of documentation and speaking with management and staff at the practice, the inspector were satisfied that only referrals for dental radiological procedures, from individuals entitled to refer as per Regulation 4, were carried out at the practice.

Judgment: Compliant

Regulation 5: Practitioners

An inspector spoke with staff and reviewed a sample of records and other documentation and found that only registered dentists took clinical responsibility for dental radiological exposures at the practice.

Judgment: Compliant

Regulation 6: Undertaking

A clear allocation of responsibility for the radiation protection of patients was in place at Touchstone Dentistry. Inspectors reviewed documentation provided and spoke with staff and the designated manager who clearly communicated the management and oversight structure in place for dental exposures to ionising radiation at the practice. All dentists were practitioners at the practice operating under the governance of the undertaking, RS Dentistry Limited. Similarly, the inspector was satisfied that a recognised MPE was also appropriately involved as required by the regulations

Judgment: Compliant

Regulation 8: Justification of medical exposures

A sample of patient records and other documentation were reviewed on the day of inspection. The inspector found that a dentist, registered with the Dental Council, took clinical responsibility for justifying all individual procedures. The process for referral and justification in advance by a practitioner was communicated to the

inspector. However, while a written record of the referral for a dental exposure was found to be accompanied by sufficient medical data in the patients' notes, the undertaking should ensure that referrals and the reason for requesting the particular procedure are clearly identifiable in order to provide evidence of compliance with the regulations going forward.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From speaking with management and staff, and reviewing documents and other records, the inspector was satisfied that only registered dentists took clinical responsibility for dental radiological procedures at Touchstone Dentistry. Similarly, the referrer and practitioner, who were the same person, were found to be involved in the justification process. Additionally, only practitioners carried out the practical aspects of dental radiological procedures. The inspector was also satisfied that a medical physics expert (MPE) and the practitioner were also involved in the optimisation process for all dental exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for dental radiological procedures conducted at Touchstone Dentistry. These DRLs were reviewed by the MPE as part of the QA programme. While the inspector was satisfied that the practice was compliant with the requirements of the regulation generally, practitioners should have access to more meaningful DRL values for use in day-to-day practice as an area for improvement.

Judgment: Compliant

Regulation 13: Procedures

While written documentation regarding the conduct of dental radiological procedures generally were reviewed by the inspector in advance of the inspection, written protocols should be updated to include more specific information for each type of standard procedure and for each type of equipment at Touchstone Dentistry. For example, written protocols should include information on exposure parameters used and how X-rays are obtained based on the type of equipment used at Touchstone

Dentistry.

Additionally, inspectors found that information relating to patient exposure did not form part of the report of the dental radiological procedure. The inspector also found that clinical audit relating to dental radiological procedures had not been carried out at Touchstone Dentistry. Conducting audits frequently can help an undertaking to evaluate and monitor a service, and plays an important role in providing assurance of the radiation protection of service users.

Judgment: Not Compliant

Regulation 14: Equipment

In advance of the inspection, records and documentation provided to the inspectors relating to the dental radiological equipment were reviewed. From the review of records, the inspector found that RS Dentistry Limited had implemented a QA programme which included a QA assessment every two years by an MPE. However on the day of inspection, the most recent QA assessment, which had been due by May 2021, was still outstanding. Management on the day of inspection acknowledged this finding and provided assurance to the inspector that they had been in contact with the MPE to arrange for QA testing to be carried out.

Additionally, acceptance testing before the first clinical use of one piece of radiological equipment had not been carried out at Touchstone Dentistry. The inspector brought this non-compliance to the attention of the designated manager on the day of inspection and was assured that this equipment would be taken out of use immediately. Subsequently, Touchstone Dentistry provided a written assurance to the inspector that the equipment would not be used until such time as an appropriate QA assessment had been completed by an MPE.

Notwithstanding the inspector's findings above, dental radiological equipment at the practice was subject to an annual service for preventative and maintenance purposes. Regular routine performance testing provides an assurance to the undertaking that the dental radiological equipment at the practice is maintained in good working condition and this was noted as a positive finding.

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

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation and policies relating to accidental and unintended exposures were reviewed by the inspector. Additionally, management at Touchstone Dentistry communicated the process for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures at the practice.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

RS Dentistry Limited had appropriate arrangements in place to ensure the continuity of medical physics expertise at Touchstone Dentistry.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, the undertaking, RS Dentistry Limited, had ensured that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users at Touchstone Dentistry. The MPE was found to contribute to optimisation, including the establishment of DRLs, evaluation of dose delivered to service users, and quality assurance at the practice.

Judgment: Compliant

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

The inspector found that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at Touchstone Dentistry.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not 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

Compliance Plan for Touchstone Dentistry OSV-0006618

Inspection ID: MON-0034640

Date of inspection: 12/11/2021

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> <ol style="list-style-type: none"> All practitioners are committed to including clinical reasons for exposure prior to exposure. This is to be treated as a "self referral". The practitioner will note that prior to exposure patient has consented. <p>Implemented on 12/12/21 Date of review 12/01/2022. A peer review by practitioners and undertaking will occur to ensure compliance 6 monthly thereafter.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <ol style="list-style-type: none"> Individual SOPs have been devised with the practitioners for each room. A separate SOP has been devised in conjunction with the practitioners for the OPG. The SOP covers Technique, referral criteria and Patient consent and pat. Implemented on 12/12/2021 A review of the SOP to take place 14/02/2022. A copy of the relevant SOP is kept in each respective room. The dentist notes are to contain information on the exposure. Date implemented 14/12/21 A sample of practitioner's notes are to be audited quarterly involving their peers and the Undertaking. This audit is to be primarily based on the findings of the HIQA inspection of November 2021. 	

Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: On December 4/12/21 the MPE for Touchstone carried out a QA assessment on the 3 intra oral x-ray systems. All systems were deemed suitable for clinical use. The report received on 15/12/21. Recommendations of the MPE are to be actioned on 16/12/21. Acceptance testing was carried out on 04/12/2021. The OPG could not be assessed on 4/12/21 due to a fault in the system. The MPE will perform the QA assessment on 20/12/21.</p>	

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	12/12/2021
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	12/12/2021
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	12/12/2021
Regulation 13(2)	An undertaking shall ensure that	Not Compliant	Orange	14/12/2021

	information relating to patient exposure forms part of the report of the medical radiological procedure.			
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	Orange	04/12/2021
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	20/12/2021
Regulation 14(3)(a)	An undertaking shall carry out the following testing on its medical radiological equipment, acceptance testing before the first use of the equipment for clinical purposes; and	Not Compliant	Red	04/12/2021