Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Rdent
Undertaking Name:	Dr Mamoon Rashid
Address of Ionising Radiation Installation:	Unit 70, Galway Shopping Centre, Headford Road, Galway
Type of inspection:	Announced
Date of inspection:	29 October 2020
Medical Radiological Installation Service ID:	OSV-0007307
Fieldwork ID:	MON-0028251

About the medical radiological installation:

Rdent provides general dentistry, cosmetic dentistry, six month smiles clear braces and dental implants. Dental imaging includes intra oral radiography, orthopantomograms and cone beam computed tomography (CBCT).

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[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] 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 29 October 2020	12:00hrs to 14:00hrs	Lee O'Hora	Lead
Thursday 29 October 2020	12:00hrs to 14:00hrs	John Tuffy	Support

Summary of findings

Inspectors found effective management arrangements at Rdent with a clear allocation of responsibility for the protection of service users undergoing dental exposures. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to inspectors on the day of inspection. Only one dental undertaking operated at Rdent at the time of inspection.

All imaging referrals reviewed by inspectors were justified by professionally recognised dental practitioners and imaging records reviewed satisfied all regulatory requirements for the appropriate justification of dental procedures. Inspectors were satisfied that the undertaking at Rdent supplied service users with adequate information relating to the radiation risks associated with dental radiology.

Inspectors were satisfied that dental radiological equipment at Rdent was kept under strict surveillance in conjunction with the medical physics expert (MPE). By reviewing documentation and communicating with staff, inspectors were assured of the appropriate qualifications, continuity of expertise and involvement of the MPE at Rdent. Evidence of systems to identify and record accidental and unintended exposure and near misses was reviewed by inspectors and staff articulated these processes to inspectors on the day of inspection. Documentary evidence that imaging parameters were regularly reviewed and subsequently optimised in conjunction with a MPE was supplied to inspectors.

However, there were areas noted for improvement within the service. Inspectors were informed that equipment calibration recommended by the MPE was scheduled to be completed in the coming weeks but was outstanding on the day of inspection.

Inspectors saw evidence of diagnostic reference levels (DRLs) being established and reviewed by the undertaking at Rdent however no evidence that this DRL data was made available or routinely used by staff in the clinical setting was available on inspection. Furthermore, although standard imaging protocols were well understood by all staff, these were not available in written format on the day of inspection. Referral guidelines were not available to referrers at Rdent and there was no evidence that information relating to patient exposure formed part of the patients records reviewed by inspectors. Finally, evidence of completed 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 there were some areas of good practice noted on inspection, there were areas requiring improvement and should be addressed in order to demonstrate full compliance with the regulations.

Regulation 4: Referrers

Rdent currently receives all referrals from within the service. Referrals are from dental practitioners and, for all referrals reviewed, the referrer and practitioner were the same person. Furthermore, evidence of professional registration of dentists involved in the service were viewed by inspectors on site.

Judgment: Compliant

Regulation 5: Practitioners

Two dentist practitioners operate at Rdent. Evidence of registration with the Dental Council was reviewed by inspectors on site. Practitioners were clearly identified in documentation of governance forwarded to HIQA in advance of the inspection and further verified by inspectors on site.

Judgment: Compliant

Regulation 6: Undertaking

Documentation of governance and key personnel clearly outlined radiation safety management and practitioners at Rdent. Inspectors were satisfied that these positions and relationships were well understood by staff. Good knowledge of reporting structures was articulated to inspectors throughout the inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

Documentation detailing the justification process and responsibilities of the undertaking, referrer and practitioner were reviewed by inspectors. All exposures reviewed on site had been justified in advance by a practitioner and evidenced in the patient record.

Documents outlining the necessary content of a dental referral were reviewed and satisfied regulatory requirements. All referrals reviewed during the inspection were in writing, stated the reason for procedure and were accompanied by sufficient data for the medical radiological procedure to proceed.

Inspectors were informed that patients were routinely asked about relevant previous imaging. Risk benefit information was evident in imaging consent forms reviewed by inspectors. Staff informed inspectors that imaging consent forms were routinely completed and signed by service users prior to imaging. Inspectors observed posters displayed in the patient waiting area and the CBCT room that detailed information on radiation exposure associated with dental imaging. Staff were confident in communicating risk benefit concepts associated with dental imaging to service users.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed quality assurance documentation, completed in June 2020, which gave a series of patient dose optimisation recommendations. A number of these recommendations had been completed or implemented at the time of inspection. One recommendation related to the calibration of a dose area product meter for a specific piece of equipment. Inspectors reviewed communications with the equipment manufacturer which indicated that this work was scheduled for the 10 November 2020 but at the time of inspection this work had not yet been completed. This should be addressed in order to demonstrate full compliance with this regulation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Documentation reviewed by inspectors clearly defined the process employed by the undertaking to ensure all dental exposures take place under the clinical responsibility of a practitioner. Staff were clear in their clinical responsibilities for individual dental exposures and articulated the process by which this was achieved to inspectors.

Evidence of practitioner and medical physics expert (MPE) involvement in the optimisation process was supplied to inspectors.

The justification process was documented and clearly articulated to inspectors during the inspection. Rdent practitioners also acted as referrers for all imaging ensuring the justification process involved the appropriate persons.

The practical aspects of dental radiological procedures were not delegated to other persons at Rdent at the time of inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Documentation reviewed confirmed that the undertaking at Rdent established and reviewed diagnostic reference levels (DRLs) in July 2020 for three routine dental imaging examinations undertaken on site. DRLS were not displayed in the clinical area on the day of inspection. The undertaking and staff articulated to inspectors that DRL data is not routinely used clinically and acknowledged the potential to use DRL data to optimise patient exposure.

Records reviewed by inspectors indicated that the local facility DRL for orthopantomography (OPG) was above the national DRL. Staff informed inspectors that the MPE was contacted for advice after comparison with the national DRL. Subsequent optimisation of exposure factors was suggested by the MPE and implemented by Rdent which was seen as a positive action to address the exposure alignment recommended by the MPE however there was an absence of documentation to verify this corrective action available on the day of inspection.

Judgment: Substantially Compliant

Regulation 13: Procedures

Staff displayed and articulated detailed knowledge of exposure factors and imaging technique to inspectors but written protocols for every type of standard dental radiological procedure were not available in the clinical area at the time of inspection.

Staff articulated that information relating to exposure did not form part of the report at the time of inspection. Reports reviewed on site by inspectors did not contain information relating to the patient exposure.

Staff demonstrated good knowledge of rationale for imaging and used bespoke referral criteria for CBCT imaging but evidence of availability of referral guidelines for dental imaging was not found on inspection.

Inspectors were informed by staff that the audit of image quality had commenced at Rdent and inspectors reviewed records of the initial image quality audits. At the time of inspection, there was no evidence of follow up actions or outcomes in relation to these audits available. The undertaking should ensure the issues identified under this regulation are addressed in order to demonstrate compliance.

Judgment: Not Compliant

Regulation 14: Equipment

After reviewing documentation and by confirming equipment information with staff, inspectors were satisfied that all radiological equipment was kept under strict surveillance regarding radiation protection. Records of acceptance testing and performance testing were reviewed by inspectors.

An up to date inventory was supplied by Rdent and verified on site by inspectors.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Local documentation reviewed by inspectors clearly categorised radiation incidents, detailed their management 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 at Rdent however inspectors were satisfied that this was due to the nature of the patient pathway in Rdent and there were no concerns in relation to an absence of reporting.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors reviewed the Irish College of Physicists in Medicine (ICPM) registration of the MPE and were satisfied that this was up to date.

Documentation evidencing continuity of MPE services until October 2022 was available and satisfied inspectors that there were arrangements in place to maintain MPE expertise at Rdent at the time of inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Documentation supplied and discussion with relevant staff satisfied inspectors that the MPE fulfilled their regulatory responsibilities, gave appropriate advice and

contributed aptly to ensure the safe delivery of dental exposures at Rdent. Documentary evidence was supplied detailing MPE acceptance testing, performance testing, exposure optimisation recommendations, diagnostic reference level establishment recommendations and practitioner training records.

Judgment: Compliant

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

After review of documentation and speaking with staff, inspectors were satisfied that the involvement of the MPE at Rdent was commensurate with the radiological risk based on documentation reviewed under Regulation 20.

Judgment: Compliant

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

On the day of inspection, evidence of completed training in the use of cone beam computed tomography (CBCT) equipment, as prescribed by dental council, was not available for review nor provided to inspectors following the inspection. 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 9: Optimisation	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Not 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 Rdent OSV-0007307

Inspection ID: MON-0028251

Date of inspection: 29/10/2020

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 9: Optimisation	Substantially Compliant
Outline how you are going to come into compliance with Regulation 9: Optimisation: On 10/11/20 A Qualified Engineer visited the site and carried out a service of the CBCT unit. Calibration of the DAP meter was carried out according to regulations.	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: DRLs are now displayed in clinical areas. DRLs are now used clinically by the Dentists.	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Written protocols for standard dental radiological procedures are available for each type of equipment for relevant categories of patients in the clinical areas. Information relating to patient exposures now forms part of the report for dental radiological procedures.	

Referral guidelines including radiation doses as recommended by EURATOM (RP 136), are now available in the clinical areas.

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: Dr. Mamoon Rashid has booked a CBCT training course that goes through both theoretical and practical aspects of CBCT. This course is a 2 day course and will take place on 20th and 27th of February 2021. The course is provided by Dentsply Sirona.

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 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.	Substantially Compliant	Yellow	10/11/20
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic	Substantially Compliant	Yellow	10/12/20

	examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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.	Substantially Compliant	Yellow	12/12/20
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.	Not Compliant	Orange	12/12/20
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	12/12/20

Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	12/12/20
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	Not Compliant	Orange	27/02/2021

	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).			