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:	Smile Design Dental
Undertaking Name:	Copper Niti Ltd
Address of Ionising Radiation Installation:	16 Main Street, Baldoyle, Dublin 13
Type of inspection:	Announced
Date of inspection:	05 May 2021
Medical Radiological Installation Service ID:	OSV-0006845
Fieldwork ID:	MON-0031217

About the medical radiological installation:

Smile Design Dental is based in Baldoyle in Dublin 13, providing general dental and orthodontic/implant treatment. The practice consists of two purpose built lead lined dental surgeries with intra-oral X-ray machines. The orthopantomgram (OPG) and cone beam computed tomography (CBCT) machine is located in a designated room. The CBCT is used infrequently with a limited field of view (FOV) function.

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
Wednesday 5 May 2021	12:00hrs to 14:00hrs	Lee O'Hora	Lead
Wednesday 5 May 2021	12:00hrs to 14:00hrs	Noelle Neville	Support

Summary of findings

Inspectors conducted an on-site inspection of the undertaking Copper Ni Ti Ltd. operating at Smile Design Dental on the 5 May 2021.

Inspectors found effective management arrangements at Smile Design Dental with a clear allocation of responsibility for the protection of service users undergoing dental radiological procedures. Key personnel and reporting structures were well defined in documentation reviewed and were clearly articulated to inspectors on the day of inspection.

Inspectors were satisfied that the undertaking had processes in place to ensure the safe conduct of dental radiological procedures. Inspectors were assured that only dentists working within the practice referred service users for dental radiological procedures and that the same individuals acted as both referrers and practitioners for all referrals. The practical aspects of dental radiological procedures were not delegated to professionals other than registered dentists at the time of inspection. Inspectors reviewed documentation and a sample of service user referrals and were assured that the justification process for dental radiological procedures was adequately recorded and satisfied all regulatory requirements. Inspectors found that Smile Design Dental made information relating to the benefits and risks associated with dental radiological procedures available to patients and staff clearly articulated risk benefit concepts to inspectors on the day of inspection.

Records of radiation safety training reviewed by inspectors on the day of inspection evidenced training for the use of cone beam computed tomography (CBCT) for the designated dentist but also demonstrated bespoke radiation safety training of all dentists working at Smile Design Dental. The training documentation reviewed on site covered the regulatory requirements associated with the role of referrer and practitioner as well as general radiation safety concepts. This was seen as a positive measure promoting good radiation safety practice.

Inspectors were satisfied that Smile Design Dental established, reviewed and used diagnostic reference levels (DRLs). Records of annual reviews and subsequent corrective actions detailed the implementation of the corrective actions which reduced service user dose for the orthopantomogram procedure at Smile Design Dental. Inspectors were informed that the corrective actions implemented also maintained diagnostic quality and this was seen as a positive use of DRL reviews to deliver patient radiation dose reduction while maintaining diagnostic quality.

Inspectors were satisfied that Smile Design Dental had systems in place to ensure information relating to the patient exposure formed part of the report of dental radiological procedures and that referral guidelines were available to the relevant staff. Written protocols for every type of standard dental radiological procedure were not available on the day of inspection however this was acknowledged by management as an area for potential improvement and should be addressed by the

undertaking to ensure regulatory compliance.

Inspectors reviewed image quality audit records for all dentists and noted medical physics expert (MPE) report recommendations from 23 April 2021 to expand the audit process to include image quality, reject analysis and justification. Senior management expressed the intention to expand the current audit process to reflect MPE recommendations but at the time of inspection this had not yet been completed. The expansion of the audit process, as suggested by the MPE, would be seen as a further quality improvement tool for Smile Design Dental.

Inspectors reviewed records of manufacturer and MPE quality assurance tests for all dental radiological equipment at Smile Design Dental. On the day of inspection, records of MPE commissioning testing were not available and inspectors were informed that this had not yet been completed. It is essential that all newly installed equipment undergoes acceptance testing before its first clinical use to ensure regulatory compliance as well as the safety of service users. Senior management acknowledged the need for this to be addressed in the short term, before the equipment is used clinically, and assured inspectors that MPE commissioning testing would be processed with urgency. Documentation of medical physics expert (MPE) professional registration, continuity of expertise and involvement was reviewed and articulated to inspectors and satisfied all regulatory requirements.

Inspectors were satisfied that Smile Design Dental had implemented the appropriate systems to record, analyse and inform HIQA of significant events as required by Regulation 17. No accidental and unintended exposures or significant events had been recorded at Smile Design Dental at the time of inspection, however inspectors were satisfied that an absence of recorded or reported incidents reflected the referral and imaging pathway for dental radiological procedures and did not pose a service user risk.

Overall, for the specific regulations considered by inspectors on the day of inspection, there were areas of good practice and areas for potential improvement and inspectors were satisfied that areas for potential improvement would be progressed by the undertaking.

Regulation 4: Referrers

Following review of professional registration documentation and communication with staff, inspectors were satisfied that referrals for dental radiological procedures were only accepted from the appropriately qualified professionals at Smile Design Dental.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed professional registration details of all practitioners operating at Smile Design Dental, all professional registration information was up to date and satisfied the requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by inspectors and staff communication outlined a clear allocation of responsibility for the protection of service users from dental exposure to ionising radiation. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to inspectors by staff and management during the course of the inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

Inspectors were informed that dentists operating at Smile Design Dental acted as both the referrer and practitioner. Patient notes reviewed on site confirmed this information. The documentation provided to inspectors clearly outlined the regulatory definition of justification and staff articulated this concept to inspectors on the day of inspection. Records reviewed on site by inspectors clearly demonstrated that individual justification of dental radiological procedures was carried out in advance of exposure and recorded in the patient notes. All referrals reviewed on the day of inspection demonstrated that referrals were in writing, stating the reason for for the procedure and were accompanied by the appropriate medical data. The digital system used to record this information was accessed using user-specific sign in details allowing a specific practitioner to be associated with the justification of individual dental radiological exposures.

Smile Design Dental supplied information relating to the risks and benefits associated with dental radiological procedures to patients in the form of pamphlets available at the practice. Staff articulated these risks clearly to inspectors and were able to communicate these principles on the day of inspection.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied after documentation review, staff communication and on site patient imaging notes review that all dental radiological procedures took place under the clinical responsibility of a practitioner at Smile Design Dental.

Following review of documentation, meeting with staff, and review of referrals for imaging, inspectors were satisfied that Smile Design Dental had robust processes in place to ensure the practitioner and referrer, the same individual in all cases, were sufficiently involved in the justification of dental radiological procedures and evidence of justification was recorded in the patient notes.

Inspectors reviewed staff radiation safety training records which detailed bespoke dentist training in the areas of referrer tasks, practitioner tasks and dental radiation safety. Inspectors were informed that only one dentist referred patients for, and subsequently conducted cone beam computed tomography (CBCT). Inspectors reviewed CBCT specific training records on site.

Inspectors also confirmed that the practical aspects of dental radiological procedures were not delegated to any individual other than dentists following review of documentation.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Documentation reviewed and staff communication demonstrated to inspectors that diagnostic reference levels (DRLs) were established, reviewed and used at Smile Design Dental.

Recent DRL reviews by the MPE highlighted that the local facility DRL for the orthopantomogram (OPG) procedure was higher than the national DRL. Inspectors found that corrective actions, suggested by the MPE, had been implemented within days. Inspectors were also informed that OPG image quality analysis confirmed no loss of diagnostic information as a result. This was seen as a positive demonstration of the use of DRLs in practice, reducing patient radiation doses while maintaining diagnostic information gained from dental radiological procedures.

Judgment: Compliant

Regulation 13: Procedures

Staff articulated good knowledge of exposure parameters used when imaging and exposure factors were well documented and displayed in the practice. Inspectors reviewed evidence of general imaging technique for OPG and CBCT procedures

available within the digital imaging systems but comprehensive written protocols for every type of standard dental radiological procedure were not available on the day of inspection.

Inspectors were satisfied that the digital system used to retain patient notes and images archived information relating to patient exposure as part of the report of the dental radiological procedure.

Dedicated referral guidelines for dental imaging were also available to referrers at Smile Design Dental and staff clearly articulated knowledge of referral criteria to inspectors on the day of inspection.

Records of image quality audits for all dentists were supplied to inspectors. Records of a CBCT justification audit was also supplied to inspectors. Inspectors were informed of plans to upgrade clinical audit to include image rejection analysis and justification audits as suggested in the MPE's most recent QA reports. At the time of inspection the plans to expand the audit had not been implemented.

Judgment: Substantially Compliant

Regulation 14: Equipment

Documents reviewed and quality assurance (QA) records satisfied inspectors that Smile Design radiological equipment was serviced by the manufacturer and quality assurance testing was carried out by the MPE. A full inventory of dental radiological equipment was also supplied in advance of the inspection.

Documentation reviewed by inspectors clearly outlined the requirement for MPE commissioning testing on newly installed dental radiological equipment, before first clinical use, and the requirement for this testing to be conducted independently of the equipment installer. Manufacturer records detailed that a new intra-oral dental unit was fitted on the 26 April 2021. Inspectors reviewed acceptance testing conducted by the installer of the equipment but staff informed inspectors that MPE acceptance testing had not yet been conducted, and therefore, evidence demonstrating compliance was not available.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documents reviewed by inspectors clearly outlined the process for record keeping and analysis of accidental or unintended dental exposures or near misses and the appropriate responsible people were also clearly identified. This process was clearly

articulated to inspectors by staff on the day of inspection.

No accidental and unintended exposures or significant events or near misses had been recorded at the practice at the time of inspection.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Documents reviewed and communication with the undertaking representative assured inspectors that the necessary arrangements to ensure continuity of MPE expertise had been established.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration records of the medical physics expert (MPE) and found that the certification available on the website of the company providing MPE services was valid until 30 April 2021. Inspectors requested and subsequently received evidence of renewed MPE registration extending until the 30 April 2023.

Inspectors were satisfied after document review and communication with staff that the responsibilities, advice and contributions of the MPE were closely aligned with regulatory requirements.

Judgment: Compliant

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

After document review and communication with staff, inspectors were assured that the involvement of the MPE at Smile Design Dental was commensurate with the radiological risk posed by the practice.

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	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially 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 Smile Design Dental OSV-0006845

Inspection ID: MON-0031217

Date of inspection: 05/05/2021

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 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Written protocols are now documented for each radiological technique and are on display for all staff members. This has been completed by and quality assured by the principal dentist. Designated personnel have been instructed and trained to follow said procedures.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Immediately after the inspection the principal dentist and the undertaking representative contacted the appointed Medical Physics expert who completed an independent assessment on the recently installed x-ray equipment. A certificate has now been issued for this. All aspects are deemed satisfactory	

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 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	24/06/2021
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	Orange	12/05/2021