



Health Information and Quality Authority

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

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| Name of Medical Radiological Installation: | Smiles Dental Wexford |
| Undertaking Name: | Xeon Dental Services Limited |
| Address of Ionising Radiation Installation: | 8 Selskar Street, Wexford |
| Type of inspection: | Announced |
| Date of inspection: | 23 October 2020 |
| Medical Radiological Installation Service ID: | OSV-0007332 |
| Fieldwork ID: | MON-0030074 |

About the medical radiological installation:

Smiles Dental Wexford is a dental clinic with four surgery rooms. The clinical areas are spread over two floors with two surgeries located on each floor. Surgery one and surgery two, both located on the ground level, have an intra-oral machine. Surgeries three and four are located on the first floor, again with an intra-oral machine in each surgery. Surgery one, three, and four are routinely used by general dentists offering routine dental treatments, for example, restorations, extractions and root canal treatments. Surgery two is almost exclusively used for orthodontic treatments with the exception of general treatments for wheelchair bound patients.

In addition, a dedicated x-ray room with an integrated scanner is also available on the ground floor. This scanner can be used to obtain:

- orthopantomograms which provide panoramic views of the jaw and teeth
- cephalometric radiographs used to provide an image of the side of the face
- cone beam computer tomography scans (CBCT) used to obtain multiple images from different angles to create a single 3-Dimensional image.

This integrated scanner is mainly used for assessment by the part-time orthodontist (three days per week) and the implantologist who is on site one day a month.

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 and management 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 complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

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.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

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 23 October 2020 | 11:00hrs to 13:30hrs | Agnella Craig | Lead |
| Friday 23 October 2020 | 11:00hrs to 13:30hrs | John Tuffy | Support |

Governance and management arrangements for medical exposures

Due to the size and scale of this undertaking, the findings for the inspection of Smiles Dental Wexford are reported under two dimensions. This undertaking was found to be compliant, in this dental facility, with all eight regulations assessed under the first dimension, 'Governance and management arrangements for medical exposures'.

Inspectors found that there was effective leadership, governance and management arrangements in place with a clear allocation of responsibility for the radiation protection of people who use services within this dental practice. The process for reporting to the undertaking was also detailed, assuring inspectors of the oversight the undertaking has of this practice.

The majority of radiological procedures conducted within this practice are as a result of referrals from those working within this practice where the referrer and the practitioner for each procedure are the same person. These individuals are registered dentists and therefore entitled to act as referrers and practitioners. Clinical responsibility was also taken by practitioners and the practical aspects of procedures were not delegated to others at the time of inspection.

Involvement of the Medical Physics Expert (MPE) across all aspects of the service was evident in the documentation reviewed in advance of inspection and this included a comprehensive quality assurance programme. As the MPE was available to meet with inspectors on the day of inspection, the role and responsibilities held by the MPE were further detailed, including how the continuity of medical physics expertise is ensured. Inspectors were assured that the level of involvement of the MPE was in line with the level of risk posed by this facility.

Regulation 4: Referrers

The majority of referrals in Smiles Dental Wexford are from the staff working within this dental practice, where the referrer and practitioner are the same person. Occasionally referrals are received from one other dental practice for patients requiring CBCT scans. Staff that spoke with inspectors on the day of inspection explained the process in place for accepting these external referrals.

Referrals for medical radiological procedures reviewed on the day of inspection were only accepted from those entitled to refer an individual for a medical exposure as per the regulations.

Judgment: Compliant

Regulation 5: Practitioners

From the records of medical exposures reviewed on the day of inspection, inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures in this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

From the documents provided in advance and the information provided on the day of inspection, inspectors were assured that the undertaking had provided a clear allocation of responsibilities within this practice. The *Radiation Safety – Policy and Guidance – ROI* document clearly outlined the responsibilities of the personnel working for Smiles Dental Wexford and staff were able to clearly communicate these responsibilities to inspectors on the day of inspection. This policy included a flow chart which clearly showed the clinical governance structures and the reporting structures in place to ensure the undertaking had oversight of this practice.

This policy is relevant to all the dental practices under the responsibility of this undertaking. Inspectors were informed that occasionally staff from a number of these dental practices share discussions and training and in some instances, this training has related to radiation protection. Although not a regulatory requirement, a structured forum such as a radiation safety oversight committee is worth considering in an undertaking of this size. This would facilitate shared learning and radiation safety discussions across practices. Notwithstanding this potential area for improvement, there were strong organisational and clinical links to the undertaking noted on inspection.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were assured that all medical exposures took place under the clinical responsibility of a practitioner. From the documentation reviewed and discussions with staff, inspectors were assured that practitioners who were recognised by the Dental Council took clinical responsibility for medical exposures. The practical aspects of medical radiological procedures, previously delegated to other individuals recognised by the Dental Council, were only carried out by practitioners at the time of inspection. Inspectors were informed that the practitioner with responsibility for the CBCT scanner had received specific training and the certificate of this training

was available for inspectors to review on the day of inspection. Inspectors were assured that the optimisation process included practitioners and the MPE.

Judgment: Compliant

Regulation 18: Estimates of population doses

Estimates of the annual number of patients undergoing medical exposures, which was differentiated for distinct types of medical radiological procedures in this dental facility, was provided to inspectors in advance of this inspection.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were assured that a recognised MPE was available to this undertaking and that formal arrangements were in place to ensure the continuity of medical physics expertise for this dental facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From documents reviewed in advance of this inspection, and from speaking with staff, it was evident that the MPE takes responsibility for dosimetry, reviewing diagnostic reference levels (DRLs), quality assurance and acceptance testing of radiological equipment. The quality assurance reports reviewed by inspectors were up-to-date, comprehensive and included actions, recommendations and a detailed risk assessment. The MPE, who was available on the day of inspection, informed inspectors of MPE involvement in training and education of staff and in advising on the selection and specification of medical radiological equipment.

Judgment: Compliant

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

From the documentation reviewed and the information provided by staff, inspectors were assured that the undertaking has arrangements in place to ensure the level of

involvement of the MPE is in line with the level of risk posed in this dental practice.

Judgment: Compliant

Safe Delivery of Medical Exposures

Of the six regulations examined under this dimension, full compliance was identified for five regulations and the remaining regulation (Regulation 13) was found to be substantially compliant. Overall, inspectors were assured of the safe delivery of medical exposures noting some areas for improvement.

As required for compliance with Regulation 13(1), written protocols for every type of equipment for relevant categories of patients were not available at the time of inspection. However, the process of conducting a standard medical radiological procedure was explained to inspectors by a practitioner available on the day of inspection. In addition, information relating to the patient exposure (Regulation 13(2)) was not included in the reports seen by inspectors, but inspectors were informed that this could be included in a template in records in the future.

From the documentation reviewed in advance of this inspection, and the information provided during the inspection, inspectors were assured that medical exposures in this facility were both justified and optimised. Diagnostic reference levels, a benchmark of the typical dose levels for types of dental procedures, had been established, reviewed and compared with national levels. The equipment was kept under strict surveillance with appropriate acceptance testing and performance testing carried out and relevant records were provided to inspectors. Although no incidents or accidental exposures to ionising radiation were identified or recorded, a policy was available to staff and known by staff, should such incidents occur.

Overall, inspectors were assured by the arrangements in place that this dental practice was providing safe medical exposures to ionising radiation for people using this service.

Regulation 8: Justification of medical exposures

The process of justification in this facility was explained to inspectors by one of the practitioners. In most instances, the referrer and the practitioner are the same person in this facility. Reports reviewed by inspectors on the day of inspection showed that referrals were documented, included the reason for the exposure and sufficient data was provided to identify that exposures were justified.

For referrals from external sources for patients undergoing CBCT, the referrer and practitioner are generally not the same person. The process of accepting referrals

and how justification is performed was explained to inspectors on the day of inspection. An example was also given of an instance when an exposure was not carried out as it was not justified. The record of a patient that was referred from outside the practice was reviewed and showed that the reason for the procedure came with sufficient data to satisfy the practitioner that the procedure was justified.

Judgment: Compliant

Regulation 9: Optimisation

From the documentation reviewed in advance of this inspection, and the information gathered on the day of inspection, inspectors were assured that doses were as low as reasonably achievable. This was demonstrated through the careful selection of equipment, comprehensive quality assurance on the equipment, and the grading of the quality of the resulting images. Inspectors were informed that the MPE would be contacted if any unexplained changes were apparent in the quality of the produced images. There was also strong evidence that management at Smiles Dental Wexford acted on the outcomes of recommendations and advice of the MPE, for example, the review and subsequent reduction of standard doses delivered to patients on one particular piece of equipment.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

From the documents provided in advance of this inspection, inspectors were assured that diagnostic reference levels (DRLs) were established, reviewed and compared to national DRLs for all pieces of radiological equipment in this dental practice. Corrective actions, identified by the MPE for one unit to ensure optimisation, were also undertaken and although the engineer's report from a recent service on one unit was not available for review at the time of inspection, this report was subsequently submitted to inspectors. Overall, from the evidence available, inspectors were satisfied that the undertaking was compliant with this regulation.

Judgment: Compliant

Regulation 13: Procedures

In the documents reviewed in advance of inspections, inspectors noted that specific

referral guidelines were available to practitioners for patients undergoing CBCT.

A list of the practitioners who completed audits was also provided in advance of inspection. On the day of inspection, audit records were reviewed by inspectors. These audits included a 6-monthly X-ray audit which included consent, quality of images, record of justification and control measures. A data collection form was also reviewed. This recorded the type of image, whether justification in advance was obtained and whether a report of the findings and the clinical outcome was included in the patients' records. In addition, the patient record card audit was reviewed and inspectors noted this was comprehensive and included a section relevant to radiological procedures.

Although the procedure for conducting a medical exposure was known and explained to inspectors by a practitioner on the day of inspection, written protocols for each type of equipment detailing the local process for conducting exposures were not available. Having written protocols in place with associated typical exposure parameters helps ensure that procedures and radiation doses received by the service user are appropriate and standardised.

On the day of inspection, information relating to patient exposure did not form part of the reports of medical radiological procedures reviewed by inspectors. Staff who spoke with inspectors also confirmed that this information was not routinely included in patient records but identified that this information could be incorporated into the existing template available to practitioners.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that all pieces of equipment were installed within the last three years. Inspectors reviewed documentation which showed that appropriate quality assurance programmes, including regular performance testing had been implemented and maintained for each piece of medical radiological equipment listed in this inventory. From the reports provided it was evident that the undertaking kept the equipment under strict surveillance regarding radiation protection.

The CBCT scanner has been upgraded to provide information at the end of the procedure of relevant parameters for assessing patient dose. The scanner's ability to function in this manner had been identified as an area requiring attention in the self-assessment questionnaire (SAQ) submitted by the practice. By independently acting on the gaps noted in the questionnaire, the undertaking had used the SAQ as a quality improvement tool and addressed potential regulatory issues in the practice.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The policy documents provided and reviewed before the inspection identified the process in place should an accidental or unintended exposure occur in this dental practice. In addition, the radiation safety file contained information relevant to incident reporting. This included copies of the guidance documents from the relevant regulators. No incidents relating to accidental or unintended exposure had been identified or reported by this practice in advance of this inspection. On the day of inspection, staff who spoke with inspectors were familiar with the reporting process and confirmed that no such incidents had occurred in this 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 |
|---|----------------------------|
| Governance and management arrangements for medical exposures | |
| Regulation 4: Referrers | Compliant |
| Regulation 5: Practitioners | Compliant |
| Regulation 6: Undertaking | Compliant |
| Regulation 10: Responsibilities | Compliant |
| Regulation 18: Estimates of population doses | 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 |
| Safe Delivery of Medical Exposures | |
| Regulation 8: Justification of medical exposures | Compliant |
| Regulation 9: Optimisation | Compliant |
| Regulation 11: Diagnostic reference levels | Compliant |
| Regulation 13: Procedures | Substantially Compliant |
| Regulation 14: Equipment | Compliant |
| Regulation 17: Accidental and unintended exposures and significant events | Compliant |

Compliance Plan for Smiles Dental Wexford OSV-0007332

Inspection ID: MON-0030074

Date of inspection: 23/10/2020

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 13: Procedures | Substantially Compliant |
| <p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>Regulation 13 (1) – Written protocols are being devised by the senior clinical team and will be shared with each practice. These protocols will form part of the radiography policy and will be reviewed annually.</p> <p>Regulation 13(2) – Our PMS currently doesn't allow the relevant exposure data to be transferred across automatically – we are moving to a new PMS early next year and discussions are underway with the providers of the new system as to the possibility of facilitating this to happen.</p> <p>Prior to this happening we have updated our reporting templates on the current PMS which allows the clinicians to complete this information manually for each radiography undertaken.</p> <p>The radiograph audits which are undertaken every 6 months will monitor that this is being completed until the PMS upgrade is complete.</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 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 | 28/02/2021 |
| 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 | 31/03/2021 |