



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dental Options (Clane)
Undertaking Name:	Follies View Ltd
Address of Ionising Radiation Installation:	Woods House, College Road, Clane, Kildare
Type of inspection:	Short Notice Announced
Date of inspection:	13 December 2023
Medical Radiological Installation Service ID:	OSV-0006784
Fieldwork ID:	MON-0041492

About the medical radiological installation:

Dental Options Clane carries out bitewing x-rays for patients as part of a routine examination appointment to assess interproximal caries and bone levels. Bitewings are not taken if a patient has had them taken in the last year, whether in our clinic or elsewhere.

We carry out periapical x-rays for patients only if there is specific need for these, such as to assess for infection at the apex, assess canal length for root canal treatment, monitor previously root canaled teeth, assess roots for extraction, etc.

We carry out orthopantomogram x-rays only for further treatment: orthodontic diagnosis, implant planning, bone loss assessment and wisdom tooth extraction planning.

We carry out cephalometry x-rays for orthodontic diagnosis only. They are needed to correctly treatment plan a patient's orthodontic needs.

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
Wednesday 13 December 2023	11:30hrs to 15:45hrs	Margaret Keaveney	Lead
Wednesday 13 December 2023	11:30hrs to 15:45hrs	Agnella Craig	Support

Summary of findings

An inspection was carried out at Dental Options Clane on 13 December 2023 to assess the undertaking's compliance with the regulations. The undertaking of this dental service is Follies View Limited. Inspectors spoke with the management team and reviewed documentation prior to and during the inspection. Inspectors also spoke with staff working in the service, including dentists and dental nurses, to determine their roles and responsibilities in the radiation protection of patients attending the service. Inspectors were satisfied from documentation reviewed and discussions with staff that only dentists employed by the undertaking acted as the referrer and as the practitioner, and took clinical responsibility for all dental medical exposures carried out in the service. Inspectors were also informed that the practical aspects of medical radiological procedures had not been allocated to any other staff in the service, and a review of a sample of patient's medical records verified this on the day of the inspection.

The inspectors found that the management arrangements in the service were understood by staff spoken with and were clearly documented. Although a comprehensive *Radiation Protection Procedure* was available to inspectors and staff in the service, it required review to ensure that the personnel allocated key radiation protection roles were clearly identifiable. For example, the list of personnel allocated the role of practitioner on the day of the inspection was not complete.

Staff who spoke with inspectors outlined the justification and optimisation processes that they completed prior to carrying out medical exposures of ionising radiation. From a review of patients' medical records, inspectors also observed that the clinical indications for medical exposures and efforts to retrieve previous imaging data were recorded. In addition, inspectors noted that information on the risk and benefits of medical exposures was displayed in clinical areas, and that it was contained in the consent form for medical exposures, although this form was not widely completed with patients attending the service. Although staff spoken with were able to describe optimisation practices, such as the use of collimators and optimal patient positioning, and justification practices that they completed for each medical exposure that they performed, inspectors were not assured that all staff spoken with were aware that in completing these practices, they were justifying in advance and optimising the exposures. Therefore, inspectors considered that dentists working in the service would benefit from further radiation protection education to ensure that they are fully aware of their responsibilities under the regulations, and as documented in local procedures.

Inspectors noted that the local *Radiation Safety Procedure* document stated that information relating to patient exposure should form part of the report for a dental radiological procedure, as required by the regulations. However, this information was not contained in all records reviewed on the day of the inspection.

On the day of the inspection, inspectors found that the undertaking was compliant

with Regulations 19, 20 and 21 and had ensured the continuity of medical physics expert (MPE) expertise and appropriate involvement in the service, as per these regulations. From speaking with the MPE and with the management team, inspectors identified that the undertaking's management team had considered and acted on most of the advice offered by the MPE in relation to regulatory compliance. For example, inspectors observed that clinical protocols had been developed and diagnostic reference levels (DRLs) and information on the risks and benefits of medical exposures had been displayed in clinical areas and patient waiting areas following their advice.

Inspectors reviewed quality assurance (QA) reports, from early 2022, for the seven pieces of radiological equipment operating in the service. However, the management team could not provide inspectors with records of equipment QA completed prior to 2022. Inspectors were informed that efforts had been made to engage the services of a MPE to complete the QA, but that these efforts had not been successful prior to 2022. Inspectors also noted that routine quarterly QA testing, as advised by the MPE, had not been performed on radiological equipment in use in the service, and therefore the inspectors were not assured that this equipment was kept under strict surveillance regarding radiation protection.

Overall, notwithstanding the gaps in compliance identified during this inspection, inspectors were satisfied that Dental Options Clane had systems in place to ensure the safe and effective delivery of dental radiological procedures to its patients.

Regulation 4: Referrers

Based on the discussions with staff and on the sample of records reviewed on the day of inspection, inspectors were satisfied that only referrals for medical radiological procedures from persons defined in Regulation 4 were carried out at this service. In Dental Options Clane, only dentists employed by the undertaking were recognised as referrers.

Judgment: Compliant

Regulation 5: Practitioners

On the day of the inspection, inspectors were satisfied that only those entitled to act as practitioners, as defined in Regulation 5, had taken clinical responsibility for medical exposures, namely dentists in the service.

Judgment: Compliant

Regulation 6: Undertaking

From speaking with staff and the management team at Dental Options Clane, inspectors were assured that, overall, the undertaking, Follies View Limited, had allocated roles and responsibilities for the protection of patients. However, improved clarity of this allocation was required in the local *Radiation Safety Procedure*. For example, inspectors noted the undertaking had included, in the procedure, a list of practitioners carrying out medical exposures in the service, however on the day of the inspection, not all practitioners employed by the undertaking and working in the service were included in this list.

In addition, inspectors noted that greater oversight was required by the management team, to ensure that allocated responsibilities were being completed. For example, the local *Radiation Safety Procedure* stated that quarterly QA testing was to be performed on medical radiological equipment, and as discussed under Regulation 14 below, this testing was not being performed. Inspectors noted that the undertaking's management team had not identified this gap in testing through their management systems.

From a review of records and documents, inspectors were assured that practitioners were completing justification and optimisation processes in relation to medical exposures carried out in the service. However, from discussions with these staff, inspectors were not assured that this allocation of practitioner responsibilities was fully understood by staff. Therefore the undertaking should avail of the support of the MPE in providing radiation protection training to staff, to help enhance the radiation protection of patients.

While a number of non-compliances with the regulations were identified on the day of inspection, inspectors were satisfied that they did not pose a current risk to the safety of patients.

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

All referrals reviewed by the inspector were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Inspectors observed that information about the benefits and risks associated with the radiation dose from medical exposures was displayed in the clinical areas and in the waiting areas of this service.

On the day of inspection, inspectors spoke with a number of practitioners who explained how medical exposures are justified in advance of the medical exposure. Inspectors also noted that the justification process was clearly outlined in the local

Radiation Protection Procedure, and inspectors also noted that audits on compliance with the process of justification had been completed by staff in the service.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures carried out in Dental Options Clane were found to have taken place under the clinical responsibility of a practitioner as defined in the regulations.

Inspectors were also satisfied that optimisation processes for medical exposures involved the practitioner and MPE. Similarly, there was sufficient evidence to satisfy inspectors that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that Dental Options Clane had established and used DRLs. Inspectors noted that some local DRLs slightly exceeded the national DRL, however, from discussions with the management team on the day of the inspection, inspectors were assured that the management team had engaged with the MPE to ensure that safe and quality medical exposures were carried out, when required.

These local DRLs were displayed prominently in the clinical areas visited by inspectors. However, from discussions with staff, inspectors were not assured that all practitioners, referenced this information when carrying out medical exposures of ionising radiation. Again further radiation protection education could highlight to practitioners the importance of DRLs in good radiation protection of patients.

Judgment: Compliant

Regulation 13: Procedures

The management team in Dental Options Clane had developed a written protocol for standard dental radiological procedures as required by Regulation 13(1). Inspectors were also satisfied that evidence based referral guidelines were available at the dental practice as required by Regulation 13(3).

In addition, inspectors reviewed a clinical audit that covered many aspects of the medical exposures carried out in Dental Options Clane, such as image quality, justification and optimisation. This audit allowed the management team to identify areas of good practice and areas of improvement in the service, which helped to ensure the safe delivery of medical radiological exposures to patients.

Inspectors noted that the local *Radiation Safety Procedure* outlined that information about the medical exposure to ionising radiation should be included in patient notes. However, from a review of a sample of patient notes on medical exposures carried out in the service, inspectors noted that this information was not available. This gap should be addressed to ensure compliance with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Prior to the inspection, records of quality assurance testing, performed by the MPE in 2022, were provided to inspectors for each piece of radiological equipment in use in Dental Options Clane. Inspectors were informed by the MPE and management team that the next QA by the MPE would take place in February 2024, which was in line with the timelines stated in the local *Radiation Safety Procedure*. On the day of the inspection, inspectors also viewed acceptance testing records for equipment installed after January 2019.

However, inspectors noted that the full quality assurance programme for equipment, as defined in the local *Radiation Safety Procedure* was not being adhered to in the service. For example, inspectors noted that quarterly QA testing, as advised by the MPE, had not been performed. The management team in Dental Options Clane must ensure that the documented and appropriate QA programme is implemented and maintained, to ensure that it meets the regulatory requirement and that all medical radiological equipment in the service is kept under strict surveillance.

From a review of QA records, inspectors also observed that, prior to 2022, the biennial QA testing programme had not been implemented. The management team informed inspectors that despite repeat efforts to engage the services of a MPE, they had not been successful prior to 2022. Therefore, records of performance testing on the equipment between January 2019 and February 2022 were not available to inspectors. Although, the QA testing completed by a MPE in February 2022 did not identify any performance issues or risks to patients, the management team in Dental Options Clane were not compliant with Regulation 14(11).

Inspectors received an inventory of medical radiological equipment in advance of the inspection. However on the day of the inspection, they noted that this inventory was not fully up-to-date. Therefore, the undertaking was not compliant with Regulation 14(10). For example, one piece of equipment was not listed in the inventory submitted prior to the inspection, and the identification number on

another piece of equipment differed to that listed in the inventory.

Although some actions were required by the management team to come into compliance with this regulation, inspectors were satisfied, from the MPE QA records viewed, that the equipment in use in the service on the day of the inspection was safe for clinical use.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed a local policy *Radiological Incidents and Accidents Management* that outlined the process for the management of accidental and unintended exposures and significant events, and staff spoken with demonstrated knowledge of this process to inspectors. Although no incidents relating to accidental or unintended exposure had been identified or reported at Dental Options Clane, inspectors were satisfied that the management team had systems in place to record and manage an incident or near miss if they occurred.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From discussions with the MPE and with the management team, and from a review of records and other documentation, inspectors were assured that arrangements were now in place to ensure the continuity of medical physics expertise in the service, when necessary. The management team informed inspectors that they had good access to medical physics expertise, at the time of the inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Dental Options Clane and were satisfied that an MPE gave specialist advice, as appropriate, on radiation physics and protection as required by the regulations. This included the definition and performance of quality assurance of equipment and optimisation processes, including the application and use of DRLs.

Judgment: Compliant

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

On the day of inspection, inspectors were assured that an MPE was involved in medical radiological procedures, at Dental Options Clane, in line with the level of radiological risk posed by the dental 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	Substantially 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 Dental Options (Clane) OSV-0006784

Inspection ID: MON-0041492

Date of inspection: 13/12/2023

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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The RSP list of practitioners has been updated and completed and will be reviewed frequently.</p> <p>The gap in testing has now been identified and the management is ensuring that QA testing is performed on equipment.</p> <p>All practitioners will/have received training regarding their responsibilities on the justification and optimisation processes.</p> <p>The undertaking has scheduled biennial MPE QA February 2024 and has requested the MPE train staff in QA Tasks as outlined in the radiation Safety procedures.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: All information about medical exposure to ionising radiation is now included in all patients charts/notes. This is now part of the note template to ensure it is not missed. This is also checked frequently as this has just been introduced to ensure all clinicians are compliant with this change.</p>	

Regulation 14: Equipment	Not Compliant
<p data-bbox="172 203 1393 353">Outline how you are going to come into compliance with Regulation 14: Equipment: The biennial MPE QA is scheduled for February 2024. During this session our MPE has scheduled time to train staff in routine QA tasks as outlined in radiation safety procedures.</p> <p data-bbox="172 398 1393 472">The inventory list of radiological equipment has been updated and sent on to HIQA as requested</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 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	01/04/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	01/03/2024

	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.	Substantially Compliant	Yellow	01/04/2024
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	01/04/2024
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	01/04/2024
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	01/04/2024
Regulation 14(11)	An undertaking shall retain records in relation to	Not Compliant	Orange	01/03/2024

	equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.			
--	--	--	--	--