



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	MW Dental
Undertaking Name:	Monika Wozniak
Address of Ionising Radiation Installation:	6 Glenn An Oir, Ballincolling, Cork
Type of inspection:	Announced
Date of inspection:	21 March 2023
Medical Radiological Installation Service ID:	OSV-0006707
Fieldwork ID:	MON-0039404

About the medical radiological installation:

MW Dental is a dental practice with one intra-oral unit.

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
Tuesday 21 March 2023	09:50hrs to 11:10hrs	Noelle Neville	Lead
Tuesday 21 March 2023	09:50hrs to 11:10hrs	Kay Sugrue	Support

Summary of findings

An on-site inspection of MW Dental was carried out by inspectors on 21 March 2023 to assess compliance with the regulations. The inspection was initiated as a result of a failure to return a regulatory self-assessment questionnaire (SAQ) that had been issued to the undertaking.

As part of this inspection, inspectors spoke with the dentist at this practice, reviewed documentation and visited the dental practice's clinical room. MW Dental demonstrated compliance across Regulations 4, 5, 8, 10, 11, 17, 19, 20 and 21. However, inspectors determined that further work was required by the Undertaking to bring Regulations 6, 13 and 14 into full compliance, further detail of which is outlined in the report. In addition, inspectors noted that the management of documentation and engagement with HIQA in relation to regulatory matters and radiation protection should be a focus for improvement by MW Dental following this inspection.

Regulation 4: Referrers

From a discussion with management and a review of documentation at MW Dental, the inspectors were satisfied that referrals were from staff working within this dental practice, where the referrer and practitioner was the same person and entitled to act as referrer and practitioner as per the regulations. The dental practice did not accept referrals for medical radiological procedures from external sources at the time of the inspection.

Judgment: Compliant

Regulation 5: Practitioners

The inspectors were satisfied that only those entitled to act as practitioner had taken clinical responsibility for medical exposures conducted at MW Dental.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed a document titled *Radiation Safety Compliance File, May 2021*, which outlined the allocation of responsibilities and structure in place for radiation protection of service users at the dental practice. This document outlined the roles and responsibilities of MW Dental's medical physics expert (MPE) and also noted that the dentist at the dental practice acted as referrer and practitioner.

The inspectors found that some improvements were required in relation to the clear allocation of responsibilities to ensure the radiation protection of service users undergoing medical exposures at this dental practice as required by Regulation 6(3). Improvements required related to Regulation 13, in particular ensuring written protocols are in place and Regulation 14, in particular ensuring the strict surveillance of equipment as the undertaking did not fully implement and maintain an appropriate quality assurance programme.

In addition, as the inspection was initiated as a result of a failure to return a regulatory self-assessment questionnaire (SAQ) that had been issued to the undertaking, inspectors noted that the management of documentation and engagement with HIQA in relation to regulatory matters and radiation protection should be a focus for improvement following this inspection.

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

From a sample of referrals reviewed, the inspectors were satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Information relating to the benefits and risks associated with radiation was available to service users.

Judgment: Compliant

Regulation 10: Responsibilities

The inspectors were satisfied that a practitioner took clinical responsibility for all medical exposures to ionising radiation at MW Dental. In addition, the inspectors were satisfied that the optimisation process included the practitioner and MPE and the justification process for all medical radiological procedures carried out at MW Dental involved the referrer and practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspectors were satisfied that MW Dental had established, regularly reviewed and used DRLs, having regard to national DRLs, as required by Regulation 11(5). In addition, where a DRL at MW Dental had slightly exceeded the national DRL, the undertaking had ensured that appropriate corrective action was taken as required by Regulation 11(6) and the DRL was reduced to below the national DRL.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for the standard dental radiological procedure used at MW Dental were not available as required by Regulation 13(1). Protocols can provide assurance that medical radiological procedures are carried out in a safe and consistent manner. Information relating to the medical exposure as required by Regulation 13(2) was available in a sample of reports reviewed. In addition, the inspectors were satisfied that referral guidelines were available at the dental practice as required by Regulation 13(3).

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspectors received an up-to-date inventory of equipment in advance of the inspection and this inventory was verified on-site. MW Dental had one intra-oral unit which had last undergone quality assurance testing by an MPE in May 2021. However, inspectors noted that improvements were required in relation to the strict surveillance of equipment as required under Regulation 14(1). The undertaking did not fully implement and maintain an appropriate quality assurance programme, including performance testing on a regular basis as required by Regulations 14(2) and 14(3). In addition, servicing of the intra-oral unit had not been completed since the commencement of the regulations in 2019 as required by Regulation 14(3).

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspectors reviewed documentation outlining the process for the management

of accidental and unintended exposures and significant events. Management explained the incident management process to inspectors and a template for recording incidents was available for review. Although no incidents or near misses relating to accidental or unintended exposure had been identified or reported at MW Dental, the inspectors were satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspectors were satisfied from speaking with management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at MW Dental as required by Regulation 19.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspectors reviewed the professional registration certificate of the MPE at MW Dental and were satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspectors noted involvement in radiation protection by the MPE across a range of responsibilities as outlined in Regulation 20(2) at the dental practice. The MPE took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to the definition and performance of a quality assurance programme. The MPE was involved in optimisation including the application and use of DRLs. The inspectors noted that the MPE also acted as the radiation protection adviser for MW Dental and therefore satisfied the requirements of Regulation 20(3).

Judgment: Compliant

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

The inspectors were satisfied that an MPE was appropriately involved at MW Dental, with the level of involvement commensurate with the radiological risk posed by the dental practice as required by Regulation 21.

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	Substantially 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 MW Dental OSV-0006707

Inspection ID: MON-0039404

Date of inspection: 21/03/2023

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: I confirm that I have allocated all responsibilities – <ul style="list-style-type: none"> - Protocols are in place, - Quality performance testing for the equipment - All procedures are in place 	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: I confirm that a written protocol for bitewing is now in place	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: I confirm that the equipment is now under strict surveillance, servicing is completed, quality performance tests now performed/initiated.	



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	01/05/2023
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for	Not Compliant	Orange	01/05/2023

	each type of equipment for relevant categories of patients.			
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	01/05/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	01/05/2023
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.	Not Compliant	Orange	04/04/2023