



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Swords Village Dental Practice
Undertaking Name:	Vivian Mongey
Address of Ionising Radiation Installation:	43 Main Street, Swords, Co. Dublin
Type of inspection:	Announced
Date of inspection:	23 March 2022
Medical Radiological Installation Service ID:	OSV-0006267
Fieldwork ID:	MON-0035860

About the medical radiological installation:

Vivian Mongey and Associates have been practicing in Swords for over 25 years. As part of routine general dental practice, intra-oral radiographs are conducted at this service.

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 23 March 2022	13:00hrs to 14:30hrs	Lee O'Hora	Lead
Wednesday 23 March 2022	13:00hrs to 14:30hrs	Kirsten O'Brien	Support

Summary of findings

An inspection was conducted remotely by inspectors on the 23 March 2022 to assess compliance against the regulations. This inspection was initiated as a result of the failure of the undertaking to submit a completed regulatory self assessment questionnaire to HIQA when requested to do so.

The inspectors were satisfied that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice. However, on the day of inspection, a recognised medical physics expert (MPE) was not appropriately involved to provide consultation and advice as required by the regulations. As a result, quality assurance (QA) testing by an MPE had not been carried out since 2017 and was overdue.

Following this inspection the undertaking was required to submit an urgent compliance plan to address urgent risks identified. The undertaking's response did provide an assurance to the inspectors that the risks were adequately addressed, however, the judgements included in this report are based on the findings on the day of the inspection.

Regulation 4: Referrers

From speaking with the undertaking on the day of inspection, the inspectors were satisfied that only referrals for dental radiological procedures from individuals entitled to refer as per Regulation 4, were carried out at the practice. Professional registration documentation for all dentists operating at the practice was requested on inspection and was subsequently provided satisfying all regulatory requirements.

Judgment: Compliant

Regulation 5: Practitioners

The inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures at the dental practice. Professional registration for all practitioners was supplied and reviewed and satisfied the requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

During the inspection, the undertaking described the allocation of responsibility for the radiation protection of service users attending the practice. Only referrals from individuals entitled to refer as per the regulations were conducted at the practice. Similarly, only individuals entitled to take clinical responsibility for dental radiological procedures acted as practitioners.

However, the inspectors were not satisfied that appropriate measures were in place on the day of inspection to demonstrate that the undertaking allocated responsibility to an MPE to provide consultation and advice on matters relating to medical physics as required by the regulations.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors spoke with the undertaking and reviewed records and documentation provided to inspectors. On the day of inspection the undertaking acknowledged that medical physicist QA had not been carried out since 2017. Previous medical physicist QA testing records, dated 31 August 2017, had been completed by a United Kingdom based medical physics service. The inspectors were informed that MPE support, in line with the regulations, was not maintained by the undertaking.

As an appropriate QA programme, including an assessment of dose, was not implemented and maintained, the inspectors were not assured that the dental radiological equipment at the practice was kept under strict surveillance regarding radiation protection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

The inspectors spoke with the undertaking in relation to the provision of medical

physics expertise at the dental practice. The undertaking acknowledged that the necessary arrangements to ensure the continuity of a registered MPE were not in place at the time of inspection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

The inspectors spoke with the undertaking and were informed that appropriate measures were not in place on the day of inspection to ensure that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

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

From speaking with the undertaking the inspectors were not satisfied that an MPE was appropriately involved with the provision of service at the time of inspection. This finding was acknowledged by the undertaking on the day of inspection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

Compliance Plan for Swords Village Dental Practice OSV-0006267

Inspection ID: MON-0035860

Date of inspection: 23/03/2022

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	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The practitioner met up with and engaged the services of a Medical physics expert (MPE) who carried out an assessment and testing of the three intraoral units and film processor in the surgery on the 27th of April 2022. The tests included image quality and dose level comparisons with the National dose reference levels. Based on a preliminary report the MPE recommended optimisation to levels comparable to the national dose reference and recommended by Carestream for the high speed film used. The final report will include updated procedures which reflect SI 256 2018.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: The practitioner met up with and engaged the services of a Medical physics expert (MPE) who carried out an assessment and testing of the three intraoral units and film processor in the surgery on the 27th of April 2022. Based on the preliminary report. The three units passed a number of tests for beam quality, consistency, filtration, timer, collimation, and qualitative image quality. These tests will be repeated every two years or after major maintenance. The default doses were also benchmarked against HIQA dose reference levels. Recommendations around quality assurance will be included in the final report.	
Regulation 19: Recognition of medical	Not Compliant

physics experts	
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: A medical physics expert has been engaged, carried out an assessment and has been in contact in relation to the optimisation of doses. The agreement will mean they are available for a period of two years.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: A medical physics expert has been engaged, carried out an assessment and has been in contact in relation to the optimisation of doses. He also will issue advice on procedures, quality assurance and training in the finalised report.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: A medical physics expert has been engaged, carried out an assessment and has been in contact in relation to the optimisation of doses. He also will issue advice on procedures, quality assurance and training in the finalised report.</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.	Not Compliant	Red	20/04/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Not Compliant	Red	20/04/2022

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	20/04/2022
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	Red	20/04/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Not Compliant	Red	20/04/2022
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing	Not Compliant	Red	20/04/2022

	the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Red	20/04/2022
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Red	20/04/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the	Not Compliant	Red	20/04/2022

	<p>following:</p> <ul style="list-style-type: none">(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;(ii) the definition and performance of quality assurance of the medical radiological equipment;(iii) acceptance testing of medical radiological equipment;(iv) the preparation of technical specifications for medical radiological equipment and installation design;(v) the surveillance of the medical radiological installations;(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;(vii) the selection of equipment required to perform radiation protection measurements;and(viii) the training of			
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	practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Red	20/04/2022