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:	Friary Dental Clinic
Undertaking Name:	Ruta Zaronskiene
Address of Ionising Radiation Installation:	Abbeyfield Centre, Francis Street, Ennis, Clare
Type of inspection:	Announced
Date of inspection:	07 August 2024
Medical Radiological Installation Service ID:	OSV-0008817
Fieldwork ID:	MON-0043949

About the medical radiological installation (the following information was provided by the undertaking):

Friary Dental Clinic is a dental practice located in Ennis, Co Clare. There is one dentist that provides dental services at this facility and one X-ray unit used for intra-oral X-rays.

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, as amended. 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 7 August 2024	11:00hrs to 12:52hrs	Kay Sugrue	Lead
Wednesday 7 August 2024	11:00hrs to 12:52hrs	Margaret Keaveney	Support

Summary of findings

An inspection was carried out at Friary Dental Clinic on 7 August 2024 to validate information provided in a self-assessment questionnaire and assess compliance with the regulations. Overall, inspectors noted that the levels of compliance assessed by the undertaking in the self-assessment questionnaire did not fully align with compliance levels found at the time of the inspection.

Inspectors identified good practices relating to the referral and justification processes, with evidence of comprehensive record keeping maintained for individual medical exposures in patient records viewed during this inspection. Inspectors were satisfied that the dentist operating in this facility, who was also the undertaking, acted as the referrer, the practitioner and took clinical responsibility for all dental X-rays performed in the Friary Dental Clinic and was therefore compliant with Regulations 4,5,8,10 and 17.

There was evidence provided that showed a medical physics expert (MPE) was engaged for this facility since February 2023, however, similar evidence to demonstrate that an MPE had been engaged for this facility since the commencement of the regulations in 2019 and up to February 2023 was not available at the time of this inspection. In addition, inspectors found from discussions with staff and the MPE and a review of available documentation, that communication between the undertaking and the MPE should be improved to provide greater assurance regarding the continuity of the MPE involvement as required under Regulation 19(9). There was also scope to improve MPE contribution to staff training of the practitioner in relevant aspects of radiation protection to meet all MPE responsibilities set out in Regulation 20(2) and to improve MPE involvement as per Regulation 21.

Inspectors also found gaps in compliance with Regulations 6,11,13 and 14. For example, in relation to Regulation 6(3), although key personnel recognised under the regulations were allocated the responsibility for medical exposures to ionising radiation, the findings discussed under Regulation 6(3) demonstrate that not all aspects relating to the allocation of responsibility were met. Inspectors also found that while facility diagnostic reference levels had been established, these DRLs were above national DRLs and a record of the review and corrective actions taken was not available as required under Regulation 11(7). Inspectors found there was a lack of evidence to demonstrate that regular performance assessments and acceptance testing of dental X-ray equipment in use had been carried out when required. In addition, the responsibility to take follow up corrective actions relating to recommendations made by the MPE in the 2023 quality assurance (QA) report had not been allocated by the undertaking to ensure the necessary measures were implemented. Therefore, inspectors were not satisfied that the dental equipment in use was kept under strict surveillance as required under Regulation 14. In relation to

Regulation 13, written protocols for standard dental X-ray procedures were not evident and clinical audits had not been implemented.

Overall, inspectors were satisfied that there were good practices evident regarding the referral, justification and optimisation of individual dental X-rays which are critical elements for the radiation protection of patients. However, given the findings of this inspection, the undertaking should take action to address the gaps in compliance and to improve staff awareness regarding regulatory requirements.

Regulation 4: Referrers

Inspectors reviewed referrals for dental X-ray procedures and found that referrals were from an individual entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that the dentist, as the sole practitioner in this service, took clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

In advance of this inspection, the undertaking had completed and submitted a self-assessment questionnaire. Inspectors reviewed documentation and spoke with the dentist practicing in this facility to verify the information submitted in the questionnaire and found the level of compliance assessed by the undertaking did not fully align with compliance levels found at the time of the inspection.

Inspectors found that Ruta Zaronskiene was the undertaking at Friary Dental Clinic and as the only dentist working there, acted as the referrer and practitioner taking clinical responsibility for all medical exposures conducted in this service. During the inspection, inspectors viewed the arrangements in place that verified a medical physics expert (MPE) had been engaged by the undertaking for the facility since 2023, thereby, satisfying inspectors that these aspects relating to the allocation of responsibilities required under Regulation 6(3) were met.

However, gaps in compliance were identified in relation to other aspects of the allocation of responsibilities. For example, the undertaking had not acted on

elements of feedback from the MPE QA report issued in February 2023. This meant that clinical audit had not been implemented in the facility, regular performance testing of medical radiological equipment in line with manufacturer's recommendations was not evident at the time of this inspection and a record of review of facility diagnostic reference levels was not available. Inspectors also noted that awareness of the content in the local rules provided by the MPE was not evident in discussions with staff.

Inspectors found that no evidence was available during the inspection to demonstrate that an MPE had been engaged at this facility from the commencement of the regulations in 2019 up to February 2023. In addition, and as part of the allocation of responsibilities, the undertaking must be aware of individual roles and responsibilities for the radiation protection of service users and must ensure that there are effective communication pathways in place. Inspectors determined from discussions with management and the MPE that communication between the undertaking and the MPE needed to improve. Furthermore, inspectors noted that medical radiological practices had commenced at the Friary Dental Clinic in December 2019 but the undertaking had not notified HIQA of this new facility until May 2024. This finding and the lack of relevant, requested information submitted by the undertaking before this inspection confirmed to inspectors that communication from the undertaking to HIQA also requires improvement.

Overall accountability rests with the undertaking who must provide a clear allocation of all aspects of responsibility for the protection of service users from medical exposure to ionising radiation. Inspectors were not satisfied from the findings of this inspection that this requirement was fully met, therefore, the allocation of responsibilities needs to be clearer for all staff working at this facility to comply with Regulation 6(3) and staff awareness regarding regulatory requirements and compliance also needs to improve.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

Records viewed by inspectors showed that justification in advance was recorded by a practitioner on the radiological information system thereby providing evidence of compliance with this regulation. Inspectors noted good practice in record keeping with respect of each medical radiological procedure performed in this facility.

Risks and benefits associated with medical exposure to ionising radiation were presented in a poster format and accessible to service users attending for medical exposure in this facility.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors found that the dentist was the referrer for each medical exposure carried out at Friary Dental Clinic and was also the practitioner with overall clinical responsibility. From a sample of records viewed, inspectors were satisfied that the clinical evaluation of the outcome of each procedure was completed by a recognised practitioner. The evidence demonstrated compliance with this regulation.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors saw evidence to demonstrate that facility DRLs were established in February 2023 by the MPE which were found to be above national DRLs for standard dental X-rays. Inspectors were informed that the practitioner had worked with the MPE to adjust the exposure parameters to reduce the dose while maintaining diagnostic image quality. While noting these measures taken by the practitioner to reduce the dose, a record of this review and corrective actions taken was not evident during this inspection as required under Regulation 11(7). In addition, facility DRLs were not available to the practitioner in the clinical area on the day of the inspection, therefore, there was a lack of assurance that facility DRLs were applied in day-to-day practice.

Judgment: Not Compliant

Regulation 13: Procedures

Protocols for standard dental X-rays delivered at this facility were not available to view at the time of the inspection.

Information relating the the dose associated with each medical exposure was recorded by the practitioner in the patient's record.

A programme of clinical audit was not in place at the time of the inspection. Discussions with staff demonstrated that there was a lack of awareness regarding the requirement to conduct clinical audits in line with the national procedures published by HIQA. In addition, inspectors noted that a recommendation to implement clinical audit in the facility which was documented by the MPE in the 2023 QA report, had not been taken on-board and actioned by the undertaking.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors found there was a lack of evidence to demonstrate that medical radiological equipment in this facility was kept under strict surveillance since the commencement of the regulations. For example, while a QA report from the MPE was completed in February 2023 which deemed the equipment fit for clinical use, previous QA reports from 2019 and up to February 2023 were not available to view by inspectors during the inspection. In addition, elements of the feedback and recommendations from the MPE in the 2023 QA report had not been addressed by the undertaking. For example, the MPE had recommended that performance testing and maintenance in line with the manufacturer's recommendations be carried out, however, there was an absence of evidence to show that this had been implemented in line with requirements set out under Regulation 14(3)(b). Furthermore, acceptance testing records for medical radiological equipment were not available to view at the time of the inspection and there was a lack of clarity from discussions with staff and the MPE if acceptance testing by an MPE before the first clinical use had been completed as required under Regulation 14(3)(a).

Since the announcement of this inspection, the undertaking had made arrangements for X-ray equipment to be serviced by an engineer which was confirmed in communication viewed by inspectors at the time of this inspection.

Overall, inspectors were not satisfied from the evidence provided at the time of the inspection that medical radiological equipment was kept under strict surveillance as required under Regulation 14(1).

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors viewed the local rules document provided by the MPE and found there was a process to follow to ensure that incidents involving unintended or accidental exposure to ionising radiation were reported to HIQA. While meeting the requirements of this regulation, inspectors identified that staff awareness in relation to this process should be improved.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were shown evidence that an MPE was engaged for this facility at the time of the inspection and these arrangements were also confirmed by the MPE in discussions with inspectors. Discussions with staff at the facility, however, identified recent gaps in communication with the MPE, therefore, further action is needed by the undertaking to improve communication pathways to ensure continuity of MPE involvement as needed at Friary Dental Clinic and in line with regulatory requirements.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Friary Dental Clinic and were satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Documentation viewed by inspectors demonstrated that the MPE was responsible for dosimetry and gave advice on medical radiological equipment. A report of QA of the X-ray equipment in February 2023 demonstrated that the MPE had contributed to quality assurance testing of medical radiological equipment and had established facility DRLs in 2023. The MPE had made recommendations in this QA report which were to be addressed by the undertaking. There was a lack of evidence in discussions with staff and documentation viewed to show that an MPE contributed to the training of the practitioner in relevant aspects of radiation protection which is required under Regulation 20(2).

Inspectors noted that the MPE had been assigned the role of radiation protection adviser (RPA) at the facility, therefore satisfying the requirements of Regulation 20(3).

Judgment: Substantially Compliant

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

Inspectors found that there was contribution and involvement of an MPE in line with most of the MPE responsibilities as per Regulation 20, with the exception of MPE contribution to staff training on radiation protection. This issue must be addressed to comply with this regulation.

Judgment: Substantially 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, as amended. 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 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Compliance Plan for Friary Dental Clinic OSV-0008817

Inspection ID: MON-0043949

Date of inspection: 07/08/2024

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, as amended.

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: Recommendations in HIQA report will be immediately actioned. Clinical audit in line with HIQA 2023 publication will be commenced. Service contract on equipment will be taken out with the supplier. DRL's will be reviewed. Training will be provided by MPE/RPA to dental staff. Communication from the practice to HIQA will improve. See regulations 14, 11 and 19 for actions to address other gaps under this regulation.	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Evidence of two yearly review of DRL's by the practice will be implemented immediately. A chart with the facility's measured DRL's will be posted beside the controller of the X-Ray unit in the surgery.	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Protocols for all dental X-Rays will be provided. A programme for clinical audit will be prepared and actioned immediately.	

Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: In the future MPE will perform QA on equipment every two years. Next assessment is due February 2025. Service contract will be taken out with work equipment providers.	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: Communication with MPE will be improved. MPE recommendations will be actioned in a future.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: Training on radiation protection will be provided by the MPE in mid-October 2024.	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:	

See response in Regulation 20.

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	Orange	30/11/2024
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	15/10/2024

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	15/10/2024
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	31/10/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	31/12/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological	Not Compliant	Orange	15/10/2024

	equipment in use by it is kept under strict surveillance regarding radiation protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	15/10/2024
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	15/10/2024
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.	Not Compliant	Orange	15/10/2024
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	Substantially Compliant	Yellow	15/10/2024

	expert under this Regulation.			
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 following: (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,	Substantially Compliant	Yellow	15/10/2024

	or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of 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.	Substantially Compliant	Yellow	15/10/2024