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

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| Name of Medical Radiological Installation: | Pro-Dental |
| Undertaking Name: | Pro-Riso Dental Clinic Limited |
| Address of Ionising Radiation Installation: | Unit 6, Jervis Street, Dublin, Dublin 1 |
| Type of inspection: | Announced |
| Date of inspection: | 22 January 2025 |
| Medical Radiological Installation Service ID: | OSV-0008467 |
| Fieldwork ID: | MON-0045223 |

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

Pro Dental is a dental clinic that offers a wide range of dental services, including preventive care, restorative dentistry, cosmetic dentistry, and further dental treatments.

## 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 |
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| Wednesday 22 January 2025 | 14:00hrs to 18:10hrs | Emma O'Brien | Lead |
| Wednesday 22 January 2025 | 14:00hrs to 18:10hrs | Agnella Craig | Support |

## Summary of findings

An inspection of Pro-Riso Dental Clinic Limited at Pro-Dental was conducted by inspectors on 22 January 2025 to identify if actions outlined in the compliance plan from the previous inspection in October 2024 were completed. During the previous inspection in October 2024 inspectors found a number of non-compliances with the Regulations and the undertaking was required to submit an urgent compliance plan to address the urgent risks identified during that inspection. Also, following the inspection in October 2024 the undertaking provided HIQA with written assurance that the equipment would not be used to conduct any medical radiological procedures until the actions outlined in the urgent compliance plan were addressed.

On the day of the inspection in January 2025, inspectors were informed by the undertaking that the equipment was not being used for medical radiological procedures as some actions from a recent Medical Physics Expert (MPE) quality assurance (QA) report were still outstanding and required action by the service engineer. During this inspection, inspectors reviewed radiation safety documentation, including the recently updated local rules document, the MPE QA report and the service engineer's report, and spoke with staff working at the service and the MPE.

Inspectors found that documentation included the allocated responsibility for the radiation safety of service users to personnel. The local rules document included the policy on the justification and optimisation of medical radiological procedures and inspectors noted that the local rules had been signed by practitioners working in the service. Local facility diagnostic reference levels (DRLs) were on display in the clinical area, as well as information on the risks and benefits of the exposure. Following the inspection in October 2024 the undertaking informed HIQA that default settings on the equipment resulted in exposures that far exceeded national diagnostic reference levels for similar procedures. As a result of this information the undertaking was asked to submit a significant event notification in line with HIQA guidance, as required by Regulation 17. On the day of this inspection in January 2025 this notification remained outstanding and the undertaking was therefore found to be not compliant with Regulation 17. Despite the failure of the undertaking to notify HIQA of this significant event within the specified time frame inspectors were assured,from a review of recent reports from the service engineer and the MPE, that the functional issues with the equipment had been addressed.

On the day of the inspection inspectors were assured from discussions with staff that cone beam computed tomography (CBCT) procedures would not be conducted until training completed by the practitioners in the facility aligned with the requirements of the Dental Council.

In summary, inspectors were satisfied from a review of radiation safety documentation and from discussions with staff that the majority of compliance plan actions had been completed resulting in improved regulatory compliance at Pro-

Dental. As the undertaking had not resumed conducting medical radiological procedures at the time of this inspection, a further follow up inspection will be conducted to assess the improvements in practice, once imaging resumes.

## Regulation 6: Undertaking

On the day of the inspection inspectors viewed the local rules document which had been recently updated and included the process for justification and optimisation of medical radiological procedures. Inspectors also viewed the internal governance structure within the service outlined in the recently developed organogram which detailed the reporting structure from the dental assistants and dentists working in the facility up to the undertaking.

Inspectors noted that staff working in the facility had recently signed the local rules document indicating that they had read and understood the radiation safety procedures included in them.

Inspectors were satisfied from reviewing the documentation and from discussions with staff that there were improvements in the allocation and understanding of roles and responsibilities for the protection of service users since the previous inspection. Inspectors were informed by staff that only practitioners could carry out the practical aspects of medical radiological procedures in this facility. However, this contradicted information in the local rules document that stated that any dental nurses or hygienists carrying out the practical aspects of radiation exposures must undergo regular training as required. The undertaking must ensure that documentation aligns with practice to provide clarity for staff working in the service regarding who can perform the practical aspects of medical exposures.

Judgment: Substantially Compliant

## Regulation 8: Justification of medical exposures

During the inspection inspectors noted that patient information posters were displayed in the clinical area which highlighted the risks and benefits of the procedure for service users.

On the day of the inspection inspectors viewed the local rules policy which included the policy on justification of medical radiological procedures in Pro-Dental. This policy outlined the criteria that should be included on a written referral from the referrer, including sufficient clinical information to allow the practitioner to make a judgment on the justification of the examination. This policy also included details on the process for maintaining a record of justification in advance of a medical exposure. Inspectors were informed that justification of medical exposures would be routinely audited to ensure compliance with the local policy on justification.

Inspectors also viewed a separate justification policy that had recently been developed. This policy contained different information to the justification process outlined in the local rules document. The undertaking must ensure that staff working in the service only have access to the most up-to-date and correct radiation safety documentation in order to support them in carrying out their roles and responsibilities and to reduce uncertainty as a result of differing information in local policies and procedure.

Notwithstanding this area for improvement inspectors were satisfied from the documents viewed and from discussions with staff that the undertaking had developed a process for the justification of medical radiological procedures in Pro-Dental.

Judgment: Compliant

## Regulation 9: Optimisation

As part of this inspection inspectors viewed recent service reports from the service engineer and the MPE. The service engineer's report confirmed that the equipment had recently undergone full calibration, routine service and correction of functional issues. Inspectors were assured from the discussion with the MPE that default dose settings on the equipment, that had resulted in examples of potentially high dose exposures to patients noted during the previous inspection in October 2024, had been rectified by the service engineer during recent QA.

Inspectors were also satisfied that the local rules document included a process for optimisation that all practitioners should adhere to when conducting medical radiological procedures. The undertaking representative outlined the actions he will take to ensure that practitioners in the service understand the optimisation policy and the importance of keeping doses as low as reasonably achievable. Inspectors were also informed by staff on the day of the inspection that regular image quality audits will be performed to ensure adherence to the optimisation policy.

Judgment: Compliant

## Regulation 10: Responsibilities

From a review of the local rules document inspectors were satisfied that practitioners have clinical responsibility for all medical exposures and that both the referrer and the practitioner have a role in the justification of medical radiological procedures.

Additionally, inspectors were satisfied from the local policies outlined in documentation viewed that the optimisation process for medical exposures at Pro-Dental involves the MPE and the practitioner, once service resumes .

As discussed under Regulation 6 the undertaking must ensure that there is a clear definition of who can carry out the practical aspects of a medical radiological procedure in the service, and if practical aspects are delegated to personnel other than a practitioner that they meet the requirements of Regulation 10.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

Inspectors were satisfied that local DRLs for all medical radiological procedures conducted at Pro-Dental had been recently reviewed and updated by the MPE and were displayed in the clinical areas. As outlined in the local rules document the undertaking has implemented a system for the local DRLs to be reviewed biennially in conjunction with the MPE.

Judgment: Compliant

## Regulation 14: Equipment

On the day of the inspection the undertaking described the QA programme to the inspectors. This programme included annual QA by the service engineer, biennial QA by the MPE and quarterly checks by practitioners working in the service. The undertaking should ensure that a comprehensive list of checks is available to staff completing the quarterly QA and that documentary evidence of the results of the quarterly QA is maintained, as recommended by the MPE.

On the day of the inspection the equipment was not in use as there were two actions outstanding on the MPE's recent report that required the attention of the service engineer. Inspectors were informed by staff that the equipment would not be used until these actions were addressed by the service engineer and this provided assurance to the inspectors that the equipment in Pro-Dental was kept under strict surveillance by the undertaking.

Judgment: Compliant

## Regulation 17: Accidental and unintended exposures and significant events

Following the previous inspection in October 2024 the undertaking identified that an incident had occurred in the service due to default dose settings on the equipment. In line with the regulations undertakings must ensure that HIQA is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines. The undertaking was requested by HIQA to submit an incident notification form as outlined in HIQA's *Statutory notifications for accidental or unintended medical exposures to ionising radiation* guidance document. At the time of this inspection Pro-Riso Dental Clinic Limited failed to meet this regulatory requirement as HIQA was not notified of this significant event using the appropriate notification form within three working days of discovery as specified in the guidance document. This notification was subsequently submitted to HIQA and the undertaking must submit the results of the investigation to HIQA within the period specified in HIQA's guidance document.

Judgment: Not Compliant

## Regulation 19: Recognition of medical physics experts

From reviewing records and associated documentation and speaking with the undertaking and the MPE, inspectors were assured that the undertaking had arrangements in place to ensure the continuity of medical physics expertise at Pro-Dental.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

From reviewing documentation and speaking with staff, inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of DRLs and the definition of the equipment QA programme. Inspectors were assured that the involvement and contribution of MPEs at Pro-Dental was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From documentation reviewed and discussions with the MPE and staff working in the service, the inspectors were satisfied that the level of MPE involvement in

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| medical radiological exposures in Pro-Dental was commensurate with the radiological risk in the service. |
| 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, as amended. The regulations considered on this inspection were:

| Regulation Title | Judgment |
|---|---|
| **Summary of findings** | |
| Regulation 6: Undertaking | Substantially Compliant |
| Regulation 8: Justification of medical exposures | Compliant |
| Regulation 9: Optimisation | Compliant |
| Regulation 10: Responsibilities | Compliant |
| Regulation 11: Diagnostic reference levels | Compliant |
| Regulation 14: Equipment | Compliant |
| Regulation 17: Accidental and unintended exposures and significant events | Not 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 Pro-Dental OSV-0008467

## Inspection ID: MON-0045223

## Date of inspection: 22/01/2025

**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 | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 6: Undertaking:<br>We created an organogram that illustrates the practice structure, from the dental assistants and dentists working in the facility to the wider service framework.<br><br>The facility staff members have recently signed the local rules, confirming that they have read and understood the radiation safety procedures outlined within them. This documentation has enhanced the understanding of, and allocation of, roles and responsibilities for protecting service users.<br><br>Our local regulations require dental nurses and hygienists involved in practical radiation exposure to undergo regular training. This policy aims to facilitate the potential expansion of our team.<br><br>Furthermore, a separate protocol titled ´Guidelines for Dental Assistance During the X-Ray Procedure' has been established, distributed, and signed by the dental assistants. | |
| Regulation 17: Accidental and unintended exposures and significant events | Not Compliant |
| Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:<br>The NF211A form was thoroughly completed and submitted on January 25th by our Radiation Protection Officer, in accordance with the request made by the relevant inspectors. | |

In addition, the MPE physics has been extensively involved in the analysis and management of each individual case of radiation exposure that has arisen. Their efforts include meticulous investigations to determine the circumstances of each incident, as well as the implementation of corrective actions to prevent future occurrences. This commitment underscores our dedication to ensuring the safety and well-being of all personnel and mitigating any potential risks associated with radiation exposure.

## 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 | 18/02/2025 |
| Regulation 17(1)(e) | An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, | Not Compliant | Orange | 25/01/2025 |

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| | as defined by the Authority in guidelines issued for that purpose, and | | | |