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:	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:	15 October 2024
Medical Radiological Installation Service ID:	OSV-0008467
Fieldwork ID:	MON-0040111

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
Tuesday 15 October 2024	12:00hrs to 16:40hrs	Emma O'Brien	Lead
Tuesday 15 October 2024	12:00hrs to 16:40hrs	Agnella Craig	Support

Summary of findings

An inspection of Pro-Riso Dental Clinic Limited at Pro-Dental was conducted by inspectors on 15 October 2024 to identify if all actions outlined in the compliance plan from the previous inspection in March 2023 were completed, and to determine if cone beam computed tomography (CBCT) training completed by practitioners in this service met the requirements of the Dental Council. On the day of inspection, inspectors visited the clinical area in the practice and assessed compliance with the regulations relating to the use of orthopantomogram (OPG) and CBCT procedures.

Since the previous inspection, inspectors were satisfied that the undertaking had engaged a medical physics expert (MPE) and that their level of involvement in the service was commensurate with the level of radiological risk. However, inspectors found that most of the other actions identified in the compliance plan from the previous inspection remained outstanding. Also, in March 2023 the MPE completed a quality assurance (QA) report for Pro-Dental which identified a number of actions and critical actions that needed to be addressed by the undertaking. On the day of the inspection the undertaking informed inspectors that these actions had not been addressed. The failure of the undertaking to implement these actions resulted in continued non-compliance with the regulations and did not assure inspectors that the undertaking was fully aware of their regulatory responsibilities.

On the day of inspection, inspectors were not assured that the undertaking, Pro-Riso Dental Clinic Limited, had provided a clear allocation of responsibilities for the radiation protection of patients attending Pro-Dental, or that staff working in the service understood the roles of key personnel involved in the radiation protection of service users.

Inspectors viewed the professional certificate documentation which verified that all dentists working in the service were registered with the relevant body. Inspectors were also satisfied that only an individual entitled to act as a practitioner took clinical responsibility for dental radiological procedures at the practice. However, a review of service user records showed that practitioners had not fully carried out their clinical responsibilities with regard to the justification, optimisation and documentation of clinical evaluation of the outcome of medical exposures.

On the day of the inspection there was no evidence available to assure inspectors that the undertaking had processes in place for optimising dental radiological procedures. From a review of documentation, inspectors saw that although the MPE had established diagnostic reference levels (DRLs) for the radiological equipment in use in the service, the undertaking had not taken the actions recommended by the MPE to review the DRLs for the OPG and CBCT procedures to ensure that doses to service users during a medical exposure were optimised. Inspectors also observed that DRLs were not available to practitioners to refer to prior to completing a medical exposure of ionising radiation.

Inspectors noted that a QA programme for the equipment had been developed by the MPE but this programme had not been fully implemented in the service, and therefore the inspectors were not assured that this equipment was kept under strict surveillance regarding radiation protection. Additionally, inspectors were not assured that an appropriate programme for the assessment of dose was in place in Pro-Dental.

Following the inspection an urgent compliance plan was issued for Regulations 6, 8, 9, 11, 14 and 22 to address the identified urgent risks. The undertaking provided assurance that the risks identified were being addressed. Additionally, the undertaking provided an assurance to HIQA that the x-ray equipment would not be used to conduct dental radiological procedures until the corrective actions outlined in the urgent compliance plan were completed.

Regulation 4: Referrers

From the review of professional registration records, inspectors were satisfied that referrals for medical radiological procedures in Pro-Dental were from individuals entitled to refer, as per the requirements of the regulations.

Judgment: Compliant

Regulation 5: Practitioners

From speaking with staff and a review of professional registration records, inspectors were satisfied that only persons, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

From a review of documentation and from speaking with staff on the day of the inspection, inspectors found that a clear allocation and understanding of the roles and responsibilities for the radiation protection of patients and other service users was not in place in Pro-Dental. For example, the undertaking representative was unable to demonstrate a clear understanding of the role of the MPE in the service and inspectors also noted that awareness of the content of the local rules provided by the MPE was not evident in discussions with staff. Additionally, a number of actions and critical actions outlined in the MPE's QA report from March 2023 had not been addressed by the undertaking, and many compliance plan actions from the

previous inspection had not been completed. Also, inspectors did not see any evidence that the undertaking had implemented the equipment QA programme that had been developed by the MPE in March 2023.

The undertaking representative, who was also the designated manager for this service, described a monthly audit process whereby all records of patients who received a medical exposure were reviewed retrospectively. However, when inspectors viewed a sample of these records numerous gaps were identified in record keeping including gaps in recording the process of justification. For example, the required information to allow the justification of procedures was not consistently available nor was the individual responsible for the justification of these procedures consistently identifiable in the records reviewed. Therefore, the inspectors were not satisfied that the undertaking had implemented effective measures to ensure the justification process was compliant with the regulations or that the appropriate oversight of this process was in place. Additionally, inspectors were not assured that the undertaking had appropriate systems and processes in place to ensure that each individual medical exposure was optimised.

Inspectors viewed training records for the practitioner conducting medical exposures in this practice and found that Pro-Riso Dental Clinic Limited had not ensured that individuals conducting CBCT procedures at Pro-Dental had completed the appropriate level of training, as specified by the Dental Council, to conduct these procedures.

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 met, therefore, improvements are required to clearly define and allocate the roles and responsibilities of staff in the 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 provided assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors viewed a sample of dental radiological procedures conducted at Pro-Dental. Inspectors found that referrals for dental X-rays were not consistently documented in the patient records viewed. Inspectors identified that action was needed as a referral was not available for some of the imaging that had been conducted, the reason for requesting a particular procedure was not always included in the referrals that were available, and sufficient medical data was not always included to enable the practitioner to carry out justification as required in Regulation 8(10). Justification in advance by a practitioner was also not

clearly evident in some of these records which meant that the regulatory requirements of Regulation 8(8) and 8(15) were not consistently met.

Similar findings had also been identified as part of the previous inspection, and inspectors were not satisfied that Pro-Riso Dental Clinic Limited had implemented measures to ensure that all dental exposures carried out at Pro-Dental were justified. Pro-Riso Dental Clinic Limited must put measures in place to ensure that records evidencing compliance with the requirements of this regulation are documented, maintained and available for review. Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking provided an assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 9: Optimisation

From a review of documentation and discussions with staff, inspectors were not assured that the undertaking had appropriate processes in place to ensure that doses to service users due to medical exposures were kept as low as reasonably possible in Pro-Dental. For example, staff who spoke with inspectors were not aware of their roles and responsibilities in dose optimisation, a robust QA programme was not in place for radiological equipment, and a system to audit and ensure consistency in the practical aspects of completing exposures was also absent.

Inspectors noted the completion of a QA assessment by the MPE since the last inspection in March 2023. However, despite issues with optimisation of patient doses having been identified to Pro-Riso Dental Clinic Limited by the MPE in 2023, no evidence was available to show that the undertaking had acted on the advice of the MPE to ensure that all dental exposures carried out at the practice were optimised. For example, inspectors spoke with staff and found no evidence that a review of the quality of the images to ensure they were appropriately and consistently optimised had been completed following the advice of the MPE as part of the QA assessment.

From a review of records inspectors observed that doses for some medical radiological procedures were considerably higher at this facility when compared with national diagnostic reference levels for similar procedures. This dose information was collected and documented for each procedure by the practitioner as part of monthly audit but there was no evidence to suggest that these doses were acknowledged as being high or that a review had been initiated to investigate these high doses.

In line with the findings of non-compliance under Regulation 11, the undertaking must take immediate steps to ensure the optimisation of all dental exposures to ionising radiation at the practice. Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking provided an assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 10: Responsibilities

To ensure compliance with Regulation 10(1) an undertaking must ensure that medical exposures take place under the clinical responsibility of a practitioner. However, inspectors found that the details of who had carried out each individual dental exposure was not available for all records that were reviewed as part of this inspection. A sample of records of internal referrals for dental exposures were reviewed on inspection. From this review, inspectors found that evidence was not always available to demonstrate that a person entitled to act as a referrer and or the practitioner was involved in the justification process for individual dental exposures. As a result, inspectors were not satisfied that the referrer or a practitioner were involved in the justification process for all dental exposures carried out at Pro-Dental.

Since the last inspection, the undertaking had put measures in place to ensure the continuity of MPE involvement and contribution to the optimisation of dental exposures. However, inspectors found that while an MPE had put forward recommendations for the optimisation of exposures these had not been addressed by the undertaking. Therefore, inspectors were not assured that practitioners were involved in the optimisation process for all dental exposures carried out at Pro-Dental.

Similar to the previous inspection in March 2023, inspectors found that certain practical aspects of medical radiological procedures were delegated to persons other than dentists at the practice. Inspectors were informed that these practical aspects were limited to patient positioning before the exposure. Although persons other than a practitioner can be delegated the practical aspects by the undertaking or a practitioner, these persons must be registered or recognised by the appropriate body, in this case the Dental Council, and a record of the delegation must be retained. However, no evidence of professional registration or record of delegation for the persons involved in patient positioning was available at the time of inspection.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

From a review of documentation, inspectors observed that the MPE had established local DRLs for the radiological equipment in use in the service, during QA testing in 2023. In the QA report the MPE noted that the local facility DRLs for both the OPG and CBCT procedures were slightly above the national DRL and as a result of this

they included an action for the undertaking to conduct an image quality clinical audit for both procedures. However, on the day of the inspection the undertaking representative informed inspectors that this action had not been completed. Inspectors also noted that DRLs were not readily available to the practitioners taking the exposures.

Inspectors were not assured that staff had a good understanding of how DRLs should be used in practice, and were therefore not aware of their responsibilities to use DRLs as a component of optimisation in the 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 provided an assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 14: Equipment

On the day of the inspection, the inspectors spoke with the MPE and staff at Pro-Dental, and reviewed documentation pertaining to the radiological equipment in the service. Although commissioning testing had been completed on the radiological equipment in use, overall, the inspectors were not satisfied that the radiological equipment at Pro-Dental was kept under strict surveillance, with regard to radiation protection.

Inspectors noted that the MPE had developed a QA programme in March 2023 however the undertaking could not provide any evidence on the day of the inspection that this QA programme had been implemented or that there was an appropriate programme in place for the assessment of dose as required by Regulation 14.

The failure of the undertaking to ensure that equipment was kept under strict surveillance and to implement and maintain an appropriate QA programme were identified as areas requiring urgent action by Pro-Riso Dental Clinic Limited. Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking provided an assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Based on the evidence gathered on the day of the inspection the undertaking was subsequently asked to review patient records to identify potential incidents of

overexposure of service users. Through further engagement between HIQA and the undertaking, the undertaking identified that an incident had occurred in the service due to default high 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 occurence 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. 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.

Overall, inspectors were not assured that the undertaking ensured that all reasonable measures were taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors spoke with management at Pro-Dental and the MPE as part of this inspection. Documentation and other records were also reviewed, including the service level agreement (SLA) with the MPE. Inspectors were satisfied that, on the day of inspection, Pro-Riso Dental Clinic Limited had taken steps since the previous inspection to ensure the continuity of medical physics expertise at the practice.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that an MPE gave specialist advice on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted involvement in radiation protection of the MPE across a range of responsibilities as outlined in Regulation 20(2), including the definition and performance of QA of the equipment and optimisation of medical exposures, including the development of DRLs. However, from discussions with staff at Pro-Dental inspectors were not assured that the undertaking had ensured that the MPE contributed to the training of practitioners and other staff in relevant aspects of radiation protection, and so did not fully meet the requirements of Regulation 20(2)(c).

Judgment: Substantially Compliant

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

Notwithstanding the finding in relation to Regulation 20, inspectors were satisfied that an MPE was involved at Pro-Dental, with the level of involvement commensurate with the level of radiological risk posed by the dental practice as required by Regulation 21.

Judgment: Compliant

Regulation 22: Education, information and training in field of medical exposure

On the day of inspection, inspectors were informed that one dentist was involved in the conduct of CBCT procedures. Records of training in CBCT were supplied for this dentist. While the information reviewed demonstrated that the dentist had completed some training in relation to the conduct of CBCT, the documentation supplied did not satisfy the relevant training requirements as prescribed by the Dental Council. The undertaking must take urgent action to ensure that practitioners who take clinical responsibility for CBCT procedures have completed training, as prescribed by the Dental Council, and successful completion of such training must be documented and retained.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking provided assurance that the risk was being addressed, and that CBCT procedures would not be conducted until the undertaking was compliant with this regulation.

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, 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	Not Compliant
Regulation 9: Optimisation	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 14: Equipment	Not 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	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

Compliance Plan for Pro-Dental OSV-0008467

Inspection ID: MON-0040111

Date of inspection: 15/10/2024

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: A review of the internal governance structure at Pro-Dental has been commenced by the undertaking. The roles and responsibilities, as per the regulations, of staff and persons engaged to work at Pro-Dental are set out in the practice radiation safety procedures (RSPs). An organogram summarising the organisational structure will be included with the radiation safety procedures. The undertaking will ensure that organogram will be kept up to date and reviewed annually. The updated radiation safety procedures will be made available to all practitioners and will henceforth form part of new practitioner's induction processes. Documentary evidence of the RSP distribution will be maintained by the undertaking. The MPE's service level agreement will be renewed when it falls due.	
Regulation 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: Pro-Dental will review, update, and circulate its practice radiation safety procedures to referrers, practitioners and persons delegated responsibilities for the practical aspects. Commencing immediately Pro-Dental will implement the practice justification policy as set out in the RSPs to ensure that documentation of the justification for dental exposures is recorded in each patient's record in advance of an exposure and for each type of radiograph prescribed. Patient information posters will be displayed in a number of public and clinical areas in the practice. The responsibility for making the patients aware of the benefits and risks of each prescribed medical exposure commences with the referrer. Documentary evidence	

of this process including evidence of patient understanding and consent to medical ionising exposure will be recorded in the patient record. This will form part of the practice acceptance of external referral policy.
The undertaking will commence with immediate effect a process of continuous clinical audit to ensure that individual practitioners are adhering strictly to the practice policy on justification. Information gathered in the justification audits will be analysed for non-compliance with the policy and for establishing trends, over time, of the findings. Corrective actions resulting from the audit findings will be time lined and the responsibility of the undertaking to ensure they are completed accordingly.

Regulation 9: Optimisation	Not Compliant

Outline how you are going to come into compliance with Regulation 9: Optimisation:
A qualified service engineer visited the new practice on 19/12/2024 to reinstall the device, carry out a full calibration, routine service and to correct the functional issues in the x-ray equipment which had caused some DRLs to far exceed the national DRLs.
The undertaking will ensure that practitioners understand the importance of keeping medical exposure doses as low as reasonably achievable. This is practice policy and is set out in the radiation safety procedures.
The undertaking will ensure that a process of continuous image quality audit will commence immediately to ensure that individual practitioners are adhering strictly to the practice policy on optimisation and dose management as set out in the radiation safety procedures. The undertaking will ensure that processes are in place to minimise the amount of retake/reject images.

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
A Medical Physics Expert has been engaged to evaluate the performance of our (CBCT) system and to refine our optimization techniques and diagnostic reference levels. Our service level agreement with the MPE ensures that Pro-Dental consistently has access to high-quality expert advice on these important matters.
Practical responsibilities will be entrusted solely to individuals registered with the Dental Council
We will take care to document all patients exposed to radiation in our management software. This includes essential details such as the reason for the procedure, the prescriber, the performer, and any findings.
For patients referred from external sources, we are committed to providing a thorough diagnostic assessment.

All referral letters from outside dentists will be digitally recorded within our clinic management software for accuracy and continuity of care.

Each referral will be meticulously reviewed and endorsed as "authorized and justified" by the responsible dentist overseeing the CBCT facilities, ensuring the highest standards of patient care and safety.

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Following adjustments made by the service engineer (19.12.2024) on the x-ray equipment the undertaking in consultation (23/12/2024) with the MPE will provide an updated exposure chart for the OPG and CBCT, to include the updated local DRLs. The exposure chart will be displayed close to the control unit of the x-ray machine. Practitioners will be directed that they should use only the exposure parameters as set out on the exposure chart for individual x-ray units. The practice radiation safety procedures direct practitioners to record the exposure parameters for each exposure in the patient's record. A process of clinical audit and image quality analysis will commence immediately to ensure that individual practitioners are adhering strictly to the practice policy on prescribing and documenting exposure parameters.
At the time of the MPE's next QA visit the DRLs will be reviewed in conjunction with the undertaking/RPO. A copy of HIQA's guide relating to DRLs will be circulated to practitioners. A hard copy will be maintained close to the x-ray equipment for ease of access.

Regulation 14: Equipment	Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The undertaking commits to ensuring that this programme of quality assurance and regular performance testing is implemented. The undertaking engaged an MPE in a service level contract (March 2023) to support and advise the undertaking's responsibility to comply with the requirements of the regulations. The service level agreement provides for a biennial QA programme and a programme of acceptance testing, as appropriate. On 19/12/2024 a qualified service engineer carried out a full service on the x-ray unit and carried out adjustments as per the MPE's quality assurance report of March 2023. Henceforth the undertaking commits to the ongoing maintenance of the x-ray unit as detailed in the manufacturers' manuals. The radiation safety procedures and MPE's

guidance document set out the requirement for the in-house programme of quality controls to be carried out and documented by the RPO at least every quarter. Documentary evidence of this will be available for inspection.
Practitioners will receive training on the importance of regular performance testing and on their role in carrying out safety checks on the x-ray equipment. Practitioners will be reminded of their responsibility, as set out in the RSPs, to record the individual patient radiation dose for each exposure in the patient record.
The medical radiological inventory has been updated and maintained to reflect the x-ray equipment in use on the premises.

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:
Pro-Dental will establish clear policies and procedures for preventing, documenting, and responding to accidental exposures and significant events. Staff will receive regular training, and robust monitoring systems will be implemented to detect and address risks effectively. A standardized incident reporting system and root cause analysis will ensure proper investigation and corrective actions. Regular audits, external reviews, and a strong safety culture will further enhance compliance, supported by comprehensive record-keeping and transparent communication with regulatory bodies.

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:
The service level agreement with MPE covers all aspects of SI 256(2018) and a continuity of service with the MPE is assured for the next two years. The clinic intends to continue engagement with the MPE following the expiration of the current contract in March 2025

Regulation 22: Education, information and training in field of medical exposure	Not Compliant

Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure:

The undertaking continues to provide the Authority with assurance that the CBCT medical radiological procedures will not be conducted until such time as a suitably qualified practitioner, as set out in the Dental Council guidance, is available.

The undertaking will ensure that the RPO, as a matter of priority, succeeds in completing CBCT training which meets the Dental Council prescribed training requirements, with respect to referring for, and taking clinical responsibility for CBCT.

Practitioners who previously attended limited curriculum CBCT training programmes, outside of this jurisdiction, will seek locally approved training courses to complete their training prior to refer for, or operate the CBCT. The undertaking/RPO will require documentary evidence to ensure that referrers and practitioners fulfil their responsibility to carry out CBCT training as per the guide to the Dental Council guidance (2023).

The undertaking will ensure that external referrals for CBCT medical imaging will only be accepted from referrers that provide written confirmation of successfully completing the Dental Council prescribed CBCT training.

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	31/10/2024
Regulation 8(1)(a)	A person shall not carry out a medical exposure unless it shows a sufficient net benefit, weighing the total potential diagnostic or	Not Compliant	Red	31/10/2024

	therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and			
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Red	31/10/2024
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Red	31/10/2024
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Red	31/10/2024
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical	Not Compliant	Red	31/10/2024

	radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).			
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Not Compliant	Red	31/10/2024
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Red	31/10/2024
Regulation 9(1)	An undertaking shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology,	Not Compliant	Red	31/10/2024

	planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.			
Regulation 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.	Not Compliant	Red	31/10/2024
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	22/01/2025

Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Not Compliant	Orange	22/01/2025
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Orange	22/01/2025
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Orange	22/01/2025
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health	Not Compliant	Orange	22/01/2025

	and Social Care Professionals Act 2005, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Red	31/10/2024
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities	Not Compliant	Red	31/10/2024

	consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	31/10/2024
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Red	31/10/2024
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	Red	31/10/2024
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any	Not Compliant	Orange	22/01/2025

	significant event, as defined by the Authority in guidelines issued for that purpose, and			
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	Substantially Compliant	Yellow	22/01/2025

	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 practitioners and other staff in relevant aspects of radiation protection.			
Regulation 22(3)	Subject to paragraph (4), the persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection— (a) prescribed by the Dental Council, (b) prescribed by the Irish College of Physicists in Medicine, (c) prescribed by the Nursing and Midwifery Board of Ireland,	Not Compliant	Red	31/03/2025

	(d) prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, or (e) approved by the Radiographers Registration Board under Part 5 of the Health and Social Care Professionals Act 2005, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).			