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:	Clontarf Aesthetic Dentistry
Undertaking Name:	Ellenger Dental Ltd
Address of Ionising Radiation Installation:	Unit 9, Seapoint Building, 44-45 Clontarf Road, Dublin 3
Type of inspection:	Announced
Date of inspection:	03 February 2022
Medical Radiological Installation Service ID:	OSV-0006841
Fieldwork ID:	MON-0035025

About the medical radiological installation:

Clontarf Aesthetic Dentistry is a specialist dental practice located in a purpose built unit providing restorative and implant dentistry to patients. The facility was planned with the input of a Radiological Protection Advisor to ensure that X-ray procedures are provided in a safe environment for both patients and staff. Following clinical examination X-rays are frequently required for diagnostic and planning purposes. There are intra-oral X-ray units in each of our 3 surgeries, and a combined orthopantomogram (OPG) and 3D imaging unit which is housed in a dedicated X-ray room. Prosthodontists and Periodontist use a combination of intra-oral X-rays, OPGs and cone-beam computed tomography (CBCTs) and select the appropriate x-rays. The type of X-rays selected is based on the clinical presentation of each patient and the complexity of the treatment being undertaken. A local Radiological protection committee is in place to oversee matters concerning X-ray equipment, procedures and standards. All X-ray procedures are for in-house patient diagnostic purposes only and there is no external referral service provided for imaging.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the 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
Thursday 3 February 2022	11:15hrs to 13:45hrs	Maeve McGarry	Lead
Thursday 3 February 2022	11:15hrs to 13:45hrs	Agnella Craig	Support

Summary of findings

The inspection of Clontarf Aesthetic Dentistry was carried out remotely on 3 February 2022. The focus of the inspection was the assessment of compliance with the regulations outlined in this report. The inspection was initiated following a failure by the undertaking to submit a self-assessment questionnaire which was issued as part of HIQA's regulatory assessment process. Inspectors were informed that this was an oversight and was in part due to staff leave. Following the announcement of the inspection the undertaking updated the medical radiological service type at the dental practice and their contact details. After the inspection, further undertaking details were updated ensuring that the information held by HIQA was up-to-date and accurate.

Inspectors were informed that external referrals for medical radiological exposures were not accepted at Clontarf Aesthetic Dentistry. Only dentists at the practice were recognised as referrers and practitioners and had clinical responsibility for medical exposures. Certain practical aspects of medical exposures were carried out by dental nurses and inspectors found that documentation around this delegation should be strengthened for clarity.

A Medical Physics Expert (MPE) was engaged by the undertaking following the announcement of the inspection by HIQA. Inspectors acknowledged that considerable improvements had been carried out between the announcement date and the day of inspection, which included quality assurance of equipment, acceptance testing and establishing local diagnostic reference levels (DRLs). However, there was a lapse in engagement with an MPE and hence some regulatory deficits were evident in relation to the continuity of, and the involvement of the MPE by the undertaking.

Documentation provided to inspectors in advance of the inspection included results of clinical audits conducted. An audit was carried out to assess image quality, recording of outcomes and justification of medical exposures. The audit was repeated after six months and found improvement in compliance with local policies. Local documentation included radiation safety procedures, a proposal for future audits and membership of a radiological protection committee. While the committee had yet to meet, inspectors recognised that this was a positive initiative and should be progressed by the undertaking.

Notwithstanding the requirement by the undertaking to strengthen the clear allocation of responsibilities locally, inspectors were assured by the steps taken thus far and future plans identified to address gaps in compliance regarding the safe delivery of dental exposures at the practice.

Regulation 4: Referrers

From discussions with management and from reviewing documentation provided in advance of the inspection, inspectors were satisfied that only referrals for dental radiological procedures, from individuals entitled to refer as per Regulation 4, were carried out at Clontarf Aesthetic Dentistry. Inspectors were informed that external referrals for medical radiological procedures were not accepted by this dental practice.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at the dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The undertaking had allocated clinical responsibility for individual medical exposures to registered dentists entitled to act as practitioner and referrer at Clontarf Aesthetic Dentistry. The designed manager outlined that the practical aspects carried out by dental nurses was limited, and inspectors found that the supporting documentation should be updated to ensure that this allocation of responsibility is clearly defined. However, an MPE was not engaged by the undertaking for a period and during this time the undertaking had failed to allocate certain key responsibilities as per regulations. Inspectors found that while the undertaking had taken measures to address gaps in compliance in advance of the inspection, the clear allocation of responsibilities at the dental practice should be strengthened.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

DRLs had been recently established in January 2022 by the MPE. Inspectors were informed that a review of optimisation was underway which was prompted by certain local DRLs exceeding the national levels. Documentation provided to inspectors demonstrated that the corrective actions taken included adjustment of

exposure parameters for the OPG procedures and a review of protocol selection for the intra-oral equipment. From communication with the MPE and management, inspectors were satisfied that the requirements of this regulation were met by the undertaking.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Clontarf Aesthetic Dentistry. From discussions with management and from documentation reviewed, inspectors determined that acceptance testing had not been carried out on a piece of medical radiological equipment installed in October 2021 before the first clinical use. On the day of inspection this oversight had been rectified by the undertaking and the equipment had undergone acceptance testing by the MPE.

Inspectors acknowledged that certain performance testing of the OPG equipment had been carried out on a monthly basis. However, the QA of equipment including an assessment of the dose had not been carried out since 2018 until prior to the inspection in January 2022 and hence inspectors were not satisfied that the undertaking maintained an appropriate quality assurance programme. These findings and the importance of ensuring acceptance testing prior to clinical use was acknowledged by management during the inspection.

Quality assurance and acceptance testing of equipment was carried out by the MPE in January 2022 and the report demonstrated that the equipment was safe for continued clinical use provided the undertaking addressed certain recommendations contained in the report. The undertaking outlined to inspectors that these recommendations were being addressed as a priority.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

The undertaking was unable to provide evidence of continuity of medical physics expertise in this service, since prior to the commencement of the regulations up to January 2022, during which time new equipment was selected, installed and used clinically. Management acknowledged the requirement for continuity of medical physics expertise and inspectors were informed that a formal arrangement was now in place with an MPE to support the service going forward.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were not satisfied that Clontarf Aesthetic Dentistry had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1). The recent engagement of an MPE addressed aspects of MPE responsibilities under this regulation including dosimetry, optimisation, DRLs and performance of quality assurance of medical radiological equipment. However, an MPE did not give advice on equipment when a new intra-oral unit was selected and an MPE was not engaged to perform acceptance testing on this equipment prior to clinical use.

Judgment: Not Compliant

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

Inspectors found that there was a lapse in MPE engagement by the undertaking during which time an MPE was not appropriately involved in the service. However, management communicated to inspectors that a formal arrangement had been put in place by the undertaking to ensure involvement of the MPE in the service going forward, in line with the radiological risk at this installation.

Judgment: Substantially Compliant

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

On the day of inspection, evidence of completed post-graduate education, which incorporated some training in the use of CBCT procedures was available for one dentist practitioner who conducted CBCT procedures at the practice. However, records evidencing the successful completion of training, as prescribed by the Dental Council, for other dentists who also used CBCT were not available for review by inspectors. Inspectors were informed that all of the dentists were due to complete training but had not done so at the time of inspection. This should be addressed by the undertaking as a matter of urgency to ensure compliance with the training requirements of Regulation 22.

Judgment: Not Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

Compliance Plan for Clontarf Aesthetic Dentistry OSV-0006841

Inspection ID: MON-0035025

Date of inspection: 03/02/2022

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance or where the non-compliance poses a significant risk to the safety, health and welfare of service users will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Existing Documentation regarding responsibilities of dental nurses will be edited according to recommendations from inspectors. An MPE has been engaged on an ongoing basis and is available to support out of hours assistance if required.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: As per the recommendation of the MPE the settings of the intra-oral units have been adjusted and the DRLs comply with HIQA recommendations. OPG settings have been adjusted following advice from MPE and a clinical audit has been established to review the diagnostic quality. All equipment has been QA tested in January 2022 before inspection and the MPE has been engaged to review this process bi-annually.	
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: MPE has been engaged to provide support on an ongoing basis.	

Regulation 20: Responsibilities of medical physics experts	Not Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:
MPE has provided QA testing of equipment. DRLs have been established. Modifications to dosage settings of Intra-oral units and OPG have been undertaken together with MPE. Any new equipment will be installed with input from MPE and performance acceptance testing undertaken prior to use.

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:
MPE has been engaged to provide ongoing service.
Radiological safety committee will continue to review audits and any findings suggesting alterations to dose /quality of images will be sent to MPE. MPE to continue bi-annual quality assurance.

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:
Practitioners have all committed to level 1 and level 2 CBCT training. Dates and confirmation of this were provided to inspectors. All practitioners will have completed this by April 2022.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	01/04/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Not Compliant	Orange	25/01/2022

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	25/01/2022
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Orange	25/01/2022
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	25/01/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	25/01/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of	Substantially Compliant	Yellow	21/01/2022

	persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Substantially Compliant	Yellow	21/01/2022
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Orange	21/01/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in	Not Compliant	Orange	21/01/2022

	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, 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	21/01/2022
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	Orange	29/04/2022

	(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).			