



**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:	Dun Laoghaire Dental
Undertaking Name:	Dr. Tom O' Connor
Address of Ionising Radiation Installation:	99 Upper George's Street, Dun Laoghaire, Co. Dublin
Type of inspection:	Announced
Date of inspection:	24 February 2022
Medical Radiological Installation Service ID:	OSV-0007123
Fieldwork ID:	MON-0034986

About the medical radiological installation:

Dun Laoghaire Dental was established more than 20 years ago by Dr. Tom O' Connor. The practice provides a broad range of treatments including general dentistry, dental implants, root canal treatment and cosmetic dentistry. Only one dentist works in this practice since 2015 and a dental hygienist attends on a part-time basis.

There are two dental surgeries each with an intra-oral X-ray unit. Surgery 1 is used exclusively by the dentist. The X-ray unit in this surgery was installed in November 2021.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is doing, we describe the overall effectiveness of an undertaking in ensuring the quality and safe conduct of medical exposures. It examines how the undertaking provides the technical systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 24 February 2022	12:00hrs to 13:45hrs	Agnella Craig	Lead

Summary of findings

The inspection of Dun Laoghaire Dental was carried out remotely on 24 February 2022 to assess compliance with the regulations. This inspection was initiated as the undertaking had not submitted a self-assessment questionnaire which was issued as part of HIQA's regulatory assessment process. The inspector was informed that this was an oversight on the undertaking's part and related to issues which included staff resources. Following the announcement of this inspection the undertaking updated the details for the designated manager to facilitate timely communication between the undertaking and HIQA.

The process of referring and carrying out medical exposures was described by the undertaking. This dental practice did not accept referrals for dental imaging from external sources. The referrer and practitioner were the same person and the practitioner completed the practical aspects and took clinical responsibility for medical exposures. On the advice of the medical physics expert (MPE), the undertaking had developed policy and procedure documents and had begun to conduct clinical audits. These measures were viewed by the inspector as examples of good practice which may help to provide the undertaking with oversight of the radiation protection of those using this service. Although some documents would benefit from a review to ensure alignment with local practices the inspector was satisfied that all staff had read the policy documents.

On the day of inspection, the inspector spoke with the MPE who was engaged by the undertaking following the announcement of this inspection. The MPE, who was registered with the Irish College of Physicists in Medicine (ICPM), described their recent involvement in this facility and the inspector was satisfied that their level of involvement was in line with the level of risk posed by a dental service such as this. However, the inspector was informed that an MPE had not been involvement in this practice from before the commencement of the regulations in 2019 up to February 2022 when this inspection was announced. The undertaking accepted the deficits that had occurred, particularly in relation to the equipment, due to the lack of continuity in accessing medical physics expertise. However, the undertaking had begun to address these deficits by acting on the advice and recommendations of the recently appointed MPE.

Notwithstanding the non-compliances identified in this facility, the inspector was assured by the undertaking's recent actions in addressing the gaps to ensure the safe delivery of ionising radiation.

Regulation 4: Referrers

From discussions with management and from reviewing documentation provided in advance of the inspection, the inspector was satisfied that only referrals for dental radiological procedures, from individuals entitled to refer as per Regulation 4, were carried out at Dun Laoghaire Dental. The inspector was informed that all referrals for medical radiological procedures originated within this service and the registered dentist acted as both the referrer and practitioner for all medical radiological exposures.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only a practitioner, as defined in the regulations, took clinical responsibility for individual medical exposures at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The undertaking had allocated clinical responsibility for individual medical exposures to the dentist who was entitled to act as referrer at Dun Laoghaire Dental. Similarly, the inspector was informed that this dentist, registered with the Irish Dental Council, was also the practitioner who took clinical responsibility for all dental radiological procedures. The inspector was informed that the practical aspects were only carried out by this practitioner and not delegated to other personnel.

However, some of the documentation provided in advance of this inspection had included details about others who are entitled to act as referrer and who can carry out the practical aspects. The undertaking accepted that the documentation should clearly define how responsibility is allocated specifically within this practice, rather than generally in line with the regulations. In addition, prior to the announcement of this inspection, the undertaking had not engaged the services of an MPE resulting in a failure to allocate certain key responsibilities as per the regulations.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Local facility diagnostic reference levels (DRLs) had recently been established by the

MPE and although the local DRLs were found to be less than the national levels, the MPE advised the undertaking about exposure times in order to achieve better image quality. The inspector discussed this with the undertaking and the designated manager on the day of inspection and the undertaking, having acted on this advice, acknowledged the benefits of the MPE's involvement.

Judgment: Compliant

Regulation 14: Equipment

From reviewing the documentation in advance of inspection and the discussion with management staff on the day of inspection, the inspector determined that acceptance testing had not been carried out on a piece of medical radiological equipment installed in November 2021 until February 2022, and therefore was found to be not in compliance with Regulation 14(3)(a).

In addition, no records or other evidence of quality assurance or performance testing from an MPE were available for the second piece of equipment in this facility. Therefore, although these issues had recently been rectified by the undertaking, the inspector was not satisfied that medical radiological equipment had been kept under strict surveillance as required by Regulation 14(1), or that performance testing and appropriate quality assurance programmes had been implemented and maintained prior to the announcement of this inspection in February 2022.

The quality assurance and acceptance testing of the equipment carried out by the MPE in February 2022 reported that the equipment was safe for clinical use, but the MPE had made some recommendations to be considered about ancillary equipment and the undertaking was acting on these recommendations.

Although the undertaking was found to be not in compliance with this regulation, details about the actions subsequently taken on the recommendations of the MPE demonstrated the undertaking's commitment to radiation protection and safety for service users.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

The risk assessment carried out by the MPE in February 2022 identified that all reasonable measures were taken to minimise the likelihood of accidental or unintended exposures of patients attending this facility. In addition, although no incidents involving radiation had been recorded for the previous 12 month period, the policy documents reviewed for this inspection had detailed the processes in

place should any incidents occur. This included details on the types of incidents that can occur in services such as this and the appropriate regulatory bodies that should be informed in the event of such incidents.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Although the undertaking had recently engaged the services of an MPE, the undertaking identified that the services of an MPE had not be engaged prior to the announcement of this inspection. The undertaking described an attempt previously taken to try to engage an MPE, for example before selecting new equipment, however, the inspector was informed that this attempt had not been successful.

Management acknowledged the requirement for continuity of medical physics expertise and the inspector was informed that an arrangement was now in place with an MPE service.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Before the announcement of this inspection the undertaking at Dun Laoghaire Dental had not ensured that an MPE acted or gave specialist advice, as required by Regulation 20(1). In addition, an MPE had not been engaged when the undertaking had selected and installed a new piece of equipment in November 2021. As a result, the acceptance and performance testing of this equipment was not completed prior to its first clinical use.

Notwithstanding these findings, the inspector recognised the work completed by the MPE who was engaged after the announcement of this inspection. This work included taking responsibility for dosimetry and completing acceptance testing, optimisation, DRLs, training and performance of quality assurance of the medical radiological equipment. The MPE had also advised on the replacement of some ancillary equipment and the undertaking was acting on these recommendations.

Judgment: Not Compliant

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

The inspector was informed that an MPE had not been involvement in this practice

from before the commencement of the regulations in 2019 up to February 2022. However, management communicated to the inspector that arrangements had now been put in place by the undertaking to ensure involvement of the MPE in this service in the future. The MPE who spoke with the inspector on the day of inspection confirmed that the level of involvement was in line with the level of radiological risk at this facility.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 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 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Compliance Plan for Dun Laoghaire Dental OSV-0007123

Inspection ID: MON-0034986

Date of inspection: 24/02/2022

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Tom O'Connor is the only undertaking/ carrying out of x-rays. We have engaged services of the MPE</p> <p>Our Documentation has been updated on 1st April 2022 to clarify updating of responsibilities from 01-04-2022.</p> <p>The medical physics expert will also be available for consultation or advice on matters relating to the radiation protection of our service user. We believe this and outlined above brings us into compliance with Regulation 6.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: We are following the MPE Recommendations sent to us. We have a new PC monitor (installed Friday 18th February 2022) and we have changed the sensor (Tuesday 15th February 2022).</p> <p>A medical physics expert has been engaged and will be available for consultation or advice on matters relating to the radiation protection of our service user over the next 2 years. We believe this and outlined above brings us into compliance with Regulation 14.</p>	
Regulation 19: Recognition of medical	Substantially Compliant

physics experts	
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: We have appointed an MPE, and had a site visit on 14.02.2022. We are following the MPE Recommendations that was sent to us: Our Radiation Safety Procedures (RSP) that was updated in February 2022. Our X-ray Compliance folder is located at front desk for all staff to view at any time. We also have a diary/Calendar in place to set up service dates etc.</p> <p>A medical physics expert has been engaged and is available for consultation or advice on matters relating to the radiation protection of our service user over the next 2 years. We believe this and outlined above brings us into compliance with Regulation 19.</p> <p>An attempt was made to try and engage an MPE before new equipment was installed. But that attempt was unsuccessful.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: We are following the MPE Recommendations that was sent to us: Our Radiation Safety Procedures (RSP) that were updated in February 2022. Our X-ray Compliance folder is located at front desk for all staff to view at any time. We also have a diary/Calendar in place to set up service dates etc.</p> <p>A medical physics expert has been engaged and is available for consultation or advice on matters relating to the radiation protection of our service user over the next 2 years. We believe this and outlined above brings us into compliance with Regulation 20.</p> <p>An attempt was made to try and engage an MPE before new equipment was installed. But that attempt was unsuccessful.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of</p>	

medical physics experts in medical radiological practices:

We are following the MPE Recommendations that was sent to us: Our Radiation Safety Procedures (RSP) that were updated in February 2022. Our X-ray Compliance folder is located at front desk for all staff to view at any time. We also have a diary/Calendar in place to set up service dates etc.

A medical physics expert has been engaged and is available for consultation or advice on matters relating to the radiation protection of our service user over the next 2 years. We believe this and outlined above brings us into compliance with Regulation 21.

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	14/02/2022

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	14/02/2022
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Orange	14/02/2022
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	14/02/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Not Compliant	Orange	14/02/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of	Substantially Compliant	Yellow	14/02/2022

	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	14/02/2022
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	14/02/2022
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement	Substantially Compliant	Yellow	14/02/2022

	being commensurate with the radiological risk posed by the practice.			
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