



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Annesley Dental Clinic
Undertaking Name:	Garrett McGann
Address of Ionising Radiation Installation:	18 Annesley Bridge Road, Fairview, Dublin 3
Type of inspection:	Announced
Date of inspection:	11 January 2022
Medical Radiological Installation Service ID:	OSV-0006775
Fieldwork ID:	MON-0034985

## About the medical radiological installation:

The Annesley Dental Clinic has been providing a broad range of general dental services since 1951. At present there are two surgeries in which intra-oral radiographs, namely bitewing and periapical x-rays are taken. There is also a dedicated x-ray room for taking orthopantomographs.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

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

<sup>4</sup> 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 11 January 2022	12:00hrs to 13:30hrs	Lee O'Hora	Lead

## Summary of findings

An inspection was conducted remotely by an inspector on the 11 January 2022 to assess compliance against the regulations. This inspection was initiated as a result of the failure of the undertaking to submit a completed regulatory self assessment questionnaire to HIQA when requested to do so.

The inspector was assured that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice. However, on the day of inspection, a recognised medical physics expert (MPE) was not appropriately involved to provide consultation and advice as required by the regulations. As a result, quality assurance (QA) testing by an MPE had not been carried out since 2014 and was overdue. While the inspector noted that an arrangement had been in place previously, this had not been maintained by the undertaking. Additionally, diagnostic reference levels (DRLs) for dental exposures had not been reviewed or used at the practice.

The inspector discussed these findings with the undertaking and an assurance was provided to inspectors that measures would be implemented to address the non-compliances identified on the day of inspection. Following this inspection the undertaking was required to submit an urgent compliance plan to address urgent risks identified. The undertaking's response did provide an assurance to the inspector that the risks were adequately addressed, however, the judgements included in this report are based on the findings on the day of the inspection.

### Regulation 4: Referrers

From speaking with the undertaking on the day of 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 the practice. Up to date professional registration documentation for all dentists operating at the practice was provided to the inspector.

Judgment: Compliant

### Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures at the dental practice. Professional registration for all practitioners was reviewed by the inspector and

satisfied requirements of Regulation 5.

Judgment: Compliant

### Regulation 6: Undertaking

During the inspection, the undertaking described the allocation of responsibility for the radiation protection of service users attending the practice. Only referrals from an individual entitled to refer as per the regulations were conducted at the practice. Similarly, only an individual entitled to take clinical responsibility for dental radiological procedures acted as a practitioner.

However, the inspector was not satisfied that appropriate measures were in place on the day of inspection to demonstrate that the undertaking allocated responsibility to an MPE to provide consultation and advice on matters relating to medical physics as required by the regulations.

Judgment: Not Compliant

### Regulation 11: Diagnostic reference levels

The inspector spoke with the undertaking and reviewed documentation and records and found that DRLs had been established for dental radiological procedures in 2014, but had not been regularly reviewed or used since.

Judgment: Not Compliant

### Regulation 14: Equipment

The inspector spoke with the undertaking and staff and reviewed records and documentation provided in advance of the inspection. Records of MPE QA testing from 19 June 2014 were supplied. On the day of inspection the undertaking acknowledged that MPE QA had not been carried out since 2014. No evidence of manufacturer service or preventative maintenance was available for review. As an appropriate QA programme, including an assessment of dose, was not implemented and maintained, the inspector was not satisfied that the dental radiological equipment at the practice was kept under strict surveillance regarding radiation protection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided

assurance that the risk was addressed.

Judgment: Not Compliant

### Regulation 19: Recognition of medical physics experts

The inspector spoke with the undertaking and reviewed documentation and records relating to the provision of medical physics expertise at the dental practice. While records provided to the inspectors indicated that a formal arrangement had been in place previously, this arrangement had not been maintained since 2014. Consequently the inspector was not assured that the undertaking had arrangements in place on the day of inspection to ensure the continuity of medical physics expertise at the dental practice.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspector spoke with the undertaking and reviewed documentation and found that appropriate measures were not in place on the day of inspection to ensure that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users. For example, the inspector was not assured that the MPE took responsibility for dosimetry, gave advice on radiological equipment or contributed to optimisation of radiation protection of patients including the application and use of DRLs at the practice.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

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

From speaking with the undertaking and from a review of documentation provided, the inspector was not satisfied that the undertaking ensured that an MPE was appropriately involved with the provision of service at the time of inspection. This

finding was acknowledged by the undertaking on the day of inspection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

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
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

# Compliance Plan for Annesley Dental Clinic OSV-0006775

Inspection ID: MON-0034985

Date of inspection: 11/01/2022

## 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	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The undertaking has formally re-established a relationship with a registered MPE. An inspection of the radiological practices and equipment at the facility was completed to the satisfaction of the MPE on 26/01/2022	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: The DRLs at the practice have been checked and verified as appropriate by a registered MPE and they will be reviewed on a regular basis going forward.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: The MPE performed QA testing on all radiological equipment at the practice and was satisfied that it was functioning safely and efficiently.	

Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:  A formal relationship with a registered MPE has been re-established and will be regularly maintained going forward.</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:  A formal relationship with a registered MPE has been re-established. The MPE has inspected and tested all radiological equipment and has advised on dosimetry, optimisation of radiation protection for patients and on appropriate DRLs at the practice</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:  The undertaking has formally re-established a relationship with an MPE who is now actively involved in all areas of radiological safety and protection at the practice.</p>	



## Section 2:

### Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	26/01/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	26/01/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	08/02/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	08/02/2022
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	Red	08/02/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom	Not Compliant	Red	08/02/2022

	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.	Not Compliant	Red	08/02/2022
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Red	08/02/2022
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological	Not Compliant	Red	08/02/2022



	practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, 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;	Not Compliant	Red	08/02/2022

	<p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>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.</p>	Not Compliant	Red	08/02/2022