



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	HSE Dental Clinic Blackrock
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Blackrock Hall, Skehard Rock, Cork
Type of inspection:	Announced
Date of inspection:	18 October 2022
Medical Radiological Installation Service ID:	OSV-0007569
Fieldwork ID:	MON-0037918

## About the medical radiological installation:

HSE Dental Clinic Blackrock is sited in Blackrock Hall Primary Care centre on the first floor of the building. It is a HSE Dental Clinic mainly treating a paediatric population (0-16 years) for dental assessment and treatment. There are three operating surgeries with 4 dental surgeons operating in them on a part-time basis. The current target of the HSE dental services is seeing dental emergencies up to 16 years and then specific classes for assessment and comprehensive dental intervention (2nd class and 6th class). Intra-oral radiographs form part of this process of assessment and treatment, based on individual justification and treatment need. Occasionally adult patients may be seen in accordance with acceptance criteria for HSE dental services. There is a designated X-ray room with a single intra-oral machine and a digital scanner. Medical Physics support is from Cork University Hospital Department of Medical Physics.

## 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 18 October 2022	10:00hrs to 11:20hrs	Noelle Neville	Lead

## Summary of findings

An inspection of HSE Dental Clinic Blackrock was carried out by an inspector on 18 October 2022 to assess its compliance with the regulations. As part of this inspection, the inspector spoke with staff and management, reviewed documentation and visited the dental practice's clinical rooms. HSE Dental Clinic Blackrock had returned a regulatory self-assessment questionnaire (SAQ) in August 2022 which had been issued by HIQA to determine the dental practice's perceived compliance with the regulations. The inspector validated the SAQ findings and noted that HSE Dental Clinic Blackrock demonstrated compliance with Regulations 4, 5, 6, 8, 10, 11, 13, 17 and 19 which was consistent with the information provided in the submitted SAQ. The inspector noted that Regulation 14 was substantially compliant at the time of the inspection rather than compliant and this was due to a lack of regular quality performance testing of equipment. In addition, the inspector found Regulations 20 and 21 to be substantially compliant as a medical physics expert (MPE) had not contributed to the training of staff in relevant aspects of radiation protection.

Overall, noting that some areas required improvement, the inspector was satisfied that the undertaking, the Health Service Executive (HSE), had systems in place to ensure the safe and effective delivery of medical radiological exposures at HSE Dental Clinic Blackrock.

### Regulation 4: Referrers

From discussion with management, staff and a review of documentation, the inspector was satisfied that referrals were from staff working within HSE Dental Clinic Blackrock, where the referrer and practitioner were the same person and entitled to act as referrer and practitioner as per the regulations.

Judgment: Compliant

### Regulation 5: Practitioners

The inspector was satisfied that only those entitled to act as practitioner had taken clinical responsibility for medical exposures at HSE Dental Clinic Blackrock.

Judgment: Compliant

## Regulation 6: Undertaking

HSE Dental Clinic Blackrock had a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3). The inspector reviewed a policy and protocol document titled *Dental Radiation Safety File* dated June 2022. This document outlined the management structure of the HSE Dental Service Cork and showed that dentists reported to the Designated Manager of HSE Dental Clinic Blackrock who in turn reported to the Head of Service Primary Care and upwards to the Chief Officer of Cork Kerry Community Healthcare. The *Dental Radiation Safety File* also outlined the responsibilities of staff including dentists, dental nurses and MPEs. HSE Dental Clinic Blackrock attended HSE South Dental/Orthodontic Radiation Safety Committee (RSC) meetings twice a year and the RSC also had a working group which followed up on items of work from the RSC. The RSC and working group ensured oversight of radiation protection for service users attending HSE Dental Clinic Blackrock.

Judgment: Compliant

## Regulation 8: Justification of medical exposures

From a sample of referrals reviewed, the inspector was satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data. The inspector noted that medical exposures were justified in advance and a record of this justification was available for review. In addition, information relating to the benefits and risks associated with radiation was available to service users and was displayed on posters at HSE Dental Clinic Blackrock.

Judgment: Compliant

## Regulation 10: Responsibilities

The inspector was satisfied that a practitioner took responsibility for all medical exposures to ionising radiation at HSE Dental Clinic Blackrock. In addition, the inspector was satisfied that the optimisation process included the practitioner and MPE and the justification process for all medical radiological procedures carried out at HSE Dental Clinic Blackrock involved the referrer and practitioner.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

The inspector was satisfied that HSE Dental Clinic Blackrock had established, regularly reviewed and used DRLs as required by Regulation 11. These local DRLs were displayed prominently at the dental practice.

Judgment: Compliant

## Regulation 13: Procedures

HSE Dental Clinic Blackrock had written protocols for standard dental radiological procedures as required by Regulation 13(1). Information relating to the medical exposure as required by Regulation 13(2) was available in a sample of reports reviewed. In addition, the inspector reviewed evidence of clinical audit carried out at HSE Dental Clinic Blackrock which allows for the identification of areas of good practice and areas of improvement to ensure the safe delivery of medical radiological exposures to service users.

Judgment: Compliant

## Regulation 14: Equipment

The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that an appropriate quality assurance programme was in place for equipment at HSE Dental Clinic Blackrock as required by Regulation 14(2). However, the inspector was informed that performance testing had not been carried out on the equipment on a regular basis as required by Regulation 14(3). It is important that equipment is kept under strict surveillance by the undertaking as required by Regulation 14(1).

Judgment: Substantially Compliant

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

The inspector reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Staff explained the radiation incident management process to the inspector and a template for recording incidents was available. Although no incidents relating to accidental or unintended exposure had been identified or reported at HSE Dental Clinic Blackrock,

the inspector was satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with management that adequate processes were in place to ensure the continuity of medical physics expertise at HSE Dental Clinic Blackrock as required by Regulation 19. Medical physics expertise was provided by a team of MPEs based at Cork University Hospital.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificates for MPEs at HSE Dental Clinic Blackrock and was satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted involvement in radiation protection by an MPE across a range of responsibilities as outlined in Regulation 20(2) including quality assurance of equipment and optimisation including the application and use of DRLs. However, the inspector noted that an MPE had not contributed to the training of staff in relevant aspects of radiation protection as required by Regulation 20(2) since the commencement of the regulations in 2019, and was therefore found to be substantially compliant with this regulation.

Judgment: Substantially Compliant

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

As outlined in Regulation 20, an MPE had not contributed to the training of staff in relevant aspects of radiation protection. Therefore, the inspector determined that further work is required to ensure that an MPE is appropriately involved at HSE Dental Clinic Blackrock, with the level of involvement commensurate with the level of radiological risk posed by the dental practice as required by Regulation 21.

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
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	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	Substantially Compliant

# Compliance Plan for HSE Dental Clinic Blackrock OSV-0007569

Inspection ID: MON-0037918

Date of inspection: 18/10/2022

## 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 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:            In accordance with the Cork HSE Dental Services Radiation Safety Policy, performance testing in the form of a stepwedge will be taken at Blackrock Hall HSE Dental Clinic on a monthly basis. A log of the performance testing and step wedge results will be kept in Blackrock Hall Dental clinic.</p>	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:            A Medical Physics Expert will deliver a presentation on all relevant aspects of radiation protection for HSE Cork dental staff in January 2023.</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 medical physics experts in medical radiological practices:            A Medical Physics Expert will deliver a presentation on all relevant aspects of radiation</p>	

protection for HSE Cork dental staff in January 2023.

## 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 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	31/12/2022
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	31/12/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1)	Substantially Compliant	Yellow	31/01/2023

	<p>contributes, in particular, to the following:</p> <ul style="list-style-type: none"> <li>(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;</li> <li>(ii) the definition and performance of quality assurance of the medical radiological equipment;</li> <li>(iii) acceptance testing of medical radiological equipment;</li> <li>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</li> <li>(v) the surveillance of the medical radiological installations;</li> <li>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</li> <li>(vii) the selection of equipment required to perform radiation protection measurements;</li> </ul>			
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	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	31/01/2023