



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Smile Hub
Undertaking Name:	Smile Hub Limited
Address of Ionising Radiation Installation:	Bayside Medical Centre, Sutton, Dublin 13
Type of inspection:	Announced
Date of inspection:	19 January 2022
Medical Radiological Installation Service ID:	OSV-0007958
Fieldwork ID:	MON-0034976

## About the medical radiological installation:

There are three intraoral units and one OPG unit within Smile Hub Dental Practice in Bayside Medical Centre. The Clinical Director liaised with the medical physics expert and the equipment vendor's radiological engineer when setting up this service. Each dentist working in this practice is registered with the Irish Dental Council and is responsible for their own patients' medical exposures. All dentists and dental nursing staff working in the service have read, understand and have signed the practice's radiological protocol handbook.

## 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
Wednesday 19 January 2022	11:00hrs to 13:30hrs	Agnella Craig	Lead

## Summary of findings

An inspection was conducted remotely on the 19 January 2022 to assess compliance against the regulations. This inspection was carried out because the undertaking had not submitted a regulatory self-assessment questionnaire when requested by HIQA. Similarly, the undertaking had not engaged with HIQA when information about the undertaking's declaration (NF200 form) had previously been requested. On the day of inspection, the inspector spoke with the undertaking who explained that the lack of communication related to issues with the contact details initially provided to HIQA. Recognising the importance of keeping HIQA up to date, the undertaking subsequently submitted the relevant forms to update the details held by 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.

Although the undertaking had measures in place such as clinical audits and protocols and guidance documents, the documents would benefit from a review and update to ensure the role of all personnel involved in medical exposures in this service is clearly detailed. Notwithstanding this finding, the inspector was satisfied that all staff had read the policy document as the signature sheet was also provided for this inspection.

On the day of inspection, the inspector also spoke with the medical physics expert (MPE) who was engaged by the undertaking since this practice opened in 2020. The MPE, who was registered with the Irish College of Physicists in Medicine (ICPM), described their involvement in the setting up of this service 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.

From speaking with personnel and reviewing the documentation provided as part of this inspection, the inspector was assured that performance testing had been completed, as required by the regulations, on all radiological equipment in this facility.

Notwithstanding the required documentation review and updates, the inspector was assured by this undertaking's commitment to the radiation protection of the users of this service.

## Regulation 4: Referrers

The inspector was informed that all referrals at this practice originated within the service, with the same referrer acting as practitioner for medical radiological exposures.

From speaking with the undertaking on the day of inspection, the inspector was satisfied that the referrals for the dental radiological procedures were from an individual entitled to refer as per Regulation 4.

Judgment: Compliant

## Regulation 5: Practitioners

The inspector found 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

During the inspection, the undertaking described the allocation of responsibility for the radiation protection of service users attending this practice. Only referrals from an individual entitled to refer as per the regulations were conducted at this practice. Similarly, only an individual entitled to take clinical responsibility for dental radiological procedures acted as a practitioner, and the practical aspects of medical exposures were only carried out by practitioners and not delegated to other personnel.

The document titled '*Smile hub's ionising radiation policy*' was reviewed in advance of this inspection and although some key roles were detailed in this document, the undertaking should review and update this document to ensure the allocation of responsibility for all personnel is included. For example, updating this to include the role of the MPE, and the personnel with responsibility for the daily quality control checks would ensure full clarity for both the undertaking and the staff working in this practice. Notwithstanding this finding, all practitioners working under this undertaking had signed a document stating they had read and agreed to comply with this policy, providing evidence of the arrangements in place in this practice for regulatory responsibility.

Judgment: Substantially Compliant

## Regulation 14: Equipment

The inventory of equipment provided to HIQA showed that all four radiological units had been installed in 2021. The reviewed documentation was evidence that the relevant acceptance testing had been carried out by the MPE on all pieces of equipment. From the information provided verbally and in the documentation, the inspector was assured of the strict oversight of the radiological equipment in this practice.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

From reviewing records and associated documentation and speaking with the undertaking and the MPE, who was registered with the ICPM, the inspector was assured that the undertaking had arrangements in place to ensure the continuity of medical physics expertise at this dental practice.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

In this practice, the Radiation Protection Advisor (RPA) and MPE were the same person. Having spoken with the undertaking and the MPE the inspector found that appropriate measures were in place to ensure that an MPE was available to act and give specialist advice on matters relating to the radiation protection of service users. The inspector was satisfied that the MPE had been involved in the selection of the medical radiological equipment initially and the MPE had taken responsibility for acceptance testing, dosimetry and optimisation at this practice.

The role of the radiation protection adviser was detailed in the reviewed documentation, but the documentation did not specifically detail the role of the MPE as distinct from the RPA. Therefore, the documentation would benefit from updating as detailed in Regulation 6.

Judgment: Compliant

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

After reviewing the documentation and speaking with the undertaking and the MPE, the inspector was satisfied that the involvement of the MPE was commensurate with the level of radiological risk posed by a service of this nature.

Judgment: 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	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

# Compliance Plan for Smile Hub OSV-0007958

Inspection ID: MON-0034976

Date of inspection: 19/01/2022

## 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	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The undertaking reviewed and updated 'Smile Hub's Ionising Radiation Policy' to ensure the allocation of responsibility for all personnel is included. For example, this included updating the role of the MPE and the personnel with responsibility for the daily quality control checks to ensure full clarity for both the undertaking and the staff working in the practice.	

## 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	11/02/2022