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:	Stillorgan Village Dental
Undertaking Name:	Patrick May
Address of Ionising Radiation Installation:	3 Old Dublin Road, Stillorgan, Co. Dublin
Type of inspection:	Announced
Date of inspection:	05 April 2022
Medical Radiological Installation Service ID:	OSV-0006433
Fieldwork ID:	MON-0034681

About the medical radiological installation:

Stillorgan Village Dental is a two surgery general dental practice run by a two operators - Dr Patrick May & Dr Siobhan Boyle. Both qualified from Trinity College Dublin (1987& 1988 respectively) and are registered with the Dental Council of Ireland. There are two x-ray machines for taking intra-oral periapical and bitewing type radiographs in the course of general practice.

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
Tuesday 5 April 2022	11:30hrs to 13:00hrs	Maeve McGarry	Lead

Summary of findings

An inspection of Stillorgan Village Dental practice took place remotely on 5 April 2022. The inspection was carried out on foot of information received through a self-assessment questionnaire completed by the undertaking which identified gaps in compliance in relation to the involvement of a Medical Physics Expert (MPE) in the service at that time. The undertaking had relayed to HIQA that the medical physics service previously involved in the dental practice had ceased to operate in Ireland. Subsequently, HIQA requested an undertaking assurance report to outline how the gaps in compliance identified by the undertaking were being addressed. The undertaking assurance report outlined that an MPE registered with the Irish College of Physicists in Medicine (ICPM) had been engaged by the undertaking to act as MPE and was scheduled to attend the practice on 14 March 2022 to consult and advise on radiation protection. The focus of this inspection was to follow up the undertaking assurance report received by HIQA and to validate the progress made by the undertaking.

The inspector spoke with the recently engaged MPE on the day of inspection and acknowledged the work that had been done following on from the undertaking assurance report by the MPE and undertaking. Quality assurance of equipment had been completed and diagnostic reference levels (DRLs) were established. On foot of the local DRL values the MPE advised that only one of the two X-ray units should be used for paediatric dental imaging. Furthermore, the MPE advised the undertaking to consult the equipment manufacturer about potentially reducing dose and inspectors were informed that this review was underway.

The inspector was informed that two dental practitioners, including the undertaking, operated at this dental practice. The process of referring and carrying out dental radiological procedures 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.

The inspector acknowledged that considerable work was done in advance of the inspection which included the development of local radiation safety procedures (RSPs). This included a technique chart which documented exposure parameters and an outline of the practical aspects of the dental radiological procedures carried out. The RSP also included an outline of the quality control checks to be completed quarterly and the responsibilities of the MPE including quality assurance of the equipment every two years. An audit was recently carried out in each of the surgery rooms which included documentation of the justification for dental X-rays. The conduct of audits was deemed a positive initiative and should be continued by the undertaking to provide assurance around meeting regulatory requirements.

Notwithstanding the areas for improvement outlined in this report, the inspector was assured by the steps taken by the undertaking thus far to address gaps in

compliance regarding the safe delivery of dental exposures at the practice.

Regulation 4: Referrers

The inspector was informed that external referrals for medical radiological procedures were not accepted at this dental practice and that the same referrer acted as practitioner for medical radiological exposures. From discussion with the undertaking and from reviewing documentation, the inspector was satisfied that the referrals for radiological procedures were from registered dentists.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, had taken clinical responsibility for individual medical exposures at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The allocation of responsibility for the radiation protection of service users attending this practice was outlined by the undertaking during the inspection. Only the two dentist practitioners working at the practice took clinical responsibility for the dental radiological procedures carried out and there was no delegation of the practical aspects to personnel other than practitioners.

The local Radiation Safety Procedures document had been recently developed and outlined the responsibilities of the MPE in the service. An ICPM registered MPE was engaged by the undertaking as per the undertaking assurance report and the contribution by this MPE ensured that certain responsibilities were allocated as per the regulations. However, the undertaking informed inspectors that the engagement of a previous MPE in the service had lapsed, due to this medical physics service no longer operating in Ireland. During this time the quality assurance of equipment was not carried out in a timely manner. Inspectors determined that while the undertaking had taken measures to address gaps in the continuity of the MPE in the service, the clear allocation of responsibilities should be strengthened.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Documentation reviewed in advance of the inspection outlined that DRLs for all procedures and equipment were recently reviewed at this dental practice and were compared to national levels. Inspectors were informed that the recent MPE review of DRLs had instigated some corrective actions. The MPE advised that paediatric patients were to be imaged on one of the X-ray units but not the other. The MPE also advised corrective actions be explored with the equipment manufacturer to potentially reduce the dose for one piece of equipment and inspectors were informed that this was progressing but was not yet completed. The undertaking should ensure that this review is progressed as a priority to ensure alignment with the requirements of this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory was provided to HIQA detailing information about the two pieces of medical radiological equipment at the practice. Quality assurance of equipment was carried out by the MPE in advance of the inspection in March 2022 but was overdue as it had not been carried out since April 2019. Furthermore, inspectors were informed by the undertaking that routine performance testing of equipment was not carried out up to the time of inspection, but that tests had been outlined by the MPE and would be carried out going forward. Hence, the inspector was not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1).

Quality assurance of equipment was carried out by the MPE in March 2022 and the report demonstrated that the equipment, although beyond nominal replace dates, were safe for continued clinical use provided the undertaking addressed certain recommendations contained in the report. These included limiting paediatric imaging to one unit and investigating optimisation options with the manufacturer. The undertaking outlined to the inspector that these recommendations were being addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

A medical physics service was involved in the dental practice prior to the regulations and in April 2019 when quality assurance was performed. However, the undertaking

confirmed that the arrangement in place with this physics service had lapsed. In advance of this inspection and following on from the issue of an undertaking assurance report by HIQA in relation to MPE involvement in the service, the undertaking engaged with an ICPM registered MPE. While the inspector acknowledged the measures taken by the undertaking to address the gap in MPE support identified, the undertaking should ensure the continuity of MPE expertise is maintained.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector spoke with the MPE on the day of the inspection and acknowledged the work recently completed which addressed aspects of responsibilities under this regulation including dosimetry, optimisation, establishing and reviewing DRLs, and completing quality assurance of the medical radiological equipment. The local RSP document outlined the responsibilities of the MPE and this should be updated to reflect all MPE responsibilities as per Regulation 20 including a contribution to the training of practitioners and other staff in relevant aspects of radiation protection. While the inspector recognised the measures taken to address gaps in this regulation in advance of the inspection, the undertaking should ensure that an MPE is engaged in the service to act and give specialist advice on matters relating to radiation physics going forward.

Judgment: Substantially 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, the undertaking communicated that an MPE was now engaged by the dental practice and that this arrangement was in line with the radiological risk at this installation to support the service going forward.

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	Substantially Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Substantially 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 Stillorgan Village Dental OSV-0006433

Inspection ID: MON-0034681

Date of inspection: 05/04/2022

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: MPE engaged and will be continuous going forward.	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: MPE has given up to date levels and are now in use from 14/3/22. We are not using the Belmont machine for children as recommended by our MPE. Have contacted the supplier who is contacting the manufacturer on our behalf re adjusting Belmont exposure times. Expect reply in the next few weeks.(latest June end) If not possible will investigate replacing machine.(timeline end of year 2022)	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Routine performance testing was not recommended by previous MPE. Have now put in place as recommended by current MPE.	

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: Have engaged a new MPE and will ensure continuity going forward. Although there was a lapse the machines were out of use for a period due to covid shutdown and the lapse was only a few months while a new MPE was being engaged.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: Will ensure continuity of MPE service going forward.	
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: Will ensure continuity of service going forward.	

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	14/03/2022
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	14/03/2022

	safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
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	Orange	14/03/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	14/03/2022
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Orange	14/03/2022
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been	Substantially Compliant	Yellow	14/03/2022

	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	14/03/2022
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 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	Substantially Compliant	Yellow	14/03/2022

	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	Substantially Compliant	Yellow	14/03/2022

	being commensurate with the radiological risk posed by the practice.			