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:	Galway Orthodontics
Undertaking Name:	Dr Hugh Gordon
Address of Ionising Radiation Installation:	Fourth Floor, Steamship House, Dock Street, Galway, Galway
Type of inspection:	Announced
Date of inspection:	05 April 2023
Medical Radiological Installation Service ID:	OSV-0006582
Fieldwork ID:	MON-0039425

About the medical radiological installation:

This is a specialist orthodontic practice. We only take lateral cephalometry and orthpantomogram (OPG) X-rays for our own patients. We do not operate a referral system for outside patients to have X-rays taken.

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
Wednesday 5 April 2023	13:00hrs to 15:00hrs	Lee O'Hora	Lead

Summary of findings

An inspection was carried out for the undertaking Dr Hugh Gordon operating at Galway Orthodontics to assess compliance with the regulations. The inspection was initiated as a result of a failure to return a regulatory self-assessment questionnaire that had been issued to the undertaking.

The inspector spoke with staff and management, reviewed documentation and visited the clinical area where radiological equipment was housed. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspector on the day of inspection. At the time of the inspection the inspector was satisfied that the engagement of the medical physics expert (MPE) had been re-established by the undertaking. However, this arrangement had been re-established after the announcement of this inspection and had been allowed to lapse prior to March 2023. It is imperative that engagement with an MPE is maintained by the undertaking to ensure the consistent quality and safety of all medical exposures carried out on service users.

The inspector was satisfied from documentation reviewed and discussions with staff that the specialist dentist practicing in this installation acted as the referrer, the practitioner and took clinical responsibility for all dental radiological medical exposures conducted there. Practical aspects of medical radiological exposures were delegated to an individual in a manner satisfying all requirements of the regulations.

Overall, despite some areas for improvement, the inspector found that the undertaking demonstrated good levels of compliance with the regulations considered on the day of inspection.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Galway Orthodontics operated with one dentist referrer generating all referrals. The associated professional registration was reviewed on site and was up to date.

Judgment: Compliant

Regulation 5: Practitioners

Similar to findings in relation to Regulation 4, the same dentist practitioner took

clinical responsibility for all individual medical exposures. Again, the associated professional registration was reviewed on site and was up to date.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by Dr Hugh Gordon operating at Galway Orthodontics. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection, however, the undertaking had allowed the allocation of responsibility and subsequent involvement of the MPE to lapse for a period of time. At the time of the inspection the inspector was satisfied that the engagement of the MPE had been re-established by the undertaking. It is imperative that an MPE's engagement is maintained by the undertaking to ensure the consistent quality and safety of all medical exposures carried out on service users.

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals. In line with Regulation 8, all referrals reviewed by the inspector on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The referrer and practitioner were the same individual for all medical imaging referrals reviewed.

The inspector visited the clinical area and observed posters which provided service users with information relating to the benefits and risks associated with the radiation dose from the medical exposures provided at this practice.

Judgment: Compliant

Regulation 10: Responsibilities

Practical aspects of medical radiological procedures were delegated by the undertaking to an individual registered by the Dental Council. This delegation was recorded in local radiation safety documentation. Records of the relevant

professional registration, radiation safety qualifications and radiation safety training were reviewed on site and subsequently supplied to the inspectors satisfying all requirements of Regulation 10(4).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was satisfied that DRLs had been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility.

Judgment: Compliant

Regulation 13: Procedures

The inspector was satisfied after document review and communication with staff that written protocols were established for standard medical radiological procedures and made available to all relevant staff at the practice.

The inspector reviewed a number of reports of medical radiological procedures which consistently included information relating to patient exposure.

Judgment: Compliant

Regulation 14: Equipment

At the time of inspection both MPE performance testing and manufacturer service engineer performance testing had been completed. However as discussed under Regulations 6, 19, 20 and 21 the undertaking had allowed this regular performance testing to lapse. Previous records of MPE performance testing from October 2018 were available. Therefore, the inspector was assured that while a QA programme had been implemented it had not been maintained since the transposition of the regulations. As a result of the lapse in performance testing the inspector was not satisfied that the undertaking ensured that all medical radiological equipment was kept under strict surveillance for the period of time before the announcement of this inspection.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the practice were described to the inspector and the details were available in a service level agreement which ensured MPE continuity of expertise until March 2025. However as discussed in Regulation 6, this arrangement had been re-established after the announcement of this inspection and had been allowed to lapse previous to March 2023.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the practice, the inspector was satisfied that arrangements were re-established to ensure that the MPE now took responsibility for dosimetry, gave advice on radiological equipment and contributed as required by the regulations. However, as discussed in Regulation 6 and 14, this arrangement had been re-established after the announcement of this inspection and had been allowed to lapse previous to March 2023.

Judgment: Substantially Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was now commensurate with the risk associated with the service provided at the Galway Orthodontics. However, this involvement was not appropriately maintained previous to the announcement of this inspection.

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 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 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 Galway Orthodontics OSV-0006582

Inspection ID: MON-0039425

Date of inspection: 05/04/2023

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: A new contract has been formed with the MPE which will ensure the continuity of the MPE's engagement.	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: New service contracts have been established with the MPE for performance testing and the manufacturer for performance testing. The responsibility for contacting the manufacturer's engineer and MPE for performance testing when due is now shared between the Undertaking and the Practice Manager. Highlighted key due dates are on display at key personnel stations to prevent a lapse in timely contact with the MPE and manufacturer.	
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: Measures have been adopted to prevent any repeated lapse in the continuity of MPE expertise through a new system of sign-posting and reviewing due dates to ensure that	

the MPE is contacted for engagement at regular intervals throughout the year. The contact details of the MPE are now readily available to key personnel to ensure that all due dates are regularly monitored; and to ensure that the expertise of the MPE is accessible to key personnel at all times. The next renewal date for the MPE level service agreement is sign-posted in colour.

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: The contact details of the MPE are now shared by multiple key personnel to ensure that all due dates are constantly reviewed and fulfilled in order to ensure and maintain the MPE's ongoing responsibility for dosimetry, giving advice and contributing under the regulations; and to ensure that the expertise of the MPE is accessible to key personnel at all times. The next renewal date for the MPE level service agreement is sign-posted in colour.	

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: New SLA with MPE will ensure all responsibilities of MPE including patient dosimetry, QA assessment etc will be provided to the Practice and any recommendations provided by the MPE will be acted on in a timely manner.	

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	16/05/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Substantially Compliant	Yellow	16/05/2023

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	16/05/2023
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	16/05/2023
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 recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	16/05/2023
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	Substantially Compliant	Yellow	16/05/2023

	evaluation of the dose delivered to the patient and other individuals subject to medical exposure,			
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	Substantially Compliant	Yellow	16/05/2023
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	Substantially Compliant	Yellow	16/05/2023

	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 being commensurate with the radiological risk	Substantially Compliant	Yellow	16/05/2023

	posed by the practice.			