



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dr Michael Gibson
Undertaking Name:	Dr Michael Gibson
Address of Ionising Radiation Installation:	26 Mount Merrion Avenue, Blackrock, Co. Dublin
Type of inspection:	Announced
Date of inspection:	21 February 2022
Medical Radiological Installation Service ID:	OSV-0006953
Fieldwork ID:	MON-0035885

About the medical radiological installation:

Dr Michael Gibson's dental practice specialises in orthodontic treatment for adults and children. Radiography taken at the practice are orthopantomogram or lateral cephalometric x-rays for orthodontic treatment.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Monday 21 February 2022	14:00hrs to 14:41hrs	Kay Sugrue	Lead
Monday 21 February 2022	14:00hrs to 14:41hrs	Noelle Neville	Support

Summary of findings

A remote inspection of Dr Michael Gibson dental practice was carried out by HIQA on 21 February 2022. Due to the manner in which this inspection was conducted, the focus was limited to the assessment of compliance with the regulations outlined in this report. This inspection was initiated as the result of the non-return of a regulatory dental self-assessment questionnaire requested by HIQA. Management informed inspectors that undertaking contact details had been changed and these updated contact details had not been provided to HIQA. As a consequence, the dental self-assessment questionnaire was overlooked and not submitted. Updated undertaking contact details have since been provided to the Authority.

Inspectors found that the undertaking as a sole trader and a registered dentist was the referrer and practitioner taking clinical responsibility for all medical exposures conducted at the dental practice and was therefore compliant with Regulations 4 and 5. However, not all responsibilities were allocated by the undertaking as required by Regulation 6(3). Specifically, management informed inspectors that a Medical Physics Expert (MPE) had not been engaged by the dental practice since the commencement of the regulations in 2019. The absence of engagement of an MPE resulted in a number of non-compliances with the regulations including Regulations 6, 11, 14, 19, 20 and 21.

Pre-inspection documentation received prior to the inspection was very limited and incomplete. The lack of documentation, together with discussion with the undertaking did not provide assurance that all medical radiological equipment was kept under strict surveillance as required by Regulation 14. Inspectors found no evidence to demonstrate that there was an appropriate quality assurance (QA) programme in place or that regular performance testing of medical radiological equipment was carried out. Overall, inspectors found that there was a general lack of awareness demonstrated by staff in discussions in relation to regulatory requirements therefore greater attention was required by the undertaking to ensure that adherence to all regulatory requirements in respect of medical exposures is maintained.

Following this inspection, the undertaking was required to submit an urgent compliance plan to address urgent risks relating to equipment and MPE continuity and responsibilities.

The undertaking's response did provide assurance that the risks identified on the day of inspection were adequately addressed following the inspection. However, more assurances were required to demonstrate that continuity of MPE engagement would be maintained for the service after the initial QA was performed.

Regulation 4: Referrers

From discussions with management at the dental clinic and review of professional registration documentation, inspectors were satisfied that referrals were from a registered dentist. External referrals were not accepted by this dental practice.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that the undertaking ensured that a registered dentist as per the regulations was the referrer. Similarly, only an individual entitled to take clinical responsibility for dental radiological procedures acted as a practitioner at this dental practice. This meant that some aspects relating to the allocation of responsibility to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) were met. However, inspectors found that urgent action was needed by the undertaking to ensure the clear allocation of responsibilities of an MPE at the practice was appropriately maintained as per regulatory requirements.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Following discussion with management, inspectors found that better awareness was needed by staff in relation to diagnostic reference levels (DRLs) and their application in a clinical setting for the radiation protection of patients undergoing medical exposure. Inspectors were not satisfied that DRLs had been established, regularly reviewed and used at the dental practice.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors spoke with the undertaking and staff and found that there was a notable lack of evidence to demonstrate that an appropriate QA programme was implemented or maintained. For example, records of MPE QA testing, manufacture service or preventative maintenance was not available for review. An inventory of medical radiological equipment requested prior to the inspection was incomplete and inaccurate; listing one piece of equipment instead of two which were located at the dental practice. An updated inventory requested to be submitted following the inspection was not provided to inspectors. Overall, inspectors were not satisfied that the dental radiological equipment at the practice was kept under strict surveillance regarding radiation protection.

The findings in relation to this regulation were discussed with the undertaking. Inspectors sought assurance from the undertaking that the dental radiological equipment at the practice would not be used until an MPE had completed QA of the equipment and had deemed it safe for continued clinical use. Inspectors received a commitment from the undertaking that an MPE would be engaged following this inspection and use of the equipment would be ceased until the appropriate assurances were provided as outlined.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed following the inspection.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were not satisfied that the undertaking had put in place the necessary arrangements to ensure the continuity of expertise of an MPE. At the time of the inspection, an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019. Management acknowledged this finding and informed inspectors that appropriate actions would be taken without delay to address this non-compliance.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed following the inspection.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were informed by management that an MPE had not been engaged at the dental clinic to act or give specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20 (1). Inspectors found that the absence of engagement of an MPE since the commencement of the regulations in 2019 resulted in deficits in the areas identified in Regulation 20(2), including optimisation, DRLs and the definition and performance of quality assurance of medical radiological equipment.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed following the inspection.

Judgment: Not Compliant

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

Inspectors were not satisfied that the undertaking had arrangements in place to ensure that an MPE was appropriately involved in the dental practice as an MPE had not been engaged at the dental practice since the commencement of the regulations in 2019. The undertaking informed inspectors that appropriate actions would be taken without delay to address this non-compliance.

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
Summary of findings	
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 Dr Michael Gibson OSV-0006953

Inspection ID: MON-0035885

Date of inspection: 21/02/2022

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: An ICPM Registered Medical Physics Expert was assigned to the practice and performed a two-yearly QA testing on the installed dental X-ray equipment on March 21, 2022. The MPE report is available on request. Clear allocation of responsibilities of an MPE is now in place in the practice and a maintenance program is now in place as per regulatory requirements. We have arranged for two-yearly QA testing as per advice of MPE. Dr. Michael Gibson is the owner of the practice and is legally responsible as the undertaking. Dr Gibson is the Radiation Protection Officer (RPO) and is responsible for delegating responsibility for practical aspects of dental radiological exposures. Allocation of responsibilities is demonstrated by the RPO in Section 4 of the Radiation Safety Manual which is available on request.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: The two yearly quality assurance tests carried out by the RPA/MPE include an assessment of representative patient doses. These facility DRLs are the patient doses which are not expected to be exceeded for a standard radiograph. They will be reviewed by the legal person and MPE on testing and compared to the national DRLS.</p>	

Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: An ICPM Registered Medical Physics Expert performed a two-yearly QA testing on the installed dental X-ray equipment on March 21, 2022. The RPA MPE report is available on request. We have arranged for two-yearly QA testing as per advice of MPE and a maintenance program is now in place as per regulatory requirements. X -ray equipment was examined by a service engineer on site in May 2022, the engineers report is available on request.</p>	
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: An MPE has been engaged for the practice by the undertaking and will assess the equipment on a two yearly basis as per MPE recommendations.</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: An MPE has been engaged to provide specialist advice to the practice and advice on SI No 256 of 2018. The MPE takes responsibility for patient dosimetry, including physical measurements for evaluation of the dose delivered to the patient, gives advice on medical radiological equipment and contributes, in particular to the following.</p> <ol style="list-style-type: none"> 1. optimisation of radiation protection of patients, including DRLS 2. acceptance testing and QA of equipment 3. technical specifications for equipment and installation design 4. analysis of accidental or unintended medical exposures. 	
Regulation 21: Involvement of medical	Not Compliant

physics experts in medical radiological practices	
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: An MPE has been engaged by the undertaking and provides MPE services to the practice and advises on SI No 256 of 2018. The MPE involvement is described under Regulation 20 and the MPE is appropriately involved as per regulations.</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	14/06/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	14/06/2022

	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	21/03/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	21/03/2022
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	Orange	23/05/2022
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for	Not Compliant	Orange	28/03/2022

	each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.	Not Compliant	Orange	23/05/2022
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 recognised as a medical physics expert under this Regulation.	Not Compliant	Red	21/03/2022
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	Not Compliant	Red	21/03/2022

	the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.			
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	21/03/2022
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	Not Compliant	Red	21/03/2022
Regulation 20(3)	The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise with the radiation protection adviser.	Not Compliant	Red	21/03/2022
Regulation 21(1)	An undertaking shall ensure that, in medical	Not Compliant	Red	21/03/2022

	radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.			
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