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Meridian Dental Partnership, OSV-0006390, 06 December 2021

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Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Meridian Dental Partnership
Undertaking Name:	Meridian Dental Partnership
Address of Ionising Radiation Installation:	The Meridian Clinic, Clarehall Shopping Centre, Malahide Road, Dublin 17
Type of inspection:	Announced
Date of inspection:	06 December 2021
Medical Radiological Installation Service ID:	OSV-0006390
Fieldwork ID:	MON-0034641

About the medical radiological installation:

Meridian Dental partnership is a private general dental practice operating 2 days per week and utilises intra-oral radiographs as part of the provision of service.

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 6 December 2021	12:00hrs to 13:30hrs	Lee O'Hora	Lead

Summary of findings

An announced inspection of the Meridian Dental Partnership at the Meridian Dental Clinic was carried out on the 6 December 2021. During the inspection, the inspector reviewed documentation and records and spoke with management and staff involved in the provision of the dental radiological service. The inspector was assured that processes were generally in place to ensure the safe conduct of dental radiological procedures at the Meridian Dental Clinic. The inspector was satisfied that all referrals originated from the sole operating dentist and subsequent dental radiological procedures were conducted entirely under the clinical responsibility of the same dental practitioner at the Meridian Dental Clinic. The inspector was also assured that all dental radiological procedures were justified in advance at the practice. However, written records of the reasons for performing each patient exposure were not consistently recorded in the patients' clinical notes. This was acknowledged by management as an area for improvement to ensure adherence with the regulations.

Although a clear understanding of dental radiological procedure protocols was articulated to the inspector on the day, written protocols for every type of standard dental radiological procedure were not available. Also diagnostic reference levels (DRLs) had not been established at the time of inspection. In order to ensure complete regulatory compliance the undertaking should address these areas for improvement in a timely manner.

Furthermore, although reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspector on the day of inspection, the involvement of a medical physics expert (MPE) to provide specialist advice for the practice had lapsed. As a result, quality assurance (QA) of equipment was outstanding. The undertaking was required to put measures in place to ensure the continuity of MPE involvement to satisfy regulatory requirements relating to the protection of service users from dental exposure to ionising radiation.

Overall, while a number of non compliances were noted during the inspection process, assurances were given by management these would be addressed immediately.

Regulation 4: Referrers

At the time of inspection Meridian Dental Partnership operating at the Meridian Dental Clinic employed one dentist who acted as both referrer and practitioner for all dental exposures carried out at the practice. Professional registration was supplied to the inspector demonstrating compliance with Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Aligned with the requirements of Regulation 4, the Meridian Dental Clinic employed one dentist who acted as both referrer and practitioner for all dental exposures carried out at the practice. Professional registration was supplied to the inspector satisfying requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

After speaking with staff and management, the overarching accountability structures of the undertaking partnership were well described and understood by staff. The inspector was assured that a clear allocation of responsibility was in place for the undertaking partnership, the individual partners and the practitioner. However on the day of inspection, the undertaking did not have arrangements in place to ensure that an MPE was appropriately involved in the radiation protection of service users as required by the regulations. Documentation reviewed by inspectors indicated that an MPE had previously provided medical physics expertise, however the undertaking had not ensured that a registered MPE was currently involved for consultation or advice on matters relating to the radiation protection of service users. The lapsed involvement of an MPE at the time of inspection directly influenced the undertakings compliance with other Regulations including 11, 14, 19, 20, and 21 and must be addressed as a matter of urgency.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

After reviewing a sample of referrals for medical imaging and speaking with staff, the inspector noted that the reason for requesting the particular procedure was not consistently recorded in the patient records. Although staff articulated a detailed knowledge of the referral and justification process, documentation of the reasons for dental exposures was not consistently recorded. Although the inspector was satisfied that every dental radiological procedure was considered and justified by the practitioner in advance of exposure, staff acknowledged that the documentation of referrals and associated decision making was required to ensure regulatory compliance.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

After speaking with staff, the inspector was satisfied that the undertaking had systems in place to ensure all dental exposures took place under the clinical responsibility of the practitioner dentist. The organisational structure at the facility ensured that a single practitioner dentist referred, justified and was responsible for practical aspects and image interpretation for each dental exposure carried out at the Meridian Dental Clinic.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

At the time of inspection, evidence demonstrating that the Meridian Dental Clinic had established DRLs was not available. Staff and management informed the inspector that this was due to recent closures and low imaging volumes at the service. Acknowledging the low volume of X-rays conducted at the facility, local DRLs should still be established for common procedures, used in practice and reviewed in line with national guidance to satisfy regulatory requirements.

Judgment: Not Compliant

Regulation 13: Procedures

Staff spoken with on the day articulated an extensive knowledge of imaging techniques and the use of equipment. However, written protocols for every type of standard dental radiological procedure were not available. Staff and management acknowledged this as an area for improvement and gave assurances that this would be addressed as part of a return to compliance.

Judgment: Not Compliant

Regulation 14: Equipment

The inspector was supplied with a copy of an engineer's report of the service of X-ray equipment from 1 December 2021 and an MPE QA report of equipment

assessment from 18 July 2019. Staff and management spoken with on the day acknowledged that MPE QA was outstanding and that this would be addressed as a matter of urgency to ensure that all dental radiological equipment is kept under strict surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Staff and management spoken with on the day informed the inspector that the engagement of the MPE had lapsed and was therefore not compliant with the requirement of Regulation 19. Management acknowledged the importance of ensuring the continuity of MPE input and gave assurances that the process was underway to re engage the services of an MPE.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Documentation in relation to the responsibilities, advice and contributions of the MPE was not available during the inspection process. Although the previous MPE QA records, dated 18 July 2019, reviewed by the inspector did provide assurances of historical contributions in relation to the definition of performance of QA and the surveillance of medical radiological equipment, QA of equipment was overdue. Furthermore, there was no evidence supplied to the inspector of the contribution of the MPE to the definition and use of DRLs in the practice.

In order to ensure that the undertaking is satisfying regulatory requirements in relation to the actions and advice of the MPE, the specific responsibilities, advice and contributions of the MPE should be formalised and recorded as a matter of urgency to ensure regulatory compliance.

Judgment: Not Compliant

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

Following documentation review and meeting with staff, the inspector noted that there were not any arrangements in place to access MPE advice and consultation as required. MPE services need to be urgently established and maintained by the undertaking in order to ensure that an MPE is appropriately involved.

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 8: Justification of medical exposures	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially 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 Meridian Dental Partnership OSV-0006390

Inspection ID: MON-0034641

Date of inspection: 06/12/2021

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: We have renewed the engagement of a registered medical physics expert from December 2021. The medical physics expert will be available for consultation or advice on matters relating to the radiation protection of our service users. We believe this brings us into compliance with Regulation 6</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: We have with immediate effect implemented a policy to ensure that documentation of the reasons for dental exposures is consistently recorded in the patient record to ensure regulatory compliance. We believe this brings us into compliance with Regulation 8</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p>	

Further to his inspection of the QA inspection on the 14th December 2021, The medical physics expert (See 6 above) provided the following: The diagnostic reference levels (DRLs) for exposures in this practice are 0.8mGy for adult mandibular molar bitewing radiographs.

We believe this brings us into compliance with Regulation 11

Regulation 13: Procedures

Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
We have drafted and published locally (on wall of surgery) written protocols for every type of standard dental radiological procedure performed in the surgery.

We believe this brings us into compliance with Regulation 13

Regulation 14: Equipment

Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
Further to his conducting a QA Test Inspection on the 14th December 2021, The medical physics expert (See 6 above) has provided a QA Report on the equipment in the surgery which is on file for inspection as required.

We believe this brings us into compliance with Regulation 14

Regulation 19: Recognition of medical physics experts

Not Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:

We have renewed the engagement of an ICPM registered medical physics expert with effect from December 2021. The medical physics expert will be available for consultation or advice on matters relating to the radiation protection of our service users.

We believe this brings us into compliance with Regulation 19

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:</p> <p>Further to his conducting a QA Test Inspection on the 14th December 2021, The medical physics expert (See 6 above) has provided the following documents:</p> <ul style="list-style-type: none"> • A radiation risk Assessment for the Kodak 2200 X-ray device in the dental surgery, • A QA Report for the X-ray equipment • A DRAFT set of radiation safety procedures which have been tailored to the practice <p>In addition to these documents the medical physics expert has highlighted several important features of the associated documents that we are to be aware of. We have set up a file for the relevant documentation and advices from the medical physics expert to be kept locally in the surgery for inspection or reference as required.</p> <p>We believe this brings us into compliance with Regulation 20</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:</p> <p>We have renewed the engagement of an ICPM registered medical physics expert with effect from December 2021. The medical physics expert will be available for consultation or advice on matters relating to the radiation protection of our service users at a level that is commensurate with the radiological risk posed by the practice.</p> <p>We believe this brings us into compliance with Regulation 21</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	14/12/2021
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical	Substantially Compliant	Yellow	07/12/2021

	exposure, and shall provide such records to the Authority on request.			
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	31/12/2021
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	14/12/2021
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	14/12/2021
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical	Substantially Compliant	Yellow	14/12/2021

	radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
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	Orange	14/12/2021
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	Not Compliant	Orange	31/12/2021

	<p>of quality assurance of the medical radiological equipment;</p> <p>(iii) acceptance testing of medical radiological equipment;</p> <p>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately</p>	Not Compliant	Orange	14/12/2021

	involved, the level of involvement being commensurate with the radiological risk posed by the practice.			
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