



Health Information and Quality Authority

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

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| Name of Medical Radiological Installation: | Fairview Dental Clinic |
| Undertaking Name: | Dr Clodagh McAllister |
| Address of Ionising Radiation Installation: | 21 Fairview, Dublin 3 |
| Type of inspection: | Announced |
| Date of inspection: | 03 March 2022 |
| Medical Radiological Installation Service ID: | OSV-0006906 |
| Fieldwork ID: | MON-0035884 |

About the medical radiological installation:

Fairview Dental Clinic has two surgeries and an OPG room. Radiography is performed by dental practitioners at the practice. The majority of radiography is intra-oral and OPG's are taken mainly for orthodontic treatment, periodontal treatments and for oral surgery relating to extraction of third molars.

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 |
|-----------------------|----------------------|----------------|---------|
| Thursday 3 March 2022 | 11:50hrs to 12:40hrs | Noelle Neville | Lead |
| Thursday 3 March 2022 | 11:50hrs to 12:40hrs | Kay Sugrue | Support |

Summary of findings

An inspection of Fairview Dental Clinic was carried out remotely by inspectors on 3 March 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. The inspection was initiated as a result of the non-return of a regulatory dental self-assessment questionnaire that had been issued to the undertaking. Management informed inspectors that this was an unintentional oversight and may have been the result of email issues at the dental practice.

Inspectors were informed that while the dental practice had a Medical Physics Expert (MPE) until July 2021, this MPE service had ceased and management had subsequently made efforts to retain a new MPE. An MPE was due to visit the dental practice during 2021 but had to cancel on two occasions. Inspectors were informed that this MPE was due onsite in the days following the inspection. However, the absence of an MPE from July 2021 to March 2022 meant that not all responsibilities were allocated by the undertaking as required by Regulation 6(3).

The absence of an MPE between July 2021 and March 2022 resulted in a number of non-compliances with the regulations including Regulations 6, 11, 14, 19, 20 and 21. Inspectors were not satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14. In addition, inspectors were not satisfied that an intra-oral unit installed in September 2021 had acceptance testing carried out. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of service users undergoing dental radiological procedures. Management acknowledged this finding and informed inspectors that an arrangement was in place with an MPE to conduct an onsite visit in the days following the inspection. While inspectors acknowledge that the radiological risk of the dental procedures conducted at the dental practice was relatively low, ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures is maintained.

Despite the issues outlined above, inspectors noted compliance with Regulations 4 and 5. Fairview Dental Clinic ensured that referrals were from registered dentists and that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at the dental practice.

Following this inspection, Fairview Dental Clinic was required to submit an urgent compliance plan to address urgent risks relating to equipment and MPE involvement. The undertaking's response did provide assurance that the risks identified on the day of inspection were adequately addressed following the inspection.

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| Regulation 4: Referrers |
| From discussions with management at Fairview Dental Clinic, inspectors were satisfied that referrals were from registered dentists. |
| 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 some allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) at Fairview Dental Clinic. However, the absence of engagement of an MPE at the practice from July 2021 to March 2022, meant that not all responsibilities were clearly allocated as required by the regulations, for example, responsibilities under Regulation 20. |
| Judgment: Not Compliant |
| Regulation 11: Diagnostic reference levels |
| Inspectors were not satisfied from discussions with management that diagnostic reference levels (DRLs) had been established, regularly reviewed and used at Fairview Dental Clinic. |
| Judgment: Not Compliant |
| Regulation 14: Equipment |
| Inspectors were not satisfied that medical radiological equipment was kept under |

strict surveillance as required by Regulation 14(1) at Fairview Dental Clinic.

Inspectors received an inventory of dental radiological equipment in advance of the inspection which listed two intra-oral units and one OPG unit. Management also provided records of daily and monthly checks performed on the different units. In the absence of engagement of an MPE between July 2021 and March 2022, inspectors found that an appropriate quality assurance programme as required by Regulation 14(2) had not been maintained. While management provided recent service records for the medical radiological equipment, inspectors were not satisfied that an intra-oral unit installed in September 2021 had been acceptance tested. It is essential that all newly installed equipment undergoes acceptance testing before its first use for clinical purposes to ensure regulatory compliance as well as safety of service users undergoing dental radiological procedures. Management acknowledged and accepted this finding and informed inspectors that this would be rectified during the MPE onsite visit in the days following the inspection.

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 Fairview Dental Clinic had put in place the necessary arrangements to ensure the continuity of expertise of an MPE from July 2021 to March 2022. At the time of the inspection, there had been a lapse in engagement of an MPE. Management acknowledged this finding and informed inspectors that an arrangement was in place with an MPE to conduct an onsite visit in the days following the inspection.

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 not satisfied that Fairview Dental Clinic had ensured that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1) from July 2021 to March 2022. Inspectors found that the absence of an MPE during this period

resulted in deficits in the areas identified in Regulation 20(2), including optimisation, DRLs, acceptance testing of medical radiological equipment, 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 Fairview Dental Clinic 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 between July 2021 and March 2022.

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

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 Fairview Dental Clinic OSV-0006906

Inspection ID: MON-0035884

Date of inspection: 03/03/2022

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 |
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| Regulation 6: Undertaking | Not Compliant |
| Outline how you are going to come into compliance with Regulation 6: Undertaking: A medical physics expert carried out an inspection in the practice on march 9th | |
| Regulation 11: Diagnostic reference levels | Not Compliant |
| Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: The medical physics expert has formulated diagnostic reference levels for all x ray machines | |
| Regulation 14: Equipment | Not Compliant |
| Outline how you are going to come into compliance with Regulation 14: Equipment: A Medical Physics expert has tested all the equipment and I have forwarded acceptance testing form. | |

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| 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: Our medical physics expert attended the practice on march 9th to bring us into compliance.</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 appointed and inspected the practice</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: A Medical physics expert has inspected the practice.</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 | 09/03/2022 |
| Regulation 11(5) | An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional | Not Compliant | Orange | 09/03/2022 |

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| | 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 | 01/04/2022 |
| Regulation 14(2)(a) | An undertaking shall implement and maintain appropriate quality assurance programmes, and | Not Compliant | Red | 01/04/2022 |
| Regulation 14(3)(a) | An undertaking shall carry out the following testing on its medical radiological equipment, acceptance testing before the first use of the equipment for clinical purposes; and | Not Compliant | Red | 01/04/2022 |
| Regulation 14(4) | A person shall not use medical radiological equipment for clinical purposes unless testing in accordance with paragraph (3)(a) has been carried out. | Not Compliant | Red | 01/04/2022 |
| Regulation 19(9) | An undertaking shall put in place | Not Compliant | Red | 01/04/2022 |

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| | 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. | | | |
| 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. | Not Compliant | Red | 01/04/2022 |
| 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 | Not Compliant | Red | 01/04/2022 |

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| | 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 | Not Compliant | Red | 01/04/2022 |
| 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 medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of | Not Compliant | Red | 01/04/2022 |

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| | <p>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 20(3) | <p>The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise with the radiation protection adviser.</p> | Not Compliant | Red | 01/04/2022 |
| Regulation 21(1) | <p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being</p> | Not Compliant | Red | 01/04/2022 |

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| | commensurate with the radiological risk posed by the practice. | | | |
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