



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: | Dental Surgery - John Canavan |
| Undertaking Name: | John Canavan |
| Address of Ionising Radiation Installation: | 86 Griffith Ave, Dublin 9 |
| Type of inspection: | Announced |
| Date of inspection: | 17 December 2021 |
| Medical Radiological Installation Service ID: | OSV-0006149 |
| Fieldwork ID: | MON-0034875 |

About the medical radiological installation:

John Canavan conducts dental exposures at his dental practice in Drumcondra, Dublin 9 as part of general dentistry service. This practice has one piece of dental radiological equipment and conducts approximately 200 dental radiological exposures each year.

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 |
|----------------------------|-------------------------|-----------------|---------|
| Friday 17 December 2021 | 14:00hrs to 14:30hrs | Kirsten O'Brien | Lead |
| Friday 17 December 2021 | 14:00hrs to 14:30hrs | Agnella Craig | Support |

Summary of findings

An inspection was conducted remotely by inspectors on the 17 December 2021 to assess compliance against the regulations. This inspection was carried out because the undertaking had not submitted a completed regulatory self-assessment questionnaire to HIQA when requested.

Inspectors were satisfied that only an individual entitled to act as a referrer and practitioner referred and took clinical responsibility for dental radiological procedures at the practice. However, on the day of inspection a recognised medical physics expert (MPE) was not appropriately involved to provide consultation and advice as required by the regulations. While inspectors noted that an arrangement had been in place previously, this had not been renewed and the arrangement had lapsed in 2019. Additionally, diagnostic reference levels (DRLs) for dental exposures had not been established at the practice.

From speaking with the undertaking and reviewing records and documentation provided, inspectors found that preventative maintenance and servicing of dental radiological equipment had been carried out at the practice in 2021. In addition, inspectors found that acceptance testing had been carried out on the equipment before it had been used for clinical purposes. However, on the day of inspection, quality assurance (QA) testing by an MPE had not been carried out since 2017 and was overdue.

Inspectors discussed these findings with the undertaking and an assurance was provided to inspectors that measures would be implemented to address the non-compliances identified on the day of inspection. Following this inspection the undertaking was required to submit an urgent compliance plan to address the identified urgent risks. The undertaking's response did provide an assurance to inspectors that the risks were adequately addressed, however, the judgements included in this report are based on the findings on the day of the inspection.

Regulation 4: Referrers

From speaking with the undertaking on the day of inspection, inspectors were satisfied that only referrals for dental radiological procedures from an individual entitled to refer as per Regulation 4, were carried out at the practice.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors found that only a practitioner, as defined in the regulations, took clinical responsibility for individual medical exposures at the dental practice.

Judgment: Compliant

Regulation 6: Undertaking

During the inspection, the undertaking described the allocation of responsibility for the radiation protection of service users attending the practice. Only referrals from an individual entitled to refer as per the regulations were conducted at the practice. Similarly, only an individual entitled to take clinical responsibility for dental radiological procedures acted as a practitioner.

However, inspectors were not satisfied that appropriate measures were in place on the day of inspection to demonstrate that the undertaking allocated responsibility to an MPE to provide consultation and advice on matters relating to medical physics as required by the regulations.

Judgment: Not Compliant

Regulation 10: Responsibilities

On the day of inspection, an individual entitled to act as a practitioner took clinical responsibility for all dental exposures conducted at the practice. Similarly, the referrer and practitioner, who were the same person, was involved in both the justification and optimisation processes. However, inspectors spoke with the undertaking on the day of inspection and were not assured that an MPE was appropriately involved in the optimisation process for all dental exposures as required by the regulations.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors spoke with the undertaking and reviewed documentation and records and found that DRLs had not been established for dental radiological procedures

carried out at the practice.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors spoke with the undertaking and reviewed records and documentation provided to inspectors in advance of the inspection. While dental radiological equipment at the practice had received a recent service in 2021 for preventative and maintenance purposes, records of compliance with the regulation, in particular, records relating to the implementation and maintenance of an appropriate QA programme, including records of acceptance testing, were not available on the day of inspection.

This was discussed with the undertaking and records of acceptance testing of the radiological equipment, carried out by an MPE in 2017, were subsequently provided to inspectors as part of the undertaking's response to the urgent compliance plan. However, QA testing by an MPE had not been carried out since 2017 and was overdue on the day of inspection. As an appropriate QA programme, including an assessment of dose, was not implemented and maintained, inspectors were not satisfied that the dental radiological equipment at the practice was kept under strict surveillance regarding radiation protection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors spoke with the undertaking and reviewed documentation and records relating to the provision of medical physics expertise at the dental practice. While records provided to the inspectors indicated that a formal arrangement had been in place previously, this arrangement had lapsed in 2019 and had not been renewed.

Consequently inspectors were not assured that the undertaking had arrangements in place on the day of inspection to ensure the continuity of medical physics expertise at the dental practice. Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors spoke with the undertaking and reviewed documentation and found that appropriate measures were not in place on the day of inspection to ensure that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users. For example, inspectors were not assured that the MPE took responsibility for dosimetry and contributed to optimisation, including the establishment of DRLs or performance of QA, at the practice. While records provided to the inspectors following the inspection indicated that a formal arrangement had been in place previously, this arrangement had lapsed in 2019 and had not been renewed.

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

Judgment: Not Compliant

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

From speaking with the undertaking and from a review of documentation provided following the inspection, inspectors noted that while a formal arrangement had been in place with an MPE previously for consultation and advice on matters relating to radiation physics at the practice, this arrangement had lapsed in 2019 and was not in place on the day of inspection.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response subsequently provided assurance that the risk was adequately addressed.

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 |
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| Summary of findings | |
| Regulation 4: Referrers | Compliant |
| Regulation 5: Practitioners | Compliant |
| Regulation 6: Undertaking | Not Compliant |
| Regulation 10: Responsibilities | Substantially 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 Dental Surgery - John Canavan OSV-0006149

Inspection ID: MON-0034875

Date of inspection: 17/12/2021

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 |
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| Regulation 6: Undertaking | Not Compliant |
| <p>Outline how you are going to come into compliance with Regulation 6: Undertaking: I contacted my MPE by phone on the day of the inspection but he had not received my email advising him of the upcoming inspection. Contact by phone, different email and in person have been re-established and he is available to answer any of my queries at short notice.</p> | |
| Regulation 10: Responsibilities | Substantially Compliant |
| <p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: Subsequent communication with inspectors showed that the MPE was involved in optimisation process for dental exposures as required following installation of a new unit in 2017. The MPE has recently attend my surgery for up to date rechecking (22/1/22).</p> | |
| Regulation 11: Diagnostic reference levels | Not Compliant |
| <p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Subsequent communication with inspectors showed that DRLs had been established after fitting of new unit in 2017 and have been rechecked recently (22/01/22).</p> | |

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| Regulation 14: Equipment | Not Compliant |
| <p>Outline how you are going to come into compliance with Regulation 14: Equipment: Undertaking submitted urgent compliance plan to address an urgent risk. My response subsequently provided assurance that the risk was addressed.</p> <p>An MPE completed a full reassessment of the X-ray machine on 22/01/2022.</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: I submitted urgent compliance plan to address an urgent risk. My response subsequently provided assurance that the risk was adequately addressed.</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: MPE visited the surgery (22/1/22) and rechecked optimisation including establishment of DRLs and performance of QA. Previous response provided assurance that the risk was adequately addressed.</p> | |
| Regulation 21: Involvement of medical physics experts in medical radiological practices | Not Compliant |

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
MPE visited surgery on 22/1/22 and is due to re-attend in 2023 to recheck optimisation/DRLs at the practice. MPE can be contacted at short notice by phone or email.

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 |
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| 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 | Red | 05/01/2022 |
| Regulation 10(2)(b) | An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and | Not Compliant | Red | 05/01/2022 |

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| 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 | 28/01/2022 |
| 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 | 05/01/2022 |
| Regulation 14(2)(a) | An undertaking shall implement and maintain appropriate quality assurance programmes, and | Not Compliant | Red | 05/01/2022 |
| Regulation 14(2)(b) | An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity. | Not Compliant | Red | 05/01/2022 |
| Regulation 14(11) | An undertaking shall retain records in relation to equipment, including records evidencing | Not Compliant | Orange | 22/01/2022 |

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| | compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request. | | | |
| 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 | 05/01/2022 |
| 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 the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive. | Not Compliant | Red | 05/01/2022 |
| Regulation 20(2)(a) | An undertaking shall ensure that, depending on the medical radiological practice, the medical physics | Not Compliant | Red | 05/01/2022 |

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| | 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, | | | |
| 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 | 05/01/2022 |
| 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 | Not Compliant | Red | 05/01/2022 |

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| | <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 | Red | 05/01/2022 |

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| | involved, the level of involvement being commensurate with the radiological risk posed by the practice. | | | |
| Regulation 21(2)(c) | In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure. | Not Compliant | Red | 05/01/2022 |