



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Castleknock Dental Practice
Undertaking Name:	Castleknock Dental Practice
Address of Ionising Radiation Installation:	Village House, Main Street, Castleknock, Dublin 15
Type of inspection:	Announced
Date of inspection:	24 January 2023
Medical Radiological Installation Service ID:	OSV-0006816
Fieldwork ID:	MON-0038116

About the medical radiological installation:

Castleknock Dental Practice is a multi-disciplinary practice which carries out in-house referrals for radiographic imaging. The practice has an orthopantomogram (OPG) and lateral cephalometric unit and five wall mounted intra-oral X-ray units. The practice is based in The Village House which is a renovated Victorian house following completion of renovations in 2010 under the guidance on a medical physics expert.

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
Tuesday 24 January 2023	08:30hrs to 11:00hrs	Kirsten O'Brien	Lead

Summary of findings

An inspection of Castleknock Dental Practice was conducted by an inspector on the 24 January 2023 to assess compliance against the regulations. On the day of inspection the inspector noted that the practice had an orthopantomogram (OPG) and lateral cephalometric unit, five wall-mounted intra-oral X-ray units and image processing equipment.

The inspector reviewed documentation and spoke with management at the practice and found evidence that a clear allocation of responsibility for the radiation protection of patients and service users was in place. Castleknock Dental Practice was found to have processes in place for the conduct of clinical audits at the practice and previous clinical audits related to dental exposures were reviewed by the inspector. The inspector also found that written protocols had been established at the practice.

A sample of referrals for dental radiological procedures were reviewed on the day of inspection for different dentists working at the practice. These referrals were in writing and contained the reason for the particular procedure. Information relating to patient exposure was also recorded on the report of the dental radiological procedure. Similarly, the inspector reviewed an example of where a dentist had recorded that they had provided information about the risks and benefits of dental exposures to the patient in advance of an X-ray procedure and this was noted as an example of good practice. The inspector also observed posters in the waiting and reception areas of Castleknock Dental Practice which provided information to patients about the risks and benefits associated with dental X-rays.

On the day of inspection, the inspector was satisfied that only individuals entitled to act as referrers and practitioners, referred and took clinical responsibility for dental radiological procedures at the practice. Similarly, only those entitled to act as practitioners carried out the practical aspects of dental exposures at Castleknock Dental Practice. Diagnostic reference levels (DRLs) were found to have been established and used at the practice to ensure the optimisation of dental radiological procedures.

Castleknock Dental Practice had engaged a recognised medical physics expert (MPE) who was available for consultation and advice on matters relating to radiation physics. The inspector found evidence that the MPE was appropriately involved and provided medical physics expertise as required by the regulations. A quality assurance (QA) programme had been implemented and maintained with a QA assessment of all dental radiological equipment carried out every two years by an MPE. However, the inspector found that while preventative maintenance and servicing of the orthopantomogram (OPG) and image processing equipment was routinely carried out, no evidence that servicing of the other intra-oral dental radiological equipment had been carried out was available to the inspector. Similarly, while the inspector was informed that regular performance checks, as recommended by the MPE, were carried out at the practice, the frequency and

outcome of these checks was not recorded.

Overall, the inspector found a good level of compliance at Castleknock Dental Practice, notwithstanding the area for improvement identified to achieve full compliance with the regulations.

Regulation 4: Referrers

The inspector reviewed a sample of referrals for dental radiological procedures and was satisfied that only referrals from registered dentists were carried out at the practice.

Judgment: Compliant

Regulation 5: Practitioners

Only registered dentists were found to take clinical responsibility for dental exposures conducted at Castleknock Dental Practice.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed documentation and spoke with staff and a representative from the undertaking on the day of inspection. The allocation of responsibility for the radiation protection of service users attending the practice was clearly documented. The inspector also noted an area of good practice where any actions arising from QA reviews by an MPE were reviewed by the principal dentist. This demonstrated good oversight by the undertaking to ensure the safe delivery of dental exposures at the practice.

Similarly, the inspector was assured that aspects of radiation protection were appropriately allocated as required by the regulations. For example, only a registered dentist was found to act as a practitioner and take clinical responsibility for dental exposures.

Judgment: Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, posters were present in the waiting room and dedicated OPG room to provide information relating to the risks and benefits associated with dental exposures to patients.

A sample of records of dental radiological procedures were reviewed during the on-site inspection. Inspectors found that a dentist, registered with the Dental Council, took clinical responsibility for all individual procedures. Referrals were found to be in writing and accompanied by sufficient medical data in the patients' notes to allow the practitioner to justify the procedure. A practitioner spoken with during the inspection also communicated to the inspector how they considered using alternative techniques with no or less radiation when justifying a dental exposure. This was noted as an example of good practice and provided an added assurance that Castleknock Dental Practice ensured that only justified dental radiological procedures were carried out at the practice.

Management at the practice also demonstrated new software that was in the process of being introduced at the practice which would improve how information and records relating to dental exposures are recorded at the practice. This proactive measure was noted as an example of good practice by Castleknock Dental Practice in identifying and implementing areas for improvement to ensure the safe delivery of dental exposures at the practice.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of inspection Castleknock Dental Practice had ensured that all medical exposures took place under the clinical responsibility of an individual entitled to act as a practitioner as per Regulation 5. Similarly, the inspector found that the practitioner and the medical physics expert were involved in the optimisation process for all dental exposures. A dentist acted as both the referrer and practitioner, and was involved in the justification process of individual dental exposures at the practice.

The inspector reviewed a sample of training records for registered dentists acting as practitioners and found evidence of on-going training and education relating to radiation protection. This was noted as an example of good practice to ensure that those taking clinical responsibility for dental radiological procedures were up-to-date on aspects of optimisation and other regulatory requirements.

Additionally, while only dentists carried out the practical aspects of dental radiological procedures on the day of inspection, the inspector noted that the practice had a system in place to record the delegation of the practical aspects

should this be required in the future. This was also noted as a positive finding.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors spoke with management at the practice and the MPE and also reviewed relevant records and documentation. DRLs had been established at Castleknock Dental Practice which had regard for Irish national DRLs. The practice's DRLs were found to be regularly reviewed by the MPE and a practitioner. The inspector also observed evidence that DRLs were available for use by practitioners when conducting dental exposures.

Judgment: Compliant

Regulation 13: Procedures

Castleknock Dental Practice had established written protocols for standard dental exposures for each type of dental radiological equipment at the practice. Written protocols can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice. The inspector also reviewed a sample of patient records and found that information relating to the dose was included on the report of the dental exposures.

The inspector also reviewed examples of data collection tools and the results of clinical audits conducted at the practice. These clinical audits also included areas for improvement and outlined specific time frames for re-audit. This was identified as a positive finding which allows the undertaking to identify areas of good practice and areas for improvement in order to ensure the continued safe delivery of dental exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

Inspectors spoke with the MPE and management at Castleknock Dental Practice on the day of inspection. Documentation and records relating to the dental radiological equipment at the practice were also reviewed. A QA programme, which included a QA assessment every two years by an MPE, had been implemented and maintained. This QA assessment also included an assessment of patient doses.

While the inspector was informed that routine quality control checks of the image processing equipment, as recommended by the MPE, were carried out, the frequency or outcome of these checks were not recorded. Additionally, while preventative maintenance of the equipment by a manufacturer or vendor was carried out regularly on the OPG and image processing equipment, preventative maintenance or servicing of the intra-oral equipment had not been carried out.

Notwithstanding this area for improvement required to come into full compliance with this regulation, the inspector was satisfied that Castleknock Dental Practice had ensured that its dental radiological equipment was kept under surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From speaking with staff and management at Castleknock Dental Practice, the inspector was assured that the practice had a system in place to record any actual, or potential, accidental or unintentional exposure to ionising radiation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Castleknock Dental Practice had engaged a recognised MPE and the inspector found evidence that the practice had appropriate access to medical physics expertise as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector spoke with the MPE, management at the clinic and reviewed documentation and records. A recognised MPE was found to act and give specialist advice as appropriate on matters relating to radiation physics. The inspector was also assured that the MPE took responsibility for dosimetry, gave advice on dental radiological equipment at the practice, and contributed to optimisation, DRLs, QA and training at Castleknock Dental Practice.

Judgment: Compliant

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

An MPE was found to be appropriately involved for consultation and advice on matters relating to the radiation protection of dental exposures.

Judgment: 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	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

Compliance Plan for Castleknock Dental Practice OSV-0006816

Inspection ID: MON-0038116

Date of inspection: 24/01/2023

Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance or where the non-compliance poses a significant risk to the safety, health and welfare of service users will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: A system has been put in place for consistently recording the routine quality control checks of the image processing equipment, as recommended by the MPE. Quarterly checks of the imaging equipment will continue, and a record maintained of the date, outcome of the quality control test and signature.</p> <p>Preventative maintenance of the intra-oral equipment by the vendor has been carried out with no substantive actions arising from the service reports.</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 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	24/02/2023