



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Castlemill Dental Clinic
Undertaking Name:	Dr Nicholas O'Kane
Address of Ionising Radiation Installation:	Hamlet Lane, Balbriggan, Co. Dublin
Type of inspection:	Announced
Date of inspection:	28 April 2022
Medical Radiological Installation Service ID:	OSV-0006489
Fieldwork ID:	MON-0036382

About the medical radiological installation:

Castlemill Dental Clinic is a dental practice located in Balbriggan, Co. Dublin. The service has three pieces of dental radiological equipment including a mobile dental X-ray unit, a fixed intra-oral X-ray unit and an orthopantomography (OPG) unit.

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 28 April 2022	11:30hrs to 13:20hrs	Maeve McGarry	Lead

Summary of findings

A remote inspection of Castlemill Dental Clinic was carried out on 28 April 2022. A self-assessment questionnaire (SAQ) was initially not submitted to HIQA in the specified time frame but was subsequently returned when re-issued. The undertaking informed the inspector that they had not recognised the SAQ was information requested as part of the regulatory process. The SAQ returned indicated that a Medical Physics Expert (MPE) was not engaged by the dental practice at the time of completion. This information received and the late submission of regulatory information to HIQA triggered an inspection.

The undertaking had identified a gap in regulatory compliance when completing the SAQ, in that the previous physics service engaged to conduct quality assurance (QA) of equipment did not conform to current regulatory requirements. Consequently, the undertaking sought to engage an MPE as per the regulations. Prior to the inspection in April 2022, an MPE registered with the Irish College of Physicists in Medicine (ICPM) was engaged by the undertaking and completed quality assurance (QA) of equipment. The MPE reviewed the local diagnostic reference levels (DRLs) and some actions were required by the undertaking following on from this review. The inspector was informed that these actions were underway.

The inspector was informed that two dentist practitioners worked at this practice, one of whom was the undertaking. The undertaking had overall responsibility for the conduct of medical exposures at the practice. The process of referring and carrying out medical exposures was described to the inspector. The referrer and practitioner were the same person and the practitioner completed the practical aspects and took clinical responsibility for medical exposures.

Documentation provided to inspectors in advance of the inspection was limited to Radiation Safety Procedures (RSP) and the recent quality assurance reports. Following on from the inspection supplementary information was provided including outcomes of audit, previous quality assurance reports and professional registration certificates. The RSP document was found to be generic and the content did not specifically pertain to activities at Castlemill Dental Clinic. The undertaking acknowledged that the documentation should be updated to reflect day-to-day practice at the dental clinic, for example, the responsibilities for the practical aspects of medical exposures should be outlined. Furthermore, the inspector found that monitoring of the service through audit had only recently been commenced in advance of the inspection and this should be progressed by the undertaking.

Overall, inspectors found that while gaps in documentation should be addressed by the undertaking as a matter of priority, the inspector was assured that the undertaking had systems in place to ensure the safe and effective delivery of medical radiological exposures for patients attending this practice.

Regulation 4: Referrers

The inspector was satisfied that the referrals for radiological procedures were from registered dentists. The inspector was informed that external referrals for medical radiological procedures were not accepted at this dental practice and that the same referrer acted as practitioner for medical radiological exposures.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, had taken clinical responsibility for individual medical exposures at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

The allocation of responsibility for the radiation protection of service users attending this practice was outlined by the undertaking during the inspection. The two dentist practitioners working at the practice took clinical responsibility for the dental radiological procedures carried out and inspectors were informed that there was no delegation of the practical aspects of medical exposures to personnel other than practitioners. However, this allocation of responsibility was not outlined in documentation. A Radiation Safety Procedures document was made available to the inspector in advance of the inspection but this had not been fully adapted for local use. For example, the document did not outline if the practical aspects of medical exposures were undertaken by non-practitioners and it did not indicate if external referrals for dental radiological exposures were accepted at this practice. Furthermore, a technique chart to aid documentation of protocols for dental exposures was supplied in the RSP but was not complete. The undertaking acknowledged that this documentation should be updated to reflect day-to-day practices at the dental clinic and to clearly outline how responsibilities are allocated locally.

An ICPM registered MPE was engaged by the undertaking in advance of the inspection and the contribution of this MPE ensured that certain responsibilities were allocated as per the regulations. Furthermore, the RSP document outlined the role of the MPE in the service. Quality assurance of equipment had been performed in February 2020 by the previous physics service and more recently by the MPE in April 2022. The inspector found that while the previous physicist was not an MPE, an ICPM registered MPE was now involved in the practice and the allocation of MPE

responsibilities were now in place, in line with regulations.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

MPE reports outlined that DRLs for all procedures and equipment were recently reviewed at this dental practice and were compared to national levels. Inspectors were informed that changes had been made following on from the recent MPE review of DRLs. These changes included altering the default settings on the OPG to reflect the clinical parameters used. Further actions as a result of the DRL review were ongoing at the time of inspection, including a review of optimisation for the mobile X-ray unit and changes to the default settings on the fixed intra-oral unit. These corrective actions should be progressed by the undertaking as a priority to ensure alignment with the requirements of this regulation.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, written protocols were not in place for all medical radiological procedures carried out at the practice. The RSP included an outline of the practical aspects for using of each piece of equipment and a template was provided to record typical exposure parameters, however, this template was incomplete. Written protocols required under Regulation 13(2) can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice.

Inspectors were informed that referral guidelines (selection criteria) for dental radiological procedures were not available for referrers at the dental clinic. The use of referral guidelines helps to ensure consistency in practices locally, particularly in the context of various imaging equipment options available to the practitioners.

Inspectors were informed that clinical audits relating to medical exposure to ionising radiation had been completed in advance of the inspection by the undertaking and evidence of these audits were supplied after the inspection. The undertaking should ensure that clinical audit is carried out on a regular basis as it is an important tool which allows undertakings to identify areas of good practice and areas for improvement to ensure the safe delivery of dental exposures to service users.

Judgment: Not Compliant

Regulation 14: Equipment

On the day of inspection an up-to-date inventory of medical radiological equipment was not available for review by the inspector in line with Regulation 14(10). Following on from the inspection an inventory was provided to HIQA.

The quality assurance of equipment was carried out in February 2020 by a medical physics service and again in April 2022 by the recently engaged MPE. The MPE provided the undertaking with guidance on equipment performance testing which should be carried regularly including quarterly quality control checks. However, the inspector was informed that while some visual checks of equipment took place, regular performance testing of equipment as per the MPE guidance had not been carried out prior to the inspection, and as such, the inspector found that the equipment was not kept under strict surveillance by the undertaking. The undertaking acknowledged and accepted this finding.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that when the undertaking was made aware that the former physicist could not act as an MPE for the practice, an alternative service was sought. Inspectors found that the undertaking had proactively addressed the compliance deficit in respect of MPE arrangements to ensure regulatory compliance was met.

From reviewing documentation and from speaking with the ICPM registered MPE engaged at the time of inspection, the inspector was assured that arrangements were in place to ensure the continuity of medical physics expertise from an appropriate individual at this dental practice.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The RSP document outlined the responsibilities of the MPE in supporting this dental practice. The inspector spoke with the MPE on the day of the inspection and discussed the responsibilities carried out under this regulation including responsibilities for dosimetry, contribution to optimisation, establishing and reviewing DRLs, and performance of QA of the medical radiological equipment. The MPE acknowledged that there was potential to improve the contribution to training for dental practitioners but in the interim had signposted the practitioners to where

training was available, such as a recent OPG image interpretation course.

Judgment: Compliant

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

From a review of documentation and from speaking with the undertaking and the MPE, the inspector was satisfied that the involvement of the MPE was commensurate with the level of radiological risk posed by this dental service.

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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not 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 Castlemill Dental Clinic OSV-0006489

Inspection ID: MON-0036382

Date of inspection: 28/04/2022

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	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: We have updated our safety report and updated all Radiation Safety Procedure Documents. Xrays are only taken by Dental professionals and we do not do any external references. We have also updated our technique chart. We are now engaged with the MPE on all updates.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Due to outcomes from the review. We have taken the advice of the MPE to change the default setting on all machines, and will ensure regular reviews of the DRLs every 2 years, or more frequently should there be a change in clinical practice or equipment. Optimal settings have been reviewed and changed by RPO. For the handheld unit. We've reduced the dose without compromising image quality.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: We have updated our template on safety procedures as per guidelines from MPE.</p>	

We have updated a selection criteria for each patient available to all practitioners.

All xray procedures taken on premises have been updated. These include periapical xrays and OPG/panoramic xrays.

Regulation 14: Equipment

Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The previous medical physics RPA service had not recommended routine performance tests for the x-ray equipment. Following engagement of an ICPM registered MPE advice was received on regular performance tests for the x-ray equipment, and these are now in place. An MPE is now engaged on a continuous basis to advise on all aspects of equipment monitoring.

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.	Substantially Compliant	Yellow	08/04/2022
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	08/04/2022

	safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
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	03/07/2022
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	03/07/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	08/04/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical	Not Compliant	Orange	03/07/2022

	radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	03/07/2022
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	03/07/2022