



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Cobh Dental Clinic
Undertaking Name:	Dr Grainne Cahill
Address of Ionising Radiation Installation:	5 Casement Square, Cobh, Cork
Type of inspection:	Announced
Date of inspection:	30 August 2022
Medical Radiological Installation Service ID:	OSV-0006924
Fieldwork ID:	MON-0037432

About the medical radiological installation:

Cobh Dental Clinic provides orthopantogram (OPG) and intra-oral X-rays. These are done in a lead lined X-ray room. The films are processed in a chemical developer. Dr. G. Cahill is the sole prescriber of all X-rays and also the only person who takes the X-rays. Patients' permission is requested prior to any X-ray, this is accompanied by an explanation of why the X-ray is needed.

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 30 August 2022	09:50hrs to 10:40hrs	Noelle Neville	Lead

Summary of findings

An inspection of Cobh Dental Clinic was carried out by an inspector on 30 August 2022 to assess its compliance with the regulations. As part of this inspection, the inspector spoke with management, reviewed documentation and visited the dental practice's clinical rooms. Cobh Dental Clinic had returned a regulatory self-assessment questionnaire (SAQ) in May 2022 which had been issued by HIQA to determine the dental practice's perceived compliance with the regulations. The inspector validated the SAQ findings and noted that Cobh Dental Clinic demonstrated compliance with Regulations 4, 5, 6, 8, 10, 11, 13, 17, 19, 20 and 21, which was consistent with the information provided in the submitted SAQ. The inspector noted that Regulation 14 was substantially compliant at the time of inspection rather than compliant as submitted in the SAQ and this was due to a lack of regular quality performance testing of equipment.

Overall, the inspector was satisfied that the undertaking, Dr Grainne Cahill, had systems in place to ensure the safe and effective delivery of medical radiological exposures at Cobh Dental Clinic.

Regulation 4: Referrers

From discussion with management and a review of documentation, the inspector was satisfied that the majority of referrals were from staff working within Cobh Dental Clinic, where the referrer and practitioner was the same person and entitled to act as referrer and practitioner as per the regulations. The inspector was informed that a small number of referrals for medical radiological procedures were accepted from dentists external to the practice who were also entitled to act as referrer as per the regulations.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only those entitled to act as practitioner had taken clinical responsibility for medical exposures conducted at Cobh Dental Clinic.

Judgment: Compliant

Regulation 6: Undertaking

There was a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3). The undertaking at Cobh Dental Clinic was the sole dentist at the dental practice and also acted as referrer and practitioner. The undertaking had also engaged the services of a medical physics expert (MPE).

Judgment: Compliant

Regulation 8: Justification of medical exposures

From a sample of referrals reviewed, the inspector was satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Information relating to the benefits and risks associated with radiation was available to service users and was displayed on posters at Cobh Dental Clinic.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that a practitioner took responsibility for all medical exposures to ionising radiation at Cobh Dental Clinic. In addition, the inspector was satisfied that the optimisation process included the practitioner and MPE and the justification process for all medical radiological procedures carried out at Cobh Dental Clinic involved the referrer and practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was satisfied that Cobh Dental Clinic had established, regularly reviewed and used DRLs as required by Regulation 11. These local DRLs were displayed prominently at the dental practice. In addition, the inspector was informed that where a particular medical radiological exam had exceeded the national DRL, a review was carried out and appropriate corrective action was taken in relation to optimising this exam as required by Regulation 11(6).

Judgment: Compliant

Regulation 13: Procedures

Cobh Dental Clinic had written protocols for standard dental radiological procedures as required by Regulation 13(1). Information relating to the medical exposure as required by Regulation 13(2) was available in a sample of reports reviewed. The inspector was satisfied that referral guidelines were available at the dental practice as required by Regulation 13(3). In addition, the inspector reviewed evidence of clinical audit carried out at Cobh Dental Clinic which allows for the identification of areas of good practice and areas of improvement to ensure the safe delivery of medical radiological exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that an appropriate quality assurance programme was in place for equipment at Cobh Dental Clinic as required by Regulation 14(2). However, the inspector was informed that performance testing was not carried out on the equipment on a regular basis as required by Regulation 14(3). It is important that equipment is kept under strict surveillance by the undertaking as required by Regulation 14(1).

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Management explained the radiation incident management process to the inspector and a template for recording incidents was available. Although no incidents relating to accidental or unintended exposure had been identified or reported at Cobh Dental Clinic, the inspector was satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with management that adequate processes were in place to ensure the continuity of medical physics expertise at Cobh Dental Clinic as required by Regulation 19. The MPE had an arrangement in place with the dental practice which ensured appropriate access to medical physics expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE at Cobh Dental Clinic and was satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted involvement in radiation protection by the MPE across a range of responsibilities as outlined in Regulation 20(2) including quality assurance of equipment and optimisation including the application and use of DRLs.

Judgment: Compliant

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

The inspector was satisfied that an MPE was appropriately involved at Cobh Dental Clinic, with the level of involvement commensurate with the level of radiological risk posed by the dental practice as required by Regulation 21.

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 Cobh Dental Clinic OSV-0006924

Inspection ID: MON-0037432

Date of inspection: 30/08/2022

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 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Since the visit we have put in place a procedure for in house performance testing based on advice from the MPE. We have incorporated this check into our regular checking and cleaning of the X-ray developer every 3-4 weeks. This procedure includes taking a low dose image without anything in the beam to assess changes in the density and uniformity. This is to be done with the small X-ray and OPG X-ray. A blank copy of each X-ray film will also be processed to check for fogging and changes in the film.	

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(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	12/10/2022
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	12/10/2022