



**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:	Ashe Street Clinic
Undertaking Name:	Gerard Hill
Address of Ionising Radiation Installation:	Tralee, Kerry
Type of inspection:	Announced
Date of inspection:	19 January 2023
Medical Radiological Installation Service ID:	OSV-0008382
Fieldwork ID:	MON-0038639

About the medical radiological installation:

Intra oral X-rays are only taken at Ashe Street Clinic dental practice. Sole responsibility for all radiological matters is taken by the dentist, Gerard Hill.

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 19 January 2023	12:05hrs to 13:05hrs	Kay Sugrue	Lead

Summary of findings

An inspection of Ashe Street Clinic was carried out on 19 January 2023 to assess compliance with the regulations. The inspector spoke with the dentist at this practice, reviewed documentation and viewed the medical radiological equipment in use as part of this inspection. The inspector was satisfied that there was a clear allocation of responsibility for the protection of service users undergoing dental radiological exposures. There was one dentist practicing at this facility who acted as the referrer and took clinical responsibility for all dental X-rays conducted there. The undertaking also had ensured a medical physics expert (MPE) was appropriately involved with continuity arrangements in place. An appropriate quality assurance (QA) programme was evident with QA of medical radiological equipment completed in May 2022. The inspector noted that the strict surveillance of equipment needed further action to ensure maintenance by a service engineer is carried out each year in line with recommendations made by the MPE.

The inspector was satisfied that the undertaking was committed to the radiation protection of service users undergoing medical radiological procedures at this facility. Diagnostic reference levels (DRLs) were established and applied at the practice. Evidence seen by the inspector demonstrated that the undertaking had acted to improve compliance with the regulations, however, more action was needed to attain full compliance. For example, gaps in documentation in relation to the referral and justification processes impacted compliance with Regulation 8. Written protocols for standard medical radiological procedures were not evident as per Regulation 13(1) and information relating to patient exposure did not consistently form part of the report of the medical radiological procedure required by Regulation 13(2). The inspector found that the management of documentation in relation to radiation protection could be improved following this inspection.

Notwithstanding the areas of non-compliance identified in this report, the inspector found that the undertaking demonstrated a commitment to the radiation protection of service users and had initiated steps to improve compliance prior to this inspection.

Regulation 4: Referrers

The inspector reviewed professional registration records of the dentist for Ashe Street Clinic which were up to date and met requirements for Regulation 4. From discussions with the dentist, the inspector was satisfied that referrals originated internally and the dentist, as a sole practitioner, acted as the referrer for all dental X-rays undertaken at this practice.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that the dentist for this practice acted as practitioner with clinical responsibility for medical exposures conducted at Ashe Street Clinic, thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found from discussions with the undertaking at Ashe Street Dental that there was a clear allocation of responsibilities to ensure the radiation protection of service users undergoing dental X-rays at this facility, thereby meeting the requirements of Regulation 6(3). The undertaking was the sole dentist operating in this dental practice and acted as the referrer and practitioner for medical exposures conducted there. The undertaking had also ensured a MPE was engaged for the service as per regulatory requirements. Records viewed showed that radiation protection training in dental practice had recently been completed by the dentist.

While meeting the requirements of Regulation 6(3), the inspector noted that the management of documentation in relation to radiation protection should be a focus for improvement following this inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

Patient records were reviewed by the inspector as part of this inspection. The inspector found that referrals for dental X-rays taken at Ashe Street Dental were not consistently documented in the patient records viewed. The inspector identified that action was needed to ensure that each referral stated the reason for requesting a particular procedure and was accompanied by sufficient medical data to enable the practitioner to carry out justification as per Regulation 8(10). Justification in advance was also not clearly evident in these records which meant that the regulatory requirements of Regulation 8(8) and 8(15) were not consistently met. An ongoing audit of image quality commenced on 21 March 2022 was viewed by the inspector, however the information included in this audit did not provide sufficient evidence of justification in advance as required by the regulations. Based on the evidence seen, the inspector found that further action was required to meet the requirements of

Regulation 8.

Judgment: Not Compliant

Regulation 10: Responsibilities

The inspector was satisfied that the dentist who was the referrer and practitioner at Ashe Street Clinic justified and took responsibility for all medical exposures to ionising radiation conducted there. In addition, the inspector was satisfied that the MPE and the dentist were involved in the optimisation process.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was satisfied that facility DRLs were established, regularly reviewed and used at Ashe Street Clinic as required by Regulation 11. These facility DRLs were last reviewed by the MPE in May 2022 and displayed on the wall in the dental surgery.

Judgment: Compliant

Regulation 13: Procedures

The inspector found that the undertaking had not ensured that there were written protocols for standard dental radiological procedures as required by Regulation 13(1). This finding was consistent with the undertaking's self assessment previously submitted to HIQA in November 2022 which had not yet been addressed by the undertaking. The inspector was informed by the undertaking that this issue would be addressed without delay to ensure compliance with Regulation 13(1).

Information relating to the patient exposure for each medical radiological procedure was captured on an ongoing audit since March 2022 and viewed by the inspector. However this information was not routinely included as part of the report of each medical radiological procedure in patient records viewed. Therefore further action is required to ensure compliance with Regulation 13(2).

There was sufficient evidence viewed to demonstrate that clinical audit was undertaken at this dental facility.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was submitted prior to this inspection which was verified by the inspector on site. Documentary evidence reviewed satisfied the inspector that the radiological equipment had been subject to performance testing by a MPE with quality assurance (QA) last completed on 4 May 2022. The inspector saw evidence that the undertaking had responded to most but not all of the recommendations made by the MPE. For example, the lack of a rectangular collimator for the equipment had been addressed and was viewed on the equipment by the inspector. Additionally, the undertaking had implemented monthly quality control checks on the advice of the MPE. The inspector noted that maintenance by an engineer was last carried out on 18 August 2021, however servicing of the equipment had not been completed within defined time lines as recommended by the MPE and as required by Regulation 14(3). Therefore greater assurance is needed to ensure that equipment is kept under strict surveillance by the undertaking as required by Regulation 14(1). The undertaking informed the inspector that this omission would be addressed without delay.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documentation demonstrating that the undertaking had appropriate continuity arrangements in place to ensure access to a MPE at Ashe Street Clinic if needed and as required by Regulation 19(9).

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector viewed the professional registration certificate of the MPE engaged by the undertaking to provide specialist advice, as appropriate, on matters relating to radiation physics which met the requirements of Regulation 20(1). Evidence viewed in documentation and discussion with the undertaking and the MPE demonstrated to the inspector that the MPE fulfilled a range of responsibilities as per Regulation 20(2) relevant to the practice. These included optimisation, application and use of DRLs and the QA of medical radiological equipment.

Judgment: Compliant

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

The inspector was satisfied that an MPE was appropriately involved at Ashe Street Clinic, with the level of involvement proportionate to the level of radiological risk posed by the dental practice thereby meeting the requirements of 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	Not Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially 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 Ashe Street Clinic OSV-0008382

Inspection ID: MON-0038639

Date of inspection: 19/01/2023

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 8: Justification of medical exposures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>Ashe Street Dental has reviewed the documentation and detail of the referral requirements for the practice. The Undertaking has updated their procedures to ensure that each patient referral is documented prior to exposure and that it states the reason for the dental x-ray along with provision of sufficient clinical information to facilitate the justification process. This was implemented immediately after inspection.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>The Undertaking in consultation with the MPE adopted a full set of written protocols for all dental radiological exposures including both adult and paediatric patients immediately after the inspection. The Undertaking updated the procedure whereby information relating to the exposure is included in all patient reports, effective immediately.</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:</p> <p>The Undertaking has arranged a service for the intraoral unit due to be carried out on</p>	

the 13th March 2023.

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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Orange	20/01/2023
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Orange	20/01/2023
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Orange	20/01/2023

Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	20/01/2023
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Orange	20/01/2023
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	20/01/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Substantially Compliant	Yellow	20/01/2023

	procedure.			
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	13/03/2023
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	13/03/2023