

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	HSE Dental Clinic Louth HC
Radiological	
Installation:	
Undertaking Name:	Health Service Executive
Address of Ionising	Louth Healthcare Unit, Dublin
Radiation Installation:	Road, Dundalk,
	Louth
—	
Type of inspection:	Announced
Date of inspection:	31 October 2024
Medical Radiological	OSV-0007678
Installation Service ID:	
Fieldwork ID:	MON-0044348

About the medical radiological installation (the following information was provided by the undertaking):

The HSE Dental Clinic is in Dundalk Primary Care Centre within the Louth County Hospital campus. It is a ground floor facility in a two storey building. The Dundalk HSE Dental Clinic is a three surgery unity, with three dental surgeons and one hygienist operating on a part-time basis. The intra-oral unit is situated in the X-ray room and the digital scanner is located in a separate room, across the corridor. The public dental service Louth Meath provides a targeted school based service in line with priorities set out by the National Oral Health Office and also provides routine services to adults and children with special needs. The schools dental programme targets only those children in sixth class national school and provides emergency care to children outside of target until aged sixteen years. Intra-oral radiographs form part of assessment and treatment planning which is based on individual risk assessment, justification and treatment need. No external radiograph referrals are received or accepted to this clinic. In addition we provide emergency cover for eligible adult medical card holder patients who may be seen in accordance with acceptance criteria for HSE dental services.

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, as amended. 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:
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Date	Times of Inspection	Inspector	Role
Thursday 31 October 2024	10:30hrs to 13:30hrs	Kirsten O'Brien	Lead

An inspection of the Health Service Executive's (HSE) Dental Clinic in Dundalk, Co. Louth was carried out on the 31 October 2024 to assess compliance with the regulations. As part of this inspection, the inspector reviewed documentation and records and spoke with staff and the management team at the clinic.

On the day of inspection, the inspector found that clear lines of oversight and management were in place at the clinic. The governance arrangements for the clinic were described to the inspector who also reviewed documentation relating to the allocation of responsibility for the radiation protection of service users. A radiation safety committee (RSC) was established with reporting relationships in place with the HSE's National Radiation Protection Committee and the National Oral Health Office.

The inspector was satisfied from evidence reviewed that roles and responsibilities were appropriately allocated to individuals defined in the regulations, in particular the allocation of clinical responsibility to a practitioner, the practical aspects to an appropriate individual and the involvement of a medical physics expert (MPE) at the clinic. The inspector also found evidence that justification in advance was carried out and documented by a practitioner.

Additionally, the inspector found evidence of compliance with the optimisation requirements as per the regulations which included an appropriate quality assurance (QA) programme for the medical radiological equipment. Several areas of good practice were identified as part of this inspection, in particular the establishment of local facility DRLs for all X-ray procedures carried out and the ongoing work to establish regional DRLs for dental services in Community Healthcare Organisation's (CHO's) 6, 7, 8 and 9. The inspector also identified that there was good oversight of practices through an on-going system of clinical audits at the clinic, in particular the formation of a quality improvement plan with a person allocated responsibility.

Overall, the inspector was satisfied that systems were in place to ensure the safe and effective delivery of medical radiological exposures at HSE Dental Clinic Louth HC in Dundalk.

Regulation 4: Referrers

On the day of inspection, the inspector was satisfied that only referrals from registered dentists employed by the HSE were carried out.

Judgment: Compliant

Regulation 5: Practitioners

The inspector found that only practitioners, who were registered dentists, took clinical responsibility for individual medical exposures at the HSE Dental Clinic in Dundalk.

Judgment: Compliant

Regulation 6: Undertaking

The inspector spoke with management and reviewed documentation and a sample of patient records. The management team described the allocation of responsibility for the radiation protection of service users attending the clinic.

An RSC for CHO's 6, 7, 8 and 9 was in place which had representation from principal dental surgeons, consultant orthodontists, senior dental surgeons and MPEs. The local RSC reports and liaises with the HSE's National Radiation Protection Committee and National Oral Health Office. The inspector reviewed the minutes of recent RSC meetings and noted that the opportunity for oversight in addition to shared learning across the different health areas was an area of good practice.

The line management structures in place were also discussed with the management team on the day of inspection. The principal dental surgeon was a designated manager and radiation protection officer for the HSE dental clinics in the Louth and Meath area and the person responsible for radiation protection. A senior dental surgeon acted as a radiation safety officer for the clinic locally and had been allocated responsibility for supporting the designated manager in a day-to-day operational role to ensure the radiation protection of service users attending the clinic.

The inspector noted that the roles and responsibilities were clearly outlined in the *Arrangements for Radiation Safety in Dental and Orthodontic Services in Community Health Organisations 6, 7, 8 and 9.* All staff were required to sign that they had read this document. The inspector also noted that all staff working in the clinic had to complete mandatory online training every three years which included information about the regulations and the different roles and responsibilities. Compliance with these on-going training requirements was monitored. These steps to ensure the clear allocation of radiation protection arrangements and the ongoing training and monitoring were identified as an area of good practice on the day of inspection.

From speaking with staff and the management team, the inspector found that clinical responsibility was appropriately allocated to dentists registered with the Dental Council. Only referrals for X-rays from dentists working at the clinic were carried out. The practical aspects of medical exposures were only carried out by

practitioners or those allocated the practical aspects. Arrangements were also in place to ensure the continuity and appropriate involvement of MPEs at the clinic.

Overall, the inspector was satisfied that a clear allocation of responsibility for the radiation protection of service users attending the clinic was in place.

Judgment: Compliant

Regulation 8: Justification of medical exposures

A sample of records were reviewed during the on-site inspection and the inspector also spoke with staff involved in the conduct of X-rays. The inspector found that a dentist, registered with the Dental Council, took clinical responsibility for justifying all individual procedures. The referrals reviewed were all in writing and contained information about the reason for requesting the dental X-ray. The inspector also reviewed policies and other documentation which clearly outlined the process for referral and justification at the clinic. Staff spoken with during the inspection described how they spoke with patients and obtained previous imaging if appropriate prior to conducting further X-rays.

Information about the risks and benefits of dental X-rays was available to service users in the form of posters in the waiting room.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, the arrangements in place to ensure that all doses due to medical exposures were kept as low as reasonably achievable were reviewed by the inspector. Overall, the inspector was satisfied from the evidence reviewed that arrangements were in place to ensure that all X-rays were optimised in line with obtaining the required diagnostic information at the clinic.

For example, arrangements were in place to ensure the consistent production of adequate diagnostic outcomes and the optimisation of the practical aspects where an image quality grade was recorded on each patient's record. Where an image had to be retaken, the reason for this retake was also documented and reviewed as required. Similarly, the medical radiological equipment at the clinic was kept under strict surveillance as discussed in Regulation 14. This assessment also included an assessment of the contrast and brightness settings of the monitors used to review the X-ray images.

The inspector found evidence that patient doses were assessed and that local DRLs were established for all X-ray procedures carried out at the clinic in line with the

requirements of Regulation 11: Diagnostic reference levels. Ongoing work relating to optimisation was discussed and a draft report comparing the typical radiation doses delivered across all equipment types used in the CHOs was also reviewed. This work was noted as good practice in further enhancing the optimisation of the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

From speaking with management, and reviewing documents and other records, the inspector was satisfied that only registered dentists took clinical responsibility for medical radiological procedures. Similarly, the referrer and practitioner, who were the same person in most cases, were involved in the justification process. The MPE, the practitioner and the individual allocated the practical aspects were also involved in the optimisation process for all dental exposures.

The principal dental surgeon, as a practitioner, had allocated responsibility to an individual registered with the Dental Council, who had completed an approved course in radiation safety as prescribed by the Dental Council. This delegation of the practical aspect was formally and clearly documented and the record was available for review on the day of inspection as required by the regulations. In addition, only registered dentists or the individual allocated the practical aspects conducted medical exposures at the clinic.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Local facility DRLs had been established for all adult and paediatric X-ray procedures conducted at the clinic. The local facility DRLs were compared to the national DRL, and where a national DRL was not available for comparison, a relevant European value was used for comparison as appropriate. These DRLs and associated exposure factors were available at the X-ray controls.

In addition, the inspector saw evidence and records that following the installation of new equipment, DRLs were established and an image quality review was carried out by practitioners to ensure that the radiation doses were appropriate to obtain the required diagnostic information. The use of DRLs is an important tool to ensure that all medical exposures conducted are appropriately optimised in line with regulatory requirements. The inspector was also informed about ongoing work being carried out to establish regional DRLs for CHO's 6, 7, 8 and 9. The draft report was reviewed by the inspector on the day of inspection and this work was noted as good practice in enhancing the oversight of doses delivered at the different clinics in the CHOs.

Judgment: Compliant

Regulation 13: Procedures

Written protocols had been established for standard medical radiological procedures carried out at the clinic. Referral guidelines (selection criteria) were also available in hard copy for use by referrers in the practice. The approved selection criteria for use in the clinic were also specified in the *Arrangements for Radiation Safety in Dental and Orthodontic Services in Community Health Organisations 6,7,8 and 9.* Written protocols and selection criteria can provide assurance that medical radiological procedures are carried out in a consistent and safe manner at the practice. Information about the radiation dose relating to the patient exposure formed part of the report of the dental radiological procedures.

The inspector reviewed the clinic's clinical audit strategy and spoke with staff and management about the arrangements in place for conducting clinical audit. The inspector noted that a clinical audit strategy had been in place at the clinic prior to the publication of HIQA's *National Procedures for Clinical Audit of Medical Radiological Procedures*.

The inspector found that the allocation of responsibility and oversight for clinical audit was in place, with the responsible individuals outlined and the audit topics which were completed quarterly. A report which contained recommendations and a quality improvement plan was then populated. Oversight for the conduct of clinical audit at the clinic was provided by the principal dental surgeon and the audit subcommittee of the RSC.

From discussions with the management team on the day of inspection, the inspector was informed that work was currently underway to enhance the current strategy to ensure it fully reflected the national procedures and to ensure that all documentation used aligned with the recommended sample templates. The inspector acknowledged the ongoing commitment to clinical audit and that while meeting the high level requirements of the regulation, some small improvements would streamline and enhance the current process to ensure sustainable and achievable proactive quality improvement through clinical audit.

Judgment: Compliant

Regulation 14: Equipment

The medical radiological equipment at the clinic was found to be kept under strict surveillance regarding radiation protection. A QA programme was established and maintained at the clinic. This included QA testing and regular surveillance by the equipment manufacturer. Staff at the clinic carried out a quarterly QA check which included a review of the integrity of phosphor plates used to obtain the X-ray images.

An appropriate programme of assessment of dose had also been implemented and maintained. The inspector was informed that during MPE QA testing, the exposure factors routinely used were identified. If these were different from the pre-programmed exposure factors, the actual exposure factors used were measured to more accurately determine the radiation doses received by patients and establish the DRLs. More examples of this programme of work are detailed in Regulations 9 and 11.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation and policies relating to accidental and unintended exposures and significant events were reviewed by the inspector. Additionally, the management team and staff at the clinic communicated the process for recording and reporting any events involving, or potentially involving, accidental or unintentional dental exposures at the clinic.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, appropriate arrangements were found to be in place through a service level agreement to ensure the continuity of medical physics expertise at the HSE Dental Clinic in Dundalk.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions with an MPE, management and staff, and a review of documentation and other records the inspector was satisfied that an MPE whose

name was entered on the voluntary register of MPEs maintained by the Irish College of Physicists in Medicine, was available to act and give specialist advice on matters relating to radiation protection of service users.

On the day of inspection, the inspector found that an MPE took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to the optimisation of the radiation protection of patients and other individuals subject to medical exposure. This included the establishment and review of DRLs as described in Regulation 11.

The inspector also noted the collaborate involvement of MPEs engaged by the HSE dental service in Dundalk with the RSC's training subcommittee to provide an online training platform for staff at the clinic which encompassed different aspects of radiation protection.

Judgment: Compliant

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

The inspector found that an MPE was appropriately involved for consultation and advice, in line with the radiological risk at the clinic, on matters relating to radiation protection as outlined in Regulations 19 and 20.

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, as amended. 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 9: Optimisation	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and	Compliant
significant events	
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