



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Eyre Square Dental
Undertaking Name:	Eoin Fleetwood
Address of Ionising Radiation Installation:	Unit 301, Eyre Square Centre, Eyre Square, Galway
Type of inspection:	Announced
Date of inspection:	21 April 2021
Medical Radiological Installation Service ID:	OSV-0006429
Fieldwork ID:	MON-0031859

About the medical radiological installation:

Eyre Square Dental provide dental and orthodontic treatment to patients. In order to appropriately diagnose a patients treatment need, following clinical examination, one of the following radiological services may be necessary: bitewing X Ray, anterior or posterior perapical X Ray, orthopantomogram (OPG), cephalometry (Ceph), sectional cone beam computed tomography (CBCT), full-arch CBCT or full-mouth CBCT. The practice has an x-ray room for extra-oral exposures (OPG, Ceph & CBCT). Our intraoral equipment comprises three portable Nomad Pro 2 machines which are shared between eight treatment rooms as well as a wall-mounted intraoral machine in treatment room one.

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
Wednesday 21 April 2021	11:00hrs to 13:30hrs	Lee O'Hora	Lead
Wednesday 21 April 2021	11:00hrs to 13:30hrs	John Tuffy	Support

Summary of findings

Inspectors conducted a remote inspection of the Undertaking Eoin Fleetwood at Eyre Square Dental on the 21 April 2021.

Inspectors found effective management arrangements at Eyre Square Dental with a clear allocation of responsibility for the protection of service users undergoing dental radiological exposures. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspectors on the day of inspection.

Inspectors were assured that processes were in place to ensure the safe conduct of dental radiological procedures at Eyre Square Dental. Inspectors were satisfied that only dentists referred patients for dental radiological procedures and that all dental radiological procedures took place under the clinical responsibility of dentists and orthodontists. Inspectors were informed that practical aspects of dental radiological procedures were delegated to dental hygienists at Eyre Square Dental. The associated dental council registration, radiation safety training records and record of delegation of responsibility for each dental hygienist was supplied to inspectors.

Inspectors reviewed staff training records which outlined a commitment to the ongoing radiation safety training of all staff involved in the exposure of service users to ionising radiation at Eyre Square Dental. Patient information pamphlets supplied to inspectors detailed the benefits and risks associated with the radiation dose for all dental radiological procedures carried out at Eyre Square Dental.

The inspectors saw evidence of diagnostic reference levels (DRLs) being established, reviewed and used at Eyre Square Dental. Records of DRL reviews and subsequent corrective actions demonstrated that corrective actions were taken without delay. Inspectors were informed that the implementation of this corrective action, initiated by an annual DRL review, resulted in patient radiation dose reductions with no loss of diagnostic yield for one particular dental radiological procedure at Eyre Square Dental and this is considered a positive example of clinical improvement through the implementation of DRL reviews required by Regulation 11.

Inspectors reviewed comprehensive and bespoke imaging protocols and referral criteria for Eyre Square dental. Records provided also demonstrated that Eyre Square Dental has systems in place to ensure that information relating to patient exposure forms part of the report. Inspectors reviewed records of image quality audits for all staff involved in the exposure of service users to ionising radiation. Inspectors were assured that the systematic use of image quality audit at Eyre Square Dental is an effective quality improvement tool driving service improvement.

Inspectors reviewed Medical Physicist Expert (MPE), manufacturer and in house equipment quality assurance records and documentation and were satisfied that Eyre Square Dental demonstrated a commitment to keeping all dental radiological

equipment under strict surveillance regarding radiation protection. MPE professional registration, continuity of expertise and involvement was well documented and articulated to inspectors and satisfied all regulatory requirements.

Eyre Square Dental used a robust system of record keeping and analysis of accidental and unintended exposures and significant events. Incident records reviewed demonstrated to inspectors that Eyre Square Dental used such events to minimise the probability and magnitude of future occurrences through incident analysis, development of improvement plans and dissemination of this information to all staff involved in the exposure of service users to ionising radiation.

Overall, for the specific regulations considered by inspectors, there were many areas of good practice noted on inspection to ensure patient safety during dental exposure to ionising radiation. Eyre Square Dental demonstrated a commitment to quality improvement through the comprehensive and effective implementation of systems and processes established to fulfill regulatory responsibilities. Not only did this demonstrate regulatory compliance for the regulations reviewed over the course of the inspection, these systems and processes were also used to improve service user outcomes in radiation protection.

Regulation 4: Referrers

Documentation reviewed by inspectors indicated that referrals for dental radiological procedures were only accepted from dentists and orthodontists. Professional registration information was supplied to inspectors for all dentists and orthodontists working at Eyre Square Dental. Inspectors were informed that Eyre Square Dental accepted external referrals from dentists and that proof of professional registration was sought routinely as part of the referral. Sample external referral forms were supplied to inspectors and inspectors were satisfied that processes were in place to ensure external referrals were from appropriately recognised professionals.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed professional registration details of all practitioners operating at Eyre Square Dental, all professional registration information was up to date and satisfied all regulatory requirements

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by inspectors outlined a clear allocation of responsibility for the protection of service users at Eyre Square Dental. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to inspectors by staff and management during the course of the inspection.

Judgment: Compliant

Regulation 10: Responsibilities

After documentation review and communication with staff and management, inspectors were satisfied that robust procedures were in place to ensure all medical exposures took place under the clinical responsibility of a practitioner. Inspectors were also assured that practitioners, MPEs and dental hygienists were involved in the optimisation process of dental radiological exposures.

Practical aspects of dental radiological procedures were delegated to dental hygienists at Eyre Square Dental. This arrangement was clearly described in documentation reviewed by inspectors and clearly articulated by staff and management. Details of the relevant professional registration and radiation protection training were supplied to inspectors. The delegation of responsibility was recorded in documentation and inspectors were satisfied that all regulatory requirements in relation to the delegation of practical aspect were being fulfilled at Eyre Square Dental.

Inspectors were also supplied with information on relevant cone beam computed tomography (CBCT) specific training undertaken by all dentists operating at Eyre Square Dental at the time of inspection.

Information sheets highlighting the benefits, risks and associated patient dose associated with dental radiological procedures done at Eyre Square Dental were provided to inspectors.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Extensive documentation pertaining to DRLs was reviewed by inspectors. Eyre Square Dental had established equipment specific DRLs in October 2020 and subsequently used these to generate local facility DRLs for all dental radiological

procedures. Staff articulated to inspectors that these DRLs were displayed in the clinical area with the relevant equipment.

Records of corrective actions to address Eyre Square Dental's DRLs exceeding the nationally established DRLs were reviewed by inspectors. The completed corrective actions were implemented on 16 October 2020 after being highlighted and recommended by the MPE on 10 October 2020. Inspectors were informed that as a result of corrective actions taken, patient radiation dose had been reduced with no loss of diagnostic information of the subsequent images for the standard orthopantomograph (OPG) procedure at Eyre Square Dental.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard dental radiological procedure done at Eyre Square Dental were supplied to inspectors. Staff clearly articulated how these protocols were made available to them.

Inspectors were informed that information relating to patient exposure formed part of the report at Eyre Square Dental. Sample redacted templates of this information was subsequently supplied to inspectors which detailed the exposure factors used for each standard dental radiological procedure. Inspectors were informed that this information was included in the patients electronic report for each dental radiological procedure they underwent.

Eyre Square Dental supplied inspectors with bespoke referral criteria for all dental radiological procedures done at the practice. Staff clearly articulated how these referral or selection criteria were made available to them.

Inspectors were supplied with a list of retrospective image quality clinical audits done at Eyre Square Dental. Further discussion with staff elaborated that these audits also included reviews of standard note taking and image report information. Inspectors were told these audits were responsible for quantifiable improvements in image quality, appropriate and comprehensive note taking as well as improving image report content by feedback of results to individual dentists and subsequent re audit.

Judgment: Compliant

Regulation 14: Equipment

MPE equipment quality assurance reports for all dental radiological equipment reviewed by inspectors was up to date. Documents reviewed by inspectors also

detailed the use of annual manufacturer equipment service and in house quarterly OPG/CBCT quality assurance testing done by staff at Eyre Square Dental. All methods of equipment performance testing detailed in documentation was confirmed by staff members spoken to on the day of inspection.

An up to date inventory of dental radiological equipment was supplied to inspectors by Eyre Square Dental.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation reviewed by inspectors detailed the process for the recording, analysis and subsequent reporting of accidental and unintended exposures and significant events and near misses. This process was articulated to inspectors by all staff on the day of inspection. Records of incidents which did not meet the threshold for external reporting were also supplied to inspectors. These records included improvement plans which recorded the measures taken by Eyre Square Dental to minimise the probability of re occurrence. Inspectors were informed that any radiation related incidents and near misses are discussed at daily morning meetings as a way to inform and update staff as well as minimising the risk of repeat incidents.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

MPE registration details were supplied and inspectors were satisfied that these were up to date.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

After relevant document review and communication with management and the MPE, inspectors were satisfied that the responsibilities and contributions of the MPE at Eyre Square Dental satisfied regulatory requirements. Records of MPE contributions to equipment quality assurance, DRL establishment and review as well as bespoke radiation safety training for relevant staff were reviewed by inspectors.

Judgment: Compliant

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

After relevant document review and communication with management and the MPE, inspectors were satisfied that the involvement of the MPE was commensurate with the radiological risk at Eyre Square Dental

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 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	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 Eyre Square Dental OSV-0006429

Inspection ID: MON-0031859

Date of inspection: 21/04/2021

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
Outline how you are going to come into compliance with :	

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