



Health Information and Quality Authority

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

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| Name of Medical Radiological Installation: | Mayo Dental & Implant Clinic |
| Undertaking Name: | Shane Curran |
| Address of Ionising Radiation Installation: | Upper James Street, Westport, Mayo |
| Type of inspection: | Announced |
| Date of inspection: | 29 September 2022 |
| Medical Radiological Installation Service ID: | OSV-0005944 |
| Fieldwork ID: | MON-0037722 |

About the medical radiological installation:

The Mayo Dental and Implant Clinic is a dental surgery providing general dental services including restorative, cosmetic and implants. There is 1 Principal Owner, 2 Associate dentists, 3 Hygienists, 5 nurses and 2 administrative staff. The Mayo Dental And Implant Clinic operate 4 surgeries each with intra-oral x-rays units and one separate, dedicated extra-oral x-ray unit capable of taking pan-oral radiographs and Cone Beam CT digital radiography. Any images obtained are used in conjunction with clinical evaluation to assist in diagnosis and identification of dental disease. We see approximately 11000 patients per year.

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 29 September 2022 | 12:00hrs to 14:00hrs | Lee O'Hora | Lead |

Summary of findings

An on-site inspection of the undertaking Shane Curran operating at Mayo Dental & Implant Clinic was completed on 29 September 2022.

The inspector found effective management arrangements at Mayo Dental & Implant Clinic 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 inspector on the day of inspection.

The inspector was satisfied that only dentists referred patients for dental radiological procedures and that all dental radiological procedures took place under the clinical responsibility of dentists operating at Mayo Dental & Implant Clinic. The inspector was assured that the undertaking had processes in place to ensure that all dental procedure referrals were accompanied by the relevant information. However, the record of justification by a practitioner was not documented for a number of external referrals reviewed on the day of inspection, this was highlighted to management as an area for improvement. Information for service users on radiation risks was available throughout the practice on the day of inspection.

The inspector was assured that all dental radiological equipment was kept under strict surveillance regarding radiation protection. Medical physics expert (MPE) professional registration, continuity of expertise and involvement was well documented and articulated to the inspector satisfying the associated regulatory requirements.

Overall the inspector found that the undertaking demonstrated good levels of compliance with the regulations considered on the day of inspection.

Regulation 4: Referrers

Documentation reviewed by the inspector indicated that referrals for dental radiological procedures were only accepted from dentists. Professional registration information was supplied to inspectors for all dentists working at Mayo Dental & Implant Clinic. The inspector was informed that Mayo Dental & Implant Clinic accepted external referrals from dentists for cone beam computed tomography (CBCT) procedures. Sample external referral forms were supplied to the inspector who was satisfied that processes were in place to ensure external referrals were from appropriately recognised professionals.

Judgment: Compliant

Regulation 5: Practitioners

The inspector reviewed professional registration details of all practitioners operating at Mayo Dental & Implant Clinic. All professional registration information was up-to-date and satisfied all regulatory requirements.

Judgment: Compliant

Regulation 6: Undertaking

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

Judgment: Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, the inspector spoke with staff who explained how medical exposures are justified in advance. All referrals reviewed by the inspector on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The inspector was satisfied that the undertaking had systems in place to ensure that all referrals were reviewed and justified by a dentist operating at Mayo Dental & Implant Clinic, however a sample of referrals reviewed for CBCT procedures from dentists operating outside the practice did not include a record of justification by a practitioner operating at the practice. This non-compliance was highlighted to staff and management on the day of inspection as an area for improvement.

Information posters with information on the benefits, risks and associated patient dose for dental radiological procedures carried out at Mayo Dental & Implant Clinic were observed throughout the practice.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

After documentation review and communication with staff and management, the inspector was satisfied that the undertaking had procedures in place to ensure all medical exposures took place under the clinical responsibility of a practitioner and that the practitioner and referrer were involved in the justification process. The inspector was also assured that practitioners and the MPE were involved in the optimisation process of dental radiological exposures.

Practical aspects of dental radiological procedures were not delegated to professionals other than dentists at Mayo Dental & Implant Clinic. Inspectors were also supplied with information on relevant cone beam computed tomography (CBCT) specific training undertaken by dentists operating CBCT equipment at Mayo Dental & Implant Clinic at the time of inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was satisfied that the undertaking had established, regularly reviewed and used DRLs at Mayo Dental & Implant Clinic. The inspector observed equipment specific DRLs displayed in the clinical area for all equipment.

Judgment: Compliant

Regulation 13: Procedures

The inspector reviewed written protocols for every type of standard dental radiological procedure carried out at Mayo Dental & Implant Clinic and observed these displayed throughout the practice.

After a review of a sample of imaging reports the inspector was assured that the undertaking had implemented a system to routinely include information relating to patient exposure on the report of the medical radiological procedure.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of dental radiological equipment was supplied to the inspector and validated on site. All information relating to equipment including policies and procedures, MPE quality assurance (QA) records and MPE acceptance testing records was reviewed. All equipment QA was up to date at the time of inspection. Records reviewed satisfied the inspector that systems and processes were in place to ensure that issues raised during QA were appropriately followed up and closed off by the undertaking.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied that the necessary arrangements were put in place to ensure the continuity of MPE expertise. This arrangement was formalised in documentation reviewed ensuring the maintenance of MPE services until 30 January 2024.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records of MPE contributions to equipment QA, DRL establishment and review as well as bespoke radiation safety training for relevant staff were reviewed by the inspector. MPE registration details were supplied and these were up to date. After relevant document review and staff communication, the inspector was satisfied that the responsibilities and contributions of the MPE at Mayo Dental & Implant Clinic satisfied regulatory requirements in relation to Regulation 20.

Judgment: Compliant

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

The inspector was assured that the involvement of the MPE was commensurate with the radiological risk at Mayo Dental & Implant Clinic.

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 | Substantially Compliant |
| Regulation 10: Responsibilities | Compliant |
| Regulation 11: Diagnostic reference levels | Compliant |
| Regulation 13: Procedures | Compliant |
| Regulation 14: Equipment | 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 Mayo Dental & Implant Clinic OSV-0005944

Inspection ID: MON-0037722

Date of inspection: 29/09/2022

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 8: Justification of medical exposures | Substantially Compliant |
| <p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>External referrals for CBCT require a referral from a practitioner and an associated form to be completed including justification this is done as a matter of course. Provision is now in place so that justification by a practitioner operating at the practice is also included. This is in the form of clinical notes being completed prior to the exposure to satisfy the operator that the image that the user has been referred for is appropriate and is as low as reasonably possible. This has been actioned immediately. Records are stored and backed up digitally and are available for a five year period following population of the record.</p> | |

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. | Substantially Compliant | Yellow | 28/10/2022 |
| 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. | Substantially Compliant | Yellow | 28/10/2022 |