



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Gorey Family Chiropractic Clinic
Undertaking Name:	Gorey Family Chiropractic Clinic Ltd.
Address of Ionising Radiation Installation:	Railway Road, Gorey, Wexford
Type of inspection:	Announced
Date of inspection:	09 September 2021
Medical Radiological Installation Service ID:	OSV-0005934
Fieldwork ID:	MON-0033748

About the medical radiological installation:

Gorey Family Chiropractic Clinic is a chiropractic clinic with four treatment rooms. The clinical areas are located over two floors with a dedicated X-ray room located on the ground floor. Gorey Family Chiropractic Ltd. acts as an undertaking which carries out medical radiological procedures at its premises on a once weekly basis. The X-ray unit is used solely for musculo-skeletal radiography. The clinic was originally established in 2005 and currently two chiropractors offer musculo-skeletal diagnosis, treatment and rehabilitative services. This service carries out approximately 240 radiography procedures per year. External referrals for medical exposures are not accepted by this clinic.

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 9 September 2021	11:00hrs to 12:30hrs	Kirsten O'Brien	Lead

Summary of findings

An inspection of Gorey Family Chiropractic Clinic was carried out to review measures taken to come into compliance with the regulations following a previous inspection carried out by inspectors on 18 March 2021.

The inspector reviewed documentation and spoke with staff and management at the clinic and was satisfied that there was now a clear allocation of responsibility to appropriate individuals, recognised in the regulations, for the radiation protection of service users attending the clinic. A radiographer registered with CORU, Ireland's multi-profession health regulator, carried out the practical aspects of medical radiological procedures. The radiographer also took clinical responsibility for medical exposures carried out at Gorey Family Chiropractic Clinic with the exception of clinical evaluation of the outcome. In particular, the radiographer was the identified practitioner with overall responsibility for justification and optimisation at the clinic. Since the previous inspection a consultant radiologist had been engaged by the undertaking and now took responsibility for the clinical evaluation of the outcome of medical exposures carried out at the clinic. Similarly, the involvement of a medical physics expert (MPE) to give advice on matters relating to medical physics had been formalised.

An appropriate quality assurance (QA) programme had been implemented and maintained since the last inspection. Gorey Family Chiropractic Clinic had purchased additional equipment to facilitate a programme of assessment of dose and regular performance testing. Consequently, the inspector was satisfied that the medical radiological equipment at Gorey Family Chiropractic Clinic was now kept under strict surveillance with regards radiation protection. Similarly, following the installation of this new equipment, the clinic's diagnostic reference levels (DRLs) have also been reviewed.

Documentation and records reviewed by the inspector demonstrated that the written protocols for medical exposures carried out at the clinic had been updated to include additional details about procedures. Additionally, since the previous inspection, the undertaking had included information relating to patient exposure as part of the report of medical radiological procedures.

Overall the inspector was assured that the undertaking had put measures in place to address any non compliance with the regulations identified on the previous inspection of Gorey Family Chiropractic Clinic.

Regulation 5: Practitioners

Based on documentation provided in advance of inspection, and speaking with

practitioners and the undertaking representative, the inspector found only persons entitled to act as practitioners took all aspects of clinical responsibility for medical exposures carried out at Gorey Family Chiropractic Clinic.

Judgment: Compliant

Regulation 6: Undertaking

The inspector spoke with staff and management at Gorey Family Chiropractic Clinic on the day of inspection and was satisfied that there was a clear allocation of responsibility for the radiation protection of service users at the clinic. A radiographer registered with CORU took clinical responsibility for medical exposures carried out at Gorey Family Chiropractic Clinic with the exception of clinical evaluation of the outcome. In particular, the radiographer was the practitioner with overall responsibility for justification and optimisation at the clinic. The radiographer, as a practitioner, also carried out the practical aspects of medical radiological procedures at the clinic. Since the previous inspection conducted at this installation, a consultant radiologist had been engaged to take responsibility for the clinical evaluation of the outcome for all medical exposures conducted at the clinic.

Similarly, the inspector reviewed documentation and other records and found that arrangements relating to MPE involvement at the clinic had been formalised and an MPE was now appropriately involved to act and give advice on matters relating to medical physics.

Judgment: Compliant

Regulation 10: Responsibilities

Gorey Family Chiropractic Clinic had put measures in place to ensure that all medical exposures at the clinic took place under the clinical responsibility of individuals entitled to act as practitioners. The inspector reviewed records and other documentation and found that a practitioner was involved in the justification and optimisation of all medical exposures. Since the previous inspection, arrangements were now in place to ensure that a practitioner also took responsibility for the clinical evaluation of the outcome of all medical exposures.

The inspector was also satisfied from speaking with staff and reviewing records and other documentation that the MPE was involved in the optimisation process for all medical exposures. Similarly, a person entitled to act as a referrer as per Regulation 4(1) was involved in the justification process for all referrals. The practical aspects of medical radiological procedures conducted at Gorey Family Chiropractic Clinic

were carried out by a person that was entitled to act as a practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation and spoke with staff at the clinic and found that DRLs had been established, reviewed and used for medical radiological procedures carried out at the clinic.

Judgment: Compliant

Regulation 13: Procedures

Since the previous inspection Gorey Family Chiropractic Clinic had taken steps to enhance their documentation to include additional information as part of their written protocols for each type of standard procedure for relevant categories of patients. The inspector reviewed a supplementary document *Protocols for General Radiography* which included information about the projections and imaging technique which should be used when imaging different anatomical areas at the clinic.

Similarly, the inspector reviewed records of routine clinical audit for medical exposures which had been carried out at the clinic. These audits included assessment that justification had been recorded, ensuring that identification of patients had been verified and that only a person entitled to refer as per the regulations had written the referral for the medical radiological procedure. The conduct of regular clinical audit can assist undertakings in monitoring and evaluating their service and provide assurances of the radiation protection of service users.

From a review of records of patient exposures on the day of inspection, the inspector found that Gorey Family Chiropractic Clinic had ensured that information about patient exposure formed part of the report of medical radiological procedures.

Judgment: Compliant

Regulation 14: Equipment

On the day of inspection, the medical radiological equipment at Gorey Family Chiropractic Clinic was found to be kept under strict surveillance regarding radiation protection. The inspector found that an appropriate QA programme had been

implemented and maintained since the last inspection.

This QA programme included performance testing which included a regular servicing by the equipment manufacturer and an annual assessment of the equipment by an MPE. The inspector noted that equipment required for routine performance testing has been purchased by the undertaking and this aspect of regular testing had recently been integrated into the overall QA programme. The undertaking had also purchased additional equipment which allowed Gorey Family Chiropractic Clinic to carry out a programme of assessment of dose at the clinic.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector spoke with staff and reviewed documentation and was satisfied that Gorey Family Chiropractic Clinic had systems in place to record events involving, or potentially involving, accidental or unintended medical exposures in line with the radiological risk at the clinic. Management and staff who spoke with the inspector explained the process for reporting and recording any incidents, or potential incidents, involving medical exposure to ionising radiation that may occur at the clinic.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection Gorey Family Chiropractic Clinic had the necessary arrangements in place to ensure the continuity of medical physics expertise at the clinic.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From a review of documentation and other records, and speaking with staff and management, the inspector was satisfied that an MPE acted and gave specialist advice on matters relating to medical physics. The MPE was found to have taken responsibility for dosimetry and had contributed to the optimisation of the radiation protection of patients, in particular, the review of DRLs at the clinic. The inspector was also satisfied that the MPE provided advice on medical radiological

equipment and was involved in the the establishment and implementation of a QA programme at Gorey Family Chiropractic Clinic.

Judgment: Compliant

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

An MPE was found to be appropriately involved for consultation and advice on matters relating to radiation protection concerning medical exposure at Gorey Family Chiropractic 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 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 Gorey Family Chiropractic Clinic OSV-0005934

Inspection ID: MON-0033748

Date of inspection: 09/09/2021

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