



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:	18 March 2021
Medical Radiological Installation Service ID:	OSV-0005934
Fieldwork ID:	MON-0031964

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 or fortnightly 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 18 March 2021	10:30hrs to 13:00hrs	Agnella Craig	Lead
Thursday 18 March 2021	10:30hrs to 13:00hrs	Kirsten O'Brien	Support

Summary of findings

An inspection of Gorey Family Chiropractic Clinic was carried out to verify the results of the self-assessment questionnaire submitted by this clinic and to assess their compliance with key regulations for the radiation protection of service users.

Inspectors found full compliance with three regulations assessed on the day of inspection however eight regulations required some improvement or substantial improvements to demonstrate compliance.

In advance of this inspection, inspectors were provided with documentation which provided assurance that all medical exposures were carried out based on a referral from a person entitled to refer as per the regulations. This person also acted as the practitioner who took clinical responsibility for most aspects of medical exposures. These aspects included justifying the procedure in advance of the medical exposure, obtaining previous relevant information, inquiring about pregnancy and involvement in optimisation to produce the best image with as low a dose as possible. However, this practitioner was not responsible for evaluating the outcome of exposures which is an integral part of clinical responsibility of medical radiological procedures. Although the undertaking had allocated responsibility to a person for the clinical evaluation of exposures, this person did not meet the requirements of Regulation 5, thus the undertaking was not in compliance with this regulation.

In addition, non-compliances were found in relation to Regulation 13 (Procedures) and Regulation 14 (Equipment). The undertaking is required to have written protocols available for each type of standard procedure, however only one protocol was available at the time of inspection and this protocol lacked detail such as typical exposure parameters. Having written protocols in place helps ensure that procedures and radiation doses received by the service user are appropriate and standardised. Furthermore, information relating to the exposure was also not included in patients' reports. In relation to Regulation 14, the implementation and maintenance of appropriate quality assurance programmes and methods of assessing dose are required to ensure the radiation protection of service users. Although Gorey Family Chiropractic Clinic had implemented a quality assurance (QA) programme, this programme had not been maintained at an appropriate level.

Additionally, the undertaking had only recently engaged a recognised Medical Physics Expert (MPE) for this clinic. Due to this recent engagement, the MPE was unable to be involved in all aspects as required in the regulations including quality assurance, dosimetry, and performance testing. However, inspectors were assured by both the undertaking and the MPE of their plans to complete these aspects in the short term.

Although the undertaking was found to be compliant with some regulations on this inspection, the undertaking should address the areas of non-compliance, identified

in this report, as a matter of priority.

Regulation 4: Referrers

The referral process for medical exposures was outlined both in the documentation and by staff. Inspectors were informed that a referral for a medical exposure is written on the basis of reviewing a clinical assessment form and speaking with the patient.

Having spoken with staff, reviewed the documentation on the process of referral, and examined a number of patients' records on the day of inspection, inspectors found that referrals for medical exposures were written by a person entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Based on documentation provided in advance of inspection, and speaking with the practitioner and the undertaking representative, inspectors found that an individual recognised as a practitioner under Regulation 5(c) takes responsibility for some aspects of clinical responsibility for medical exposures. However, responsibility for the clinical evaluation of the outcome of medical exposures, an integral part of clinical responsibility, was allocated to an individual who is not recognised within Regulation 5. The undertaking representative recognised that as a result of this, they were not in compliance with this regulation.

Judgment: Not Compliant

Regulation 6: Undertaking

Gorey Family Chiropractic Clinic Ltd. had declared to HIQA as an undertaking during the stipulated notification period as required by the regulations. From reviewing the documentation and speaking with staff, personnel who spoke with inspectors were aware of the allocation of responsibilities within this clinic. However, the documentation should be elaborated to fully demonstrate the allocation of responsibilities for the radiation protection of service users.

In addition, the allocation of clinical responsibility for the evaluation of the outcome of medical exposures was not allocated to a person recognised within the regulations. Inspectors also found that the allocation of responsibilities to a medical

physics expert (MPE), as recognised within the regulations, was very recent and had not yet been formalised. Based on these findings, inspectors were not assured of the undertaking's compliance with Regulation 6(3).

The undertaking must address the allocation of responsibility for the evaluation of the outcome of medical exposures to a practitioner as defined in Regulation 5 and formalising the arrangements with the MPE will help to assure the undertaking of the radiation protection of service users.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

The process of justification of medical exposures in the Gorey Family Chiropractic Clinic was explained to inspectors by the practitioner. The referrer, acting in dual roles of referrer and practitioner in this facility, justified procedures before acquiring the X-rays.

Records reviewed by inspectors on the day of inspection showed that referrals for medical exposures were written, included the reason for the exposure and were justified in advance by a practitioner.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that Gorey Family Chiropractor Clinic Ltd. had engaged a person recognised as a practitioner, as defined in Regulation 5, to take clinical responsibility for some aspects of medical exposures carried out at this clinic. Additionally, the practical aspects of all medical exposures at this clinic were only conducted by this practitioner. From the documentation reviewed and speaking with staff, inspectors found that the optimisation process for all medical exposures involved this practitioner. More recently, an MPE had become involved in advising on optimisation. In addition, inspectors were assured that the justification process involved the practitioner who also acted as the referrer in this clinic.

However, in order to come into compliance with Regulation 10 (1), the undertaking should ensure that all aspects of clinical responsibility are held by practitioners as recognised within the regulations. As described in Regulation 5, a deficit in relation to responsibility for the clinical evaluation of the outcome of medical exposures was noted on the day of inspection.

Judgment: Substantially Compliant

Regulation 13: Procedures

From the documents reviewed on this inspection and from speaking with the referrer, inspectors were assured that referral guidelines for patients undergoing medical exposures in this clinic were available to the referrer.

A data collection template for clinical audit was provided in advance of this inspection and the records of a recent audit were reviewed by inspectors on the day of inspection. As part of this audit, a number of patient records were randomly selected from a three month period. Information on the recording of the referrer, the operator, and if justification was acceptable and appropriate was gathered as part of this audit. Inspectors noted that only one audit was available at the time of inspection. Conducting audits frequently can help an undertaking to evaluate and monitor a service, and plays an important role in providing assurance of the radiation protection of service users.

Although the procedure for conducting a medical exposure was known by the practitioner and a document titled *Gorey Family Chiropractic Protocols for Standard Radiological Practices* was provided in advance of inspection, specific written protocols for each type of standard procedure carried out at this clinic were not available.

Information relating to patient exposure did not form part of the reports of medical radiological procedures reviewed by inspectors on the day of inspection. Staff who spoke with inspectors also confirmed that this information was not included in patient reports. On the day of inspection, the undertaking recognised the steps required in order to come into compliance with Regulation 13.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that the X-ray equipment had been installed in 2016.

The *Radiation Safety Procedures* document reviewed in advance of this inspection detailed that the undertaking should implement and maintain QA testing annually in line with the guidance on QA provided by HIQA for general X-ray equipment. However, the last QA report available for review was dated November 2019, and the undertaking explained it was not possible to complete the standard annual QA testing in November 2020 due to COVID-19 restrictions.

Therefore, although the undertaking had implemented a quality assurance programme this programme had not been sufficiently maintained. In addition, routine performance testing was also not carried out as required. Based on these findings, inspectors were not assured that the undertaking had the appropriate testing and QA in place to be in compliance with this regulation.

However, inspectors noted that the undertaking had arranged two recent services with the manufacturer; one of which was completed in August 2020 and more recently in March 2021. In addition, inspectors were informed by the MPE on the day of inspection that the deficit in QA and performance testing will be remedied shortly.

Judgment: Not Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From the documentation reviewed and speaking with staff, inspectors were assured of the systems in place to inquire about pregnancy status with service users. Posters alerting service users to inform staff of their pregnancy status were on display in the X-ray unit. The role and responsibilities of the practitioner with respect to the pregnancy policy were documented and the practitioner demonstrated a knowledge and understanding of this when speaking with inspectors.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From speaking with the undertaking representative and reviewing recent communications between the undertaking and an MPE, inspectors were assured that the undertaking was in the process of formalising arrangements with an MPE service. The undertaking acknowledged the importance of ensuring continuity of services when finalising these arrangements. The MPE confirmed when speaking with inspectors that continuity of service was available and would be detailed in the finalised arrangements.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

The undertaking had recently engaged the services of an MPE who is recognised

within the regulations and evidence of the MPE's registration was provided to inspectors. Inspectors were informed that this engagement was relatively recent with evidence of communications dating back by just a few weeks. Inspectors were informed that the finalised arrangements were imminent.

In the short term of engagement, the MPE had provided advice on purchasing a specific piece of equipment which would facilitate dose measurements to be taken, and evidence that the undertaking is acting on this advice was also provided to inspectors. The MPE had also begun to review the documentation and previous quality assurance reports for the equipment.

However, inspectors were informed that due to the short time frame of engagement, the MPE had not yet been able to take responsibility for other aspects detailed in this regulation such as dosimetry, training, and quality assurance but inspectors were advised that this was currently being planned and would occur in the near future.

From the information provided during the course of this inspection, inspectors were assured of the undertaking's commitment to formalise the arrangements with the recently appointed MPE as recognised in the regulations, and that this MPE had started to work with this undertaking in addressing regulatory gaps in the practice.

Judgment: Substantially Compliant

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

On the day of inspection, inspectors was satisfied that Gorey Family Chiropractic Clinic Ltd. were working towards formalising the arrangements with the recently engaged MPE service as per the requirements of this regulation. From speaking with the MPE and reviewing communications, inspectors were informed of the work already carried out by this MPE and informed that the level of involvement will be appropriate and in line with the level of risk posed by this service.

Judgment: Substantially 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	Not Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Compliance Plan for Gorey Family Chiropractic Clinic OSV-0005934

Inspection ID: MON-0031964

Date of inspection: 18/03/2021

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
Regulation 5: Practitioners	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 5: Practitioners: We are actively sourcing an IMC registered tele radiology service as opposed to the non IMC radiology reporting service engaged at the time of our inspection. It is our intention to transition to this service with an appropriate service level agreement as soon as possible. Currently we are in discussion with a tele radiology service provider and they are examining the technical IT specification of our system so as to have a secure cloud based system of accessing the patient data and posting the patients reports back. This will facilitate achieving full compliance within this regulation.</p>	
Regulation 6: Undertaking	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Minister for Health has not yet published the Medical Physics Register and this led to a delay in finding a suitable MPE for our Undertaking. We have engaged with a member of the Irish College of Medical Physicists and a service level agreement is in place between the Undertaking and the MPE. The allocation of clinical responsibility for the evaluation of the outcome of medical exposures to an IMC registered radiologist as required by the regulations as opposed to a non IMC registered radiologist shall take place as soon as possible with an appropriate service level agreement between both parties.</p>	

Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: We are actively sourcing an IMC registered tele radiology service as opposed to the non IMC radiology reporting service engaged at the time of our inspection. It is our intention to transition to this service with an appropriate service level agreement as soon as possible thereby ensuring that all aspects of clinical responsibility are held by practitioners as recognised within the regulations and facilitating full compliance within this regulation.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Protocols must be written out in relation to all standard examinations the Undertaking carries out.</p> <p>As an undertaking, we have discussed the required protocols relating to each individual standard radiological procedure that our Undertaking carries out with both our MPE and radiographer. Our radiographer is currently in the process of drafting each written protocol in conjunction with our MPE and it is our understanding that this is nearly finalised.</p> <p>Information relating to patient exposure such as kV, mA must form part of each patient's radiology report.</p> <p>As an undertaking we have briefed our clinic administrative team on the new system of transfer of relevant patient exposure data for inclusion on each patient's radiology report. This system has been implemented and standardised successfully.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: The engagement of an MPE facilitates annual quality assurance in full compliance with the regulations. This engagement also provides valuable local support which helps avoid a situation whereby the routine performance testing in Nov 2020 was negatively affected by the inability of the Undertaking's overseas engineer to travel to conduct routine performance testing due to the Covid 19 restrictions. Q&A testing has now been carried out by the MPE as of the 20th of April 2021.</p>	

A suitable DAP meter has been successfully ordered and confirmed for delivery within 4 weeks facilitating the following of procedures developed by the National Radiation Protection Committee of the HSE for recording the dose in the radiology report.

Further QA testing will be provided by the MPE after the point of DAP meter installation.

Routine QC will be conducted by the MPE.

Regulation 19: Recognition of medical physics experts

Substantially Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:

A service level agreement exists between the undertaking and the MPE. The SLA ensures continuity of MPE support with additional MPE's available for support in the event the named MPE is not available. The MPE will be providing support for compliance, including quality assurance as well as responsibility for dosimetry and training.

Regulation 20: Responsibilities of medical physics experts

Substantially Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:

A service level agreement exists between the undertaking and the MPE. The SLA ensures continuity of MPE support with additional MPE's available for support in the event the named MPE is not available. The MPE will be providing support for compliance, including quality assurance as well as responsibility for dosimetry and training.

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

Substantially Compliant

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
Involvement of medical physics experts in medical radiological practices:
A service level agreement exists between the undertaking and the MPE. The SLA ensures continuity of MPE support with additional MPE's available for support in the event the named MPE is not available. The MPE will be providing support for compliance, including quality assurance as well as responsibility for dosimetry and training.

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 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	21/05/2021
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence	Not Compliant	Orange	21/05/2021

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	21/05/2021
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	05/05/2021
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	22/04/2021
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	30/05/2021
Regulation 14(2)(a)	An undertaking shall implement and maintain	Not Compliant	Orange	30/05/2021

	appropriate quality assurance programmes, and			
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.	Not Compliant	Orange	30/05/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	21/04/2021
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals	Not Compliant	Orange	21/05/2021

	subject to medical exposure,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving,	Substantially Compliant	Yellow	30/05/2021

	<p>or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.</p>	Substantially Compliant	Yellow	21/04/2021