



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Clontarf Chiropractic
Undertaking Name:	Owgar Ltd
Address of Ionising Radiation Installation:	126 Clontarf Road, Clontarf, Dublin 3
Type of inspection:	Announced
Date of inspection:	04 March 2021
Medical Radiological Installation Service ID:	OSV-0005953
Fieldwork ID:	MON-0031734

About the medical radiological installation:

Owgar Limited, operating at Clontarf Chiropractic, provide both chiropractic and X-ray services. Clontarf Chiropractic advertise the availability of standing X-ray imaging to diagnose back or neck complaints and have a computed radiography system to process and archive X-ray images.

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 4 March 2021	14:00hrs to 17:30hrs	John Tuffy	Lead

Summary of findings

A short notice announced inspection of Clontarf Chiropractic was carried out due to continued non-compliances found on inspection in December 2019 and September 2020. Following the inspection on 3 September 2020, Owgar Limited was issued with a compliance notice directing the undertaking to come into compliance with eight regulations by 22 January 2021. This inspection was carried out on 4 March 2021 to verify the actions taken by Owgar Limited to address these particular non-compliances.

Assessment of compliance was carried out by reviewing information provided in advance of the inspection, an on-site review of processes in place at Clontarf Chiropractic and by speaking with the practitioner and the medical physics expert on the day of inspection. It was found that Owgar Limited had taken considerable action to come into compliance with the regulations inspected against on the day. This involved the engagement of additional personnel within the service, for example a person entitled to act as practitioner and a medical physics expert, to fulfil key aspects of the regulations. In addition, Owgar Limited had invested in an information technology (IT) system to manage the process of medical exposures to include patient assessments, referrals for medical exposures, archiving and viewing of X-ray images and subsequent reporting of X-ray images taken.

In relation to non-compliances found on the previous inspection regarding Regulation 4, Regulation 6, Regulation 10 and Regulation 22, Owgar Limited had engaged a medical practitioner to act as referrer and as practitioner, as defined in the regulations, to take clinical responsibility for individual medical exposures, including the clinical evaluation of the outcome. Furthermore, Owgar Limited had engaged a medical physics expert, as required in Regulation 19, Regulation 20 and Regulation 21, to contribute to matters relating to medical physics which were seen as deficits in previous inspections. Furthermore, Owgar Limited had established diagnostic reference levels for general X-rays provided at the Clontarf Chiropractic.

Overall, although areas for improvement were noted on the day of inspection, Owgar Limited had demonstrated an assurance to HIQA of compliance with the directions of the compliance notice.

Regulation 4: Referrers

In advance of the inspection, Owgar Limited provided updated documentation to demonstrate how a new process for referral and justification had been initiated within the service since the previous inspection. On the day of inspection, the inspector reviewed records of referrals for medical exposures. All referrals reviewed, were requested by a medical practitioner entitled to refer an individual for medical

radiological procedures under Regulation 4(1)(c).

Judgment: Compliant

Regulation 5: Practitioners

Since the previous inspection on 3 September 2020, Clontarf Chiropractic had adapted existing processes and engaged the services of a medical practitioner to act as practitioner, as defined in the regulations. Based on documentation provided in advance of inspection, speaking with the medical practitioner and meeting with the undertaking representative for Owgar Limited, the inspector was assured that the medical practitioner, recognised as a practitioner under Regulation 5(b) had been engaged to take clinical responsibility for all individual medical exposures carried out at Clontarf Chiropractic.

Judgment: Compliant

Regulation 6: Undertaking

Following the previous inspection on 3 September 2020, Owgar Limited had revised the allocation of responsibility for the protection of services users from medical exposures to ionising radiation. An organogram describing this revised approach had been provided to the inspector in advance of the inspection. In addition, referral and report templates used by the referrer, radiographer and practitioner were provided in advance and evidence of referral and subsequent imaging reports were reviewed on the day of inspection. Owgar Limited had engaged the services of a medical practitioner to refer service users for medical exposures and to act as practitioner with clinical responsibility for all medical exposures carried out at Clontarf Chiropractic. A radiographer registered with CORU, Ireland's multi-profession health regulator, was engaged to conduct medical exposures within the service. Furthermore, Owgar Limited had engaged the services of a medical physics expert to meet the requirements of the regulations and to supplement the work of the radiation protection adviser already engaged by Clontarf Chiropractic. The revised process was articulated and understood by individuals met or spoken with on the day of inspection.

Acknowledging that the reorganisation of responsibility had been recently put into place to meet the requirements of the compliance notice issued to the service, Owgar Limited should update the revised allocation of responsibilities into existing radiation safety procedures explaining the clear lines of clinical and organisational responsibility for medical exposure to ionising radiation. Furthermore, the nature of the service arrangement with the practitioner and medical physics expert should also be formalised as this was not documented on the day of inspection. Management at

Owgar Limited had assured the inspector that a local radiation safety committee meeting scheduled for the coming weeks would provide a forum to finalise necessary documentary updates.

Notwithstanding these areas for improvement, overall, the inspector was assured that the revised allocation of responsibility reflected the requirements of the regulations and provided an assurance of safety to service users undergoing medical radiological procedures.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the previous inspection on 3 September 2020, inspectors had noted that Owgar Limited had put some measures in place to move towards compliance with this regulation, however non-compliances had been found on that day.

Since then, management at Owgar Limited had engaged the services of a medical practitioner to take full clinical responsibility for all aspects of clinical responsibility, as defined in Part 1 of the regulations, including the clinical evaluation of the outcome of individual medical exposures. The medical practitioner also confirmed this arrangement and also stated that imaging provided at the service was of a satisfactory quality for reporting.

The medical physics expert informed the inspector that a review of the quality assurance of the equipment, imaging protocols and exposure parameters used within the service had been conducted. The medical physics expert also assured the inspector of the intention to continue to identify areas for improvement in conjunction with the radiation protection adviser and radiographer. Furthermore, it was found that the practical aspects of all medical exposures were solely conducted by the registered radiographer at the practice, noting that this included the recording of exposure parameters for each individual exposure and pregnancy status of female service users when required.

Overall, noting the additional personnel incorporated within the service and intention to further improve the optimisation process for all medical exposures was seen as an additional positive measure, the inspector was satisfied that key measures had been taken by the undertaking since the previous inspection to demonstrate compliance with the requirements of Regulation 10.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Information provided to HIQA in advance of the inspection as part of a diagnostic reference level survey request indicated that diagnostic reference levels for general X-rays provided at the service had been established and were found to be below or comparable to national diagnostic reference levels. This was seen as positive outcome, indicating the alignment of radiation doses to similar X-ray procedures nationally and provided an assurance to the inspector that further corrective actions were not required.

As an area for improvement, management at Owgar Limited should update the radiation safety procedures or equivalent document(s) to describe the process by which diagnostic reference levels (DRLs) for common radiological procedures conducted at the service are established and the frequency of such a review. Furthermore, noting the recent engagement of a registered medical physics expert, advice on the application and use of diagnostic reference levels should be sought to improve awareness and use in everyday practice.

Notwithstanding these areas for improvement, Owgar Limited had demonstrated substantial compliance with the requirements of this regulation.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

An individual recognised as a medical physics expert had been engaged by Owgar Limited to provide advice and consultation and this was confirmed by individuals met with or spoken to on the day of inspection. The nature of the work carried out and advice given as medical physics expert is further explained under Regulation 20.

In order to fully meet the requirements of this particular regulation, Owgar Limited should finalise the service arrangements provided by the medical physics expert and continuity arrangements should they be required. Overall, pending the formalisation of the medical physics arrangement or engagement with the service, the inspector was satisfied that Owgar Limited were found to have the substantively addressed the deficit in medical physics expertise at Clontarf Chiropractic identified on the at previous inspection.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Following a meeting with representatives of the undertaking and speaking with the medical physics expert, a review of exposure parameters related to patient dosimetry had already been conducted, although the medical physics expert had

only become involved in the service from January 2021. In addition, the medical physics experts informed the inspector that they had worked with the radiation protection adviser to contribute to other matters relating to medical physics, for example, the review of equipment and quality assurance records, noting that diagnostic reference levels had been established in the service prior to his involvement. The medical physics expert had also proposed to provide further radiation safety training to individuals within the service, as needed following a gap analysis. Overall, management at Owgar Limited had demonstrated an assurance that a registered medical physics expert as required by the regulations was engaged to act or give specialist advice on matters relating to medical physics.

Judgment: Compliant

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

On the day of inspection, the inspector was satisfied that Owgar Limited had ensured that a registered medical physics expert, as per the requirements of this regulation, was appropriately involved for consultation and advice on matters relating to radiation protection concerning medical exposure to ionising radiation.

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	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

Compliance Plan for Clontarf Chiropractic OSV-0005953

Inspection ID: MON-0031734

Date of inspection: 04/03/2021

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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: We have initiated several actions which we believe will allow us to further enhance our compliance in the short to medium term. As follows:</p> <p>1: We have entered discussions with a second CORU registered radiographer as 'backup', to allow our current practitioner some time off and to give us the option to allocate some more time in our weekly schedule to our referrals. A SP contract should be in place, subject to satisfactory agreement with one month.</p> <p>2: We have agreed to purchase a nearly new X-ray unit which will provide for more accurate images with less exposure. Its installation is currently being planned with installer and MPE and should be completed by end April.</p> <p>3: We've since contacted an alternative MPE who is also willing to act for us. Given the possible change to MPE we postponed our initial RSC meeting. It is planned that the initial RSC meet will review documentation and DRL data, set up a DRL monitoring system and allow us to finalise contracts with service providers and move forward from there. We anticipate an onsite meeting with our MPE within the current month with a full RSC meeting and sign off on service provider agreements by end May 21 latest.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: See section 6 point 3 above</p>	

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: See section 6 point 3 above	

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 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 of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/05/2021
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	31/05/2021

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	30/04/2021