



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

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:	Unannounced
Date of inspection:	06 December 2019
Medical Radiological Installation Service ID:	OSV-0005953
Fieldwork ID:	MON-0028228

About the medical radiological installation:

Owgar Limited operating at Clontarf Chiropractic is one of Ireland's longest established chiropractic practices. It provides both a walk-in and appointment led chiropractic and x-ray service. Clontarf Chiropractic advertise the availability of standing X-ray imaging to diagnose back or neck complaints and have a modern 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
Friday 6 December 2019	10:50hrs to 11:30hrs	John Tuffy	Lead
Friday 6 December 2019	10:50hrs to 11:30hrs	Aileen Keane	Support

Summary of findings

An unannounced inspection was conducted of the undertaking Owgar Limited operating at Clontarf Chiropractic on the 6th December 2019 following receipt of information from the undertaking stating that the service was not compliant with Regulation 4, Regulation 5, Regulation 10 of the Regulations. The undertaking representative and designated manager were not available on the day of inspection to verify the findings of the inspectors. However, based on the information provided to HIQA and the findings on the day, inspectors were not sufficiently assured that Owgar Limited ensured compliance with Regulation 4, Regulation 5 and Regulation 10.

Following this inspection, HIQA issued an invitation to representatives of Owgar Limited to attend a meeting to discuss the findings of the inspection and facilitate an opportunity to bring supporting documentation that demonstrates compliance with Regulations 4, 5 and 10 which was not available on the day of inspection. A meeting was held on the 12th December 2019 to discuss the findings of the inspection with the undertaking representative and designated manager of Owgar Limited. The representatives of Owgar Limited did not present any supporting evidence that demonstrated compliance with Regulations 4, Regulation and Regulation 10 and accepted the non compliances found in respect of these regulations. Overall, the absence of appropriately trained and recognised individuals involved in the justification and optimisation process raises concerns on the conduct of medical exposures within the service and the ability of Owgar limited to demonstrate compliance with the full suite of regulations that explicitly require the involvement of a practitioner within the service.

Regulation 4: Referrers

On the day of inspection, there were no professional registration records available to indicate that the individuals that refer within Clontarf Chiropractic were entitled to refer individuals for medical radiological procedures. A review of a patient exposure log within the X-ray room indicated that there were 41 X-rays conducted between the 2nd of November and the 4th of December 2019. Patient records assessed at Clontarf Chiropractic indicated that X-ray referrals were made by professionals who were not recognised by the Regulations. Furthermore, upon review of a number of patient assessment records with associated x-ray referrals and upon viewing of the X-rays images on the computer archival system, all patients reviewed had lumbar spine x-rays conducted based on referrals from individuals not recognised under Regulation 4. This was subsequently accepted by representatives of Owgar Limited at the meeting on the 12th of December with authorised persons from HIQA.

Judgment: Not Compliant

Regulation 5: Practitioners

There were no professional registration records available on the day of inspection to assure inspectors that individual medical exposures took place under the clinical responsibility of those recognised and registered in Regulation 5. Furthermore, upon review of a number of patient assessment records with associated x-ray referrals, all patients reviewed had lumbar spine x-rays conducted based on referrals from individuals not recognised under Regulation 4 nor authorised by an individual who, under Regulation 5, can take clinical responsibility for a medical exposure. This was accepted by representatives of Owgar Limited at the meeting on the 12th of December with authorised persons from HIQA.

Judgment: Not Compliant

Regulation 10: Responsibilities

There was an absence of documentation available on the day of inspection to indicate that Owgar Limited had the necessary measures in place to demonstrate compliance with Regulation 10. There were no professional registration records available to demonstrate that the undertaking ensured all medical exposures took place under the clinical responsibility of a practitioner as defined in Regulation 5. In respect of the requirements that optimisation of medical exposures involves the practitioner, the medical physics expert and the person entitled to take x-rays, there was evidence that the radiation protection adviser associated with the service had outlined an annual QA plan to assess output of the equipment and there was a recent service of the equipment in August 2019. However, inspectors were not assured that all three individuals as required by Regulation 10(2) were involved in the optimisation process. Laminated procedures on the wall stated that three individuals within Clontarf Chiropractic were authorised to take x-rays and had signed a confirmation they had reviewed the local radiation rules. There was a training certificate displayed on the wall to indicate one staff member had attended a radiation protection supervisor update course however there was no supporting documentation to indicate those three individuals locally authorised to take X-rays at Clontarf Chiropractic were registered and recognised under Regulation 10(4) and had completed a course in radiation safety as required by Regulation 22. The findings in respect of this regulation was accepted by representatives of Owgar Limited at the meeting on the 12th of December.

Judgment: Not 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	Not Compliant
Regulation 5: Practitioners	Not Compliant
Regulation 10: Responsibilities	Not Compliant

Compliance Plan for Clontarf Chiropractic OSV-0005953

Inspection ID: MON-0028228

Date of inspection: 06/12/2019

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 4: Referrers	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 4: Referrers: Owgar Ltd, t/a Clontarf Chiropractic has contracted a CORU registered radiographer to act as a referrer (CORU #xxxxxx) to whom requests for x rays deemed necessary by our chiropractors are submitted. We believe this individual to be complaint under regulation 4(1)(d). The request will be assessed and a referral generated or refused on a case by case basis. This procedure is effective immediately and requests are now being generated for certain patients. A copy of our request form is attached.</p>	
Regulation 5: Practitioners	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 5: Practitioners: Our referrer is also our practitioner and is complaint under Regulation 5 (c) A copy of our referral form is attached. No images have been taken since our meeting at HIQA on 12/12/19. None will be taken until our practitioner commences on 18/1/20.</p>	
Regulation 10: Responsibilities	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: We believe that the request/referral system now in place with our registered practitioner</p>	

brings us substantially in compliance with Regulation 10.
A copy of our policy/procedure note for staff is attached.

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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Red	31/01/2020
Regulation 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a practitioner unless	Not Compliant	Red	31/01/2020

	the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),			
Regulation 4(1)(c)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),	Not Compliant	Red	31/01/2020
Regulation 4(1)(d)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or	Not Compliant	Red	31/01/2020
Regulation 4(1)(e)	A person shall not refer an individual for medical	Not Compliant	Red	31/01/2020

	radiological procedures to a practitioner unless the person referring ("the referrer") is a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner.			
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	31/01/2020
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Not Compliant	Red	31/01/2020
Regulation 5(b)	A person shall not take clinical responsibility for an individual	Not Compliant		31/01/2020

	<p>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</p>			
Regulation 5(c)	<p>A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).</p>	Not Compliant	Red	31/01/2020
Regulation 10(1)	<p>An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.</p>	Not Compliant	Red	31/01/2020
Regulation 10(2)(a)	<p>An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,</p>	Not Compliant	Red	31/01/2020

Regulation 10(2)(c)	An undertaking shall ensure that the optimisation process for all medical exposures involves those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under paragraph (4).	Not Compliant	Red	31/01/2020
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Red	31/01/2020
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Red	31/01/2020
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is	Not Compliant	Red	31/01/2020

	<p>entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or</p> <p>(v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.</p>			
Regulation 10(4)(b)	<p>Practical aspects of a medical radiological procedure may be delegated by the practitioner as appropriate, to one or more individuals,</p> <p>(i) registered by the Dental Council,</p> <p>(ii) registered by the Medical Council,</p> <p>(iii) registered by the Nursing and Midwifery Board of Ireland,</p> <p>(iv) whose name is entered in the register established and maintained by the Radiographers Registration Board</p>	Not Compliant	Red	31/01/2020

	<p>pursuant to section 36 of the Health and Social Care Professionals Act 2005, or</p> <p>(v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.</p>			
Regulation 10(5)	<p>An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.</p>	Not Compliant	Orange	
Regulation 10(6)	<p>An undertaking or practitioner shall not delegate practical aspects of a medical radiological procedure to a person other than an individual referred to in paragraph (4).</p>	Not Compliant	Red	31/01/2020
Regulation 10(7)	<p>A person shall not carry out practical aspects of a medical radiological procedure unless he or she is a</p>	Not Compliant	Red	31/01/2020

	practitioner or a person delegated pursuant to paragraph (4).			
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