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:	ACD Practice Management Ltd
Undertaking Name:	ACD Practice Management Ltd
Address of Ionising Radiation Installation:	Ardrum House, Bishopstown, Cork
Type of inspection:	Announced
Date of inspection:	16 May 2023
Medical Radiological Installation Service ID:	OSV-0005979
Fieldwork ID:	MON-0039354

About the medical radiological installation:

ACD Practice Management Ltd dental practice is located at Ardrum clinic in Bishopstown, Co Cork. We at Ardrum clinic provide professional dental and surgical treatments including cosmetic, implant, prosthetic, endodontic and periodontal treatment. The practice has one orthopantomogram (OPG) unit and one mobile intra-oral X-ray unit.

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 inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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 users[4] 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
Tuesday 16 May 2023	11:50hrs to 14:35hrs	Kay Sugrue	Lead
Tuesday 16 May 2023	11:50hrs to 14:35hrs	Noelle Neville	Lead

Summary of findings

An inspection of ACD Practice Management Ltd at Ardrum Clinic was carried out by inspectors on 16 May 2023. The inspection was initiated as a result of the non-return of a regulatory dental self-assessment questionnaire that had been issued to the undertaking in November 2022. Management informed inspectors that the dental self-assessment questionnaire was overlooked in error.

Management informed inspectors that there was one dentist performing dental X-rays under this undertaking. The dentist acted as the sole referrer and was the practitioner with clinical responsibility for all medical exposures performed in this practice, thereby meeting the requirements set out in Regulations 4 and 5 respectively. Regulation 6(3) requires an undertaking to provide a clear allocation of responsibilities for the protection of service users undergoing medical exposure. While noting that some responsibilities had been allocated as per Regulation 6(3), inspectors were informed that arrangements to ensure the continuity and access to Medical Physics Expert (MPE) services had not been maintained. Documentation viewed during the inspection showed that an MPE had been engaged for this dental practice up to April 2019, however, this arrangement had lapsed from that time up to the day of the inspection. Consequently, the lack of engagement of an MPE impacted compliance levels with several regulations including Regulations 6, 11, 14, 19, 20 and 21.

Inspectors found that there was a lack of evidence available to show that regular performance checks and quality assurance (QA) of medical radiological equipment had been carried at the time of the inspection. Consequently, inspectors were not assured that medical radiological equipment was kept under strict surveillance as required in Regulation 14. As an assurance measure, management informed inspectors that the dental X-ray equipment would not be used until such time as QA performance testing was conducted by an MPE.

A non-compliance was also found in relation to Regulation 8. Inspectors were informed by the dentist that orthopantomogram (OPG) examinations were routinely performed on service users attending for a first time consultation. The rationale for this approach was to out-rule any potential underlining diseases. Inspectors were not satisfied that each medical exposures performed using this described approach met the requirements as set out under Regulation 8 (1). Furthermore, a sample of patient records reviewed by inspectors showed that information relating to medical exposures taken in this practice was not consistently documented. Consequently, gaps in documentation resulted in a lack of evidence to show that there was a written referral for each medical radiological procedure performed, or that justification in advance of a medical exposure had occurred for each examination. As a result, inspectors were not satisfied that each medical exposure conducted at this clinic was appropriately justified on an individual basis and on the basis of a written referral as per the regulations.

Improvement in compliance was also required with respect of Regulation 13. Inspectors found that there was a lack of evidence to show that protocols for standard medical radiological procedures performed in this service had been established as per Regulation 13(1). Other aspects of this regulation also needed action by the undertaking to improve compliance including the requirement to ensure that referral guidelines were available, that information relating to the dose is included in the report of each medical exposure conducted and that a programme of clinical audit is undertaken and maintained at this installation.

Overall, the undertaking must take action to address the non-compliances identified by inspectors and should ensure that more attention is directed to improving staff awareness with respect of all regulatory requirements in relation to medical exposures following this inspection. The findings of this inspection were discussed with management and assurances were provided to inspectors that identified deficiencies would be addressed as a priority.

Following this inspection, ACD Practice Management Ltd was required to submit an urgent compliance plan to address urgent risks relating to equipment and MPE involvement. The undertaking's response did provide assurance that the risks identified on the day of inspection were addressed following the inspection.

Regulation 4: Referrers

From a review of documentation provided after this inspection and discussion with management at ACD Practice Management Ltd on site, inspectors were satisfied that referrals were from a registered dentist.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that as the sole practitioner for this undertaking, the dentist had clinical responsibility for medical exposures conducted at this dental practice thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that the undertaking had ensured that responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation were

allocated to the dentist who was the sole referrer and practitioner for this facility. However, not all aspects of responsibilities were allocated as required by Regulation 6(3). For example, the arrangement to ensure the continuity of involvement by an MPE in this service had not been maintained by the undertaking since April 2019. This meant that responsibilities under Regulation 20 had not been allocated to an MPE as per the regulations. Additionally, inspectors found that there was an overall lack of awareness on the requirement to engage a MPE for radiological practices. This lack of awareness regarding regulatory requirements was also evident in the lack of engagement with HIQA during the self-assessment process and also across the spectrum of regulations assessed during this inspection. Therefore, the undertaking needs to take action to ensure regulatory compliance regarding medical exposures to ionising radiation.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, the inspectors spoke with staff who explained how medical exposures are justified in advance. From the service user records reviewed, inspectors found that referrals for dental X-rays were not consistently documented in all cases and that justification in advance by a practitioner was not clearly evident in a sample of records viewed as required under this regulation.

Inspectors were informed by management that orthopantomagrams (OPGs) were routinely performed as a screening method for underlying conditions in service users attending the clinic for the first time. While this type of medical exposure can be beneficial for the early detection of disease and is considered a low dose procedure, the regulations required that each medical exposure is justified in advance by a practitioner in consideration of the risks and benefits and individual clinical details of the service user. From the process described, inspectors were not satisfied that the approach applied in this scenario gave sufficient consideration to the risk and benefits that an exposure may potentially cause while also considering alternative means of assessment that did not involve medical exposure to ionising radiation.

Staff informed inspectors that information relating to the risks and benefits was provided by the practitioner to services users in simple terms as required. Management informed inspectors that a poster conveying this information had been displayed in the waiting area but had been removed and not replaced when the waiting room was refurbished.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Following discussions with staff and review of documentation, inspectors were not satisfied that the undertaking had established, regularly reviewed and used DRLs at this facility as per Regulation 11(5).

Judgment: Not Compliant

Regulation 13: Procedures

Written protocols for standard dental radiological procedures were not available to view on the day of the inspection. Management verified to the inspectors that protocols had not been established as per Regulation 13(1).

From a sample of service user records viewed, inspectors determined that information relating to the dose of each medical exposure was not routinely documented in these records.

While staff referenced the criteria applied for carrying out medical imaging, inspectors were not assured that referral guidelines were consistently applied for all dental imaging, for example, the use of OPG as a screening tool previously discussed under Regulation 8. Additionally, referral guidelines were not available to view at the time of the inspection

Documentation to show that clinical audit relating to medical exposures was undertaken was not evident during this inspection. Staff demonstrated a lack of awareness regarding the requirement for clinical audit in this setting.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors spoke with the undertaking and reviewed records and documentation provided during the inspection. The records reviewed showed that medical radiological equipment had been subject to QA testing and acceptance testing by an MPE in April 2019. Since then, there was a lack of evidence to show that regular performance testing of medical radiological equipment by an MPE had been carried out. Additionally, inspectors found that an appropriate QA programme, including an assessment of dose and internal quality control checks, were not implemented and maintained at this facility. The evidence gathered during the course of this inspection did not satisfy inspectors that the dental radiological equipment at this practice was kept under strict surveillance regarding radiation protection.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. Information provided by the undertaking following

the issue of an urgent compliance plan did provide assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

At the time of inspection, inspectors were not satisfied that ACD Practice Management Ltd had put in place the necessary arrangements to ensure an MPE was engaged for the service. Consequently, this meant that continuity of expertise of an MPE was not evident as per Regulation 19(9). From documentation reviewed and discussions with management, the last MPE site visit occurred in April 2019 with a lack of evidence to demonstrate that any of the arrangements that had been in place in the past had been maintained by the undertaking.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. Information provided by the undertaking following the issue of an urgent compliance plan did provide assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

The lack of MPE engagement as detailed under Regulation 19 impacted compliance against Regulation 20. Evidence gathered by inspectors following documentation review and discussion with management did not provide assurance that an MPE acted or gave specialist advice, as appropriate, on matters relating to radiation physics at the dental practice as required by Regulation 20(1). This also meant that MPE responsibilities as outlined under Regulation 20(2) were not met, providing little assurance regarding dosimetry, optimisation and the strict surveillance of medical radiological equipment.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. Information provided by the undertaking following the issue of an urgent compliance plan did provide assurance that the risk was addressed.

Judgment: Not Compliant

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

From documentation reviewed and discussions with management, inspectors found that ACD Practice Management Ltd had not maintained arrangements to ensure that an MPE was appropriately involved in this dental practice. This meant that the undertaking did not meet the requirements set out under this regulation.

Under this regulation, the undertaking was required to submit an urgent compliance plan to address an urgent risk. Information provided by the undertaking following the issue of an urgent compliance plan did provide assurance that the risk was addressed.

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	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant

Compliance Plan for ACD Practice Management Ltd OSV-0005979

Inspection ID: MON-0039354

Date of inspection: 16/05/2023

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	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: **The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.**	
Regulation 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: **The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.**	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: **The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality**	

Authority that actions will be taken which will result in compliance with the regulations.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:

The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.

Regulation 14: Equipment	Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:

The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.

Regulation 19: Recognition of medical physics experts	Not Compliant

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

The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.

Regulation 20: Responsibilities of medical physics experts	Not Compliant

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

The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.

Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: **The undertaking did not submit a compliance plan for this report. Therefore, the undertaking did not adequately assure the Health Information and Quality Authority that actions will be taken which will result in compliance with the regulations.**	

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.	Not Compliant	Orange	
Regulation 8(1)(a)	A person shall not carry out a medical exposure unless it shows a sufficient net benefit, weighing the total potential diagnostic or	Not Compliant	Orange	

	therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and			
Regulation 8(1)(b)	A person shall not carry out a medical exposure unless it takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.	Not Compliant	Orange	
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.	Not Compliant	Orange	
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Orange	
Regulation 8(10)(b)	A referrer shall not refer an individual	Not Compliant	Orange	

	to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and			
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Not Compliant	Orange	
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that	Substantially Compliant	Yellow	

	the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.			
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.	Not Compliant	Orange	
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical	Not Compliant	Orange	

	radiological procedure are established for each type of equipment for relevant categories of patients.			
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	
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	15/06/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	15/06/2023
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Red	15/06/2023

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	Red	15/06/2023
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.	Not Compliant	Red	15/06/2023
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Red	15/06/2023

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 subject to medical exposure,	Not Compliant	Red	15/06/2023
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Red	15/06/2023
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	Not Compliant	Red	15/06/2023

	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, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			

Regulation 20(3)	The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise with the radiation protection adviser.	Not Compliant	Red	15/06/2023
Regulation 21(1)	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.	Not Compliant	Red	15/06/2023