

## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Complete DXA Solutions
Undertaking Name:	Complete DXA Solutions
Address of Ionising Radiation Installation:	Rm 203 Regus Building, City Gate Plaza, Mahon, Cork
Type of inspection:	Announced
Date of inspection:	03 September 2024
Medical Radiological Installation Service ID:	OSV-0008250
Fieldwork ID:	MON-0040056

## About the medical radiological installation (the following information was provided by the undertaking):

Complete DXA Solutions, established in 2022, specialises in providing dual-energy X-ray absorptiometry (DXA) scans to patients in County Cork and Kerry. Our primary objective is to serve both public and private sector patients by delivering prompt, high-quality, and accurate medical radiological services. We are dedicated to ensuring exceptional patient care by collaborating closely with medical clinicians. This partnership enables us to provide the necessary DXA scans as requested, recognising the critical role these scans play in diagnosing and managing various medical conditions. Our focus on accuracy is paramount, as it directly impacts patient outcomes. At Complete DXA Solutions, we adhere to industry best practices to ensure the reliability and efficiency of our DXA scans. Our team of radiology professionals is rigorously trained to uphold stringent quality and safety standards throughout the scanning process, prioritising the well-being of our patients. We operate with a patient-centric philosophy, striving to create a seamless and comfortable experience for individuals undergoing DXA scans. We recognise and value the trust that both medical clinicians and patients place in our services, and we are committed to continuously enhancing our offerings to meet the evolving needs of the community.

## 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, as amended. 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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 3 September 2024	09:05hrs to 10:15hrs	Noelle Neville	Lead

## Summary of findings

An inspection of the undertaking at Complete DXA Solutions was carried out on 3 September 2024 by an inspector to assess compliance with the regulations at this facility. As part of this inspection, the inspector visited the dual energy X-ray absorptiometry (DXA) unit, spoke with staff and management and reviewed documentation. The inspector noted that the undertaking, Complete DXA Solutions, demonstrated compliance with all regulations reviewed.

The undertaking had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. The inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Overall, the inspector was satisfied that a culture of radiation protection was embedded at Complete DXA Solutions and clear and effective management structures were in place to ensure the radiation protection of service users.

### Regulation 4: Referrers

The inspector was satisfied from discussions with staff and management and from reviewing a sample of referrals that medical exposures were only accepted from individuals entitled to refer as per Regulation 4 at Complete DXA Solutions.

Judgment: Compliant

### Regulation 5: Practitioners

The inspector was satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Complete DXA Solutions.

Judgment: Compliant

## Regulation 6: Undertaking

The inspector found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. The inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures. Overall, the inspector was satisfied that the undertaking had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the facility.

Judgment: Compliant

## Regulation 8: Justification of medical exposures

The inspector was satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. The undertaking at Complete DXA Solutions had a document titled *Justification Policy*. This document outlined the justification process in place at the facility and staff responsibilities in relation to same. The inspector reviewed a sample of records in DXA and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

## Regulation 10: Responsibilities

The inspector noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at Complete DXA Solutions by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The inspector found that facility DRLs had been established, regularly reviewed and used for DXA having regard to national DRLs.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols were in place at Complete DXA Solutions for standard radiological procedures as required by Regulation 13(1). Regulation 13(2) states that an undertaking shall ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for DXA and found that the requirements of Regulation 13(2) were met. Referral guidelines were also adopted at the facility and were available to staff and referrers as required by Regulation 13(3). Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's national procedures document, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). The inspector found that the undertaking and staff at Complete DXA Solutions had sought to align clinical audit practices with the national procedures and had a document titled *Clinical Audit Strategy*. This document included information on the duration of the strategy, the schedule and oversight of audit, communication methods, team involvement and tools to be used when carrying out audit at the facility. The inspector noted that audits of LMP check, triple identification and peer review - image quality audits had been carried out at Complete DXA Solutions.

Judgment: Compliant

### Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Complete DXA Solutions as required by Regulation 14(1). The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The inspector reviewed records of regular performance testing and was satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to

report any equipment faults or issues arising if needed. In addition, the inspector was satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at Complete DXA Solutions had a document titled *Pregnancy and LMP Policy*. This document included information on the pregnancy procedures in place at the facility. From a sample of records reviewed and discussion with staff, the inspector was satisfied that a referrer or practitioner inquired as to the pregnancy status of service users and recorded the answer to the query in writing.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

The inspector was satisfied from discussions with staff and management and a review of documents that Complete DXA Solutions had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The incident management process in place at the facility was outlined in a document titled *Incident Reports Policy*. The inspector noted that there had been no incidents reported to HIQA since the commencement of the regulations in 2019.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Complete DXA Solutions.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts



The inspector reviewed the professional registration certificate of the MPE at Complete DXA Solutions and was satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted that the MPE was involved in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Complete DXA Solutions. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). The MPE was available to carry out dose calculations if needed for any incidents relating to ionising radiation and contributed to the training of staff in relevant aspects of radiation protection. In addition, the MPE also acted as radiation protection adviser (RPA) at the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, the inspector was satisfied that the level of involvement of the MPE at Complete DXA Solutions was commensurate with the radiological risk posed by the facility as required by Regulation 21.

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, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
<b>Summary of findings</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant