



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Osteoporosis Scanning Centre
Undertaking Name:	Digital Diagnostics Ltd
Address of Ionising Radiation Installation:	Mayo Medical Centre, Lawn Road, Castlebar, Mayo
Type of inspection:	Announced
Date of inspection:	15 October 2025
Medical Radiological Installation Service ID:	OSV-0006418
Fieldwork ID:	MON-0048476

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

The Osteoporosis Scanning Centre has been a provider of Dual-energy X-ray Absorptiometry (DXA) services for over 30 years. Beginning with peripheral DXA assessments, the centre has evolved to offer axial evaluations using fanbeam technology, consistently upgrading to state-of-the-art equipment to ensure diagnostic precision and patient safety. The centre is committed to serving both public and private patients, ensuring equitable access to high-quality osteoporosis screening. It is a resource for local general practitioners and hospital-based clinicians, who refer patients for assessment and monitoring. This broad integration into community and hospital care pathways underscores the centre's role in supporting bone health across the region. Oversight is provided by fully ISCD-certified clinician with over two decades of experience in bone densitometry who maintains current credentials with the International Society for Clinical Densitometry (ISCD), ensuring adherence to best practices and international standards in DXA interpretation and quality assurance. Patient safety and accessibility are central to the centre's operational ethos. The facility is fully accessible to individuals with limited mobility, and all procedures are conducted with a strong emphasis on radiation protection. The centre adheres to the ALARA principle (As Low As Reasonably Achievable), ensuring that ionizing radiation exposure is minimized through optimized protocols, regular equipment calibration, and staff training. All scans are performed using the lowest effective dose necessary to achieve diagnostic accuracy.

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 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
Wednesday 15 October 2025	10:00hrs to 12:30hrs	Lee O'Hora	Lead

Summary of findings

As part of this inspection, the inspector reviewed documentation and visited the DXA scanning room and spoke with staff and management. On this inspection, the inspector found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures.

The inspector was assured that the undertaking, Digital Diagnostics Ltd, had robust systems and processes in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. This allocation of responsibility was clearly defined in documentation supplied and staff knowledge of their individual roles in the safe delivery of this service was consistently articulated to the inspector.

In this service, practical aspects of medical radiological procedures were delegated to individuals registered with the Nursing and Midwifery Board of Ireland. The associated professional registration and radiation safety training records satisfied the requirements of the regulations and also demonstrated a commitment to ongoing education and training in the area of radiation protection which was facilitated and supported by the undertaking.

The inspector was assured that the undertaking kept the equipment under strict surveillance using a well defined and maintained multidisciplinary quality assurance (QA) programme. The undertaking utilised its medical physics expert (MPE) appropriately in the safe delivery of medical exposures and the inspector was satisfied that all associated regulatory requirements were met as a result of this strong relationship and engagement.

However, while many areas of good practice were noted during the inspection, two areas needing the attention of the undertaking were highlighted, namely: the documented delegation of responsibility for the practical aspects of DXA exposures and a clear process to ensure that the referrers or practitioners are involved in the inquiry of pregnancy status.

Overall, the inspector was assured that the undertaking had appropriate systems in place to support the safe delivery of medical exposures and both management and staff consistently demonstrated a commitment to the continual improvement of DXA services provided.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Osteoporosis Scanning Centre only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Similarly, following record review and staff communication, the inspector was satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures. Documentation reviewed clearly identified the practitioners and their specific roles in relation to clinical responsibility at Osteoporosis Scanning Centre.

Judgment: Compliant

Regulation 6: Undertaking

Overall responsibility for the radiation protection of service users lay with Digital Diagnostics Ltd. Lines of communication and governance structures were clearly defined in documentation reviewed as part of this inspection and clearly and consistently communicated to the inspector on the day of inspection. All staff involved in the provision of this service were available on the day of inspection, the clear allocation of responsibility and staff's knowledge of their individual roles in the safe delivery of this service was well defined in documentation and consistently articulated to the inspector.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals for a number of DXA scans on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure that all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. In line with Regulation 8, all referrals reviewed by the inspector were available in writing, stated the reason for the request and were accompanied by medical data which

allowed the practitioner to consider the benefits and the risk of the medical exposure.

Osteoporosis Scanning Centre provided service users with pamphlets which included information relating to the benefits and risks associated with the radiation dose from DXA scanning.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector reviewed radiation safety procedure documentation, a sample of referrals for medical radiological procedures and spoke with staff and was satisfied that all medical exposures at Osteoporosis Scanning Centre took place under the clinical responsibility of a practitioner. The inspector was also assured that the optimisation process involved the practitioner and the MPE and that the justification process for individual medical exposures involved the practitioner and the referrer.

In this service, practical aspects of medical radiological procedures were delegated to individuals registered with the Nursing and Midwifery Board of Ireland. The associated professional registration and radiation safety training records were reviewed as part of the inspection process and were found to satisfy the requirements of Regulation 10(4). Staff who spoke with the inspector on the day demonstrated a commitment to ongoing education and training in the area of radiation protection. Similarly, records reviewed and staff communication satisfied the inspector that the undertaking facilitated and supported this commitment.

However, despite the good practice noted around the training of the relevant staff, a record of the delegation was not available on the day of the inspection. This regulatory requirement should be addressed by the undertaking to ensure compliance with all aspects of Regulation 10.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Following a review of diagnostic reference level (DRL) documentation, the inspector was satisfied that DRLs had been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility.

Where local facility DRLs exceeded national DRLs, documentation detailing the associated reviews and corrective actions was available. However, while meeting the requirements of the regulations in this case, potential for further patient dose optimisation was being considered by the undertaking in consultation with their

MPE. This was seen as an area worthy of further consideration and would improve the undertaking's ability to ensure all patient dose optimisation possibilities are considered.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for all standard medical radiological procedures and a sample of these were reviewed in the clinical area. Staff who spoke with the inspector in the clinical area clearly articulated how these protocols were made available to them.

The inspector spoke with staff and reviewed a sample of DXA scan imaging reports on the day of inspection. The inspector observed that information relating to patient exposure formed part of all reports reviewed.

The inspector reviewed information relating to clinical audit via documents supplied and by speaking with staff and management and was assured that the approach to clinical audit was in accordance with national procedures established by HIQA.

Judgment: Compliant

Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. The process to ensure this included the implementation and maintenance of a QA programme including appropriate MPE acceptance and regular performance testing, manufacturer equipment service and in-house daily and weekly testing.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector observed and was informed by staff that Osteoporosis Scanning Centre asked all service users attending for DXA scans to complete a DXA consent form. This form included a pregnancy status inquiry, where the service user indicated a yes or no answer to the pregnancy question. This form also acted as the record of the inquiry. The inspector was informed that the pregnancy question was then asked again by the DXA technologist at the point of imaging when relevant,

namely for female patients of childbearing potential. The inspector was assured that in cases where pregnancy was confirmed or could not be ruled out, clear procedural pathways involving the input of the referrer and practitioner were well defined.

However, after a review of the evidence available, the inspector was not assured that the current measures involved the referrer or the practitioner in the inquiry and associated record of the answer when relevant. Therefore, further work to ensure that a practitioner or a referrer is involved in the inquiry and recording of the answer is necessary to satisfy Regulation 16.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector was satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by the undertaking.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise were described to the inspector by staff. All evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at Osteoporosis Scanning Centre.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and associated records and speaking with staff, the inspector was satisfied that the undertaking had arrangements in place to ensure the involvement and contribution of the MPE was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided.

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
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially 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

Compliance Plan for Osteoporosis Scanning Centre OSV-0006418

Inspection ID: MON-0048476

Date of inspection: 15/10/2025

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, as amended.

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 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: The practitioner has prepared a document formally delegating the practical aspects of DXA scanning to the appropriate staff members in accordance with Regulation 10. A completed and signed copy of this document is also retained in the relevant staff members' personnel files.</p>	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: The pre-existing practice, whereby women of childbearing age (55 and under) completed a pregnancy status declaration form in the presence of the RGN conducting the scan, has been revised to fall in line with Regulation 16 as required. Henceforth, patients attending the Osteoporosis Scanning Centre will be provided with the newly revised form, which must be completed within a suitable timeframe and submitted prior to their appointment date being confirmed. The form will be reviewed and signed by the practitioner, who assumes clinical responsibility for all scans performed. The relevant policy and procedure has been updated to reflect this change.</p>	

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 10(5)	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.	Not Compliant	Orange	24/11/2025
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Not Compliant	Orange	14/12/2025

Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Not Compliant	Orange	14/12/2025
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