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:	GP Scans
Undertaking Name:	GP Scans Ltd
Address of Ionising Radiation Installation:	Harrmack House, Tuam Road, Galway, Galway
Type of inspection:	Announced
Date of inspection:	24 January 2024
Medical Radiological Installation Service ID:	OSV-0007023
Fieldwork ID:	MON-0042303

About the medical radiological installation:

GP Scans DXA service was established in 2019 with the primary aim of delivering high quality bone densitometry and body composition scanning to patients within our practice and referred from other qualified practitioners.

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
Wednesday 24 January 2024	13:00hrs to 15:00hrs	Lee O'Hora	Lead

Summary of findings

An inspection of GP Scans Ltd at GP Scans was conducted by an inspector on the 24 January 2024 to assess compliance against the regulations. As part of this inspection, the inspector reviewed documentation and visited the DXA scanning room and spoke with staff. This inspection related to DXA procedures used as part of service user's medical diagnosis or treatment.

On this inspection, the inspector found effective governance, leadership and management arrangements were in place. The clear allocation of responsibility and subsequent delegation of responsibility for practical aspects of DXA medical radiological procedures was appropriately documented and communicated which satisfied all regulatory requirements.

Following a review of documents and records, and speaking with staff, the inspector was satisfied that systems and processes were 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.

After speaking to staff and reviewing radiation safety related documentation and records, the inspector was assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided and satisfied the requirements of the regulations**.**

Some areas for improvement included the completion and record keeping of all equipment quality assurance (QA) testing as specified in policies, procedures and guidelines (PPG) as well as documenting and maintaining training requirements for all individuals carrying out the practical aspects of DXA scanning in line with regulatory requirements and the Nursing and Midwifery Board of Ireland's (NMBI) standards and requirements.

One other area noted as not meeting the requirements of the regulations from their transposition in 2019 was the inclusion of information relating to patient exposure forming part of the DXA report. However the inspector was satisfied that processes had been implemented at the time of inspection to address this area of non-compliance.

Overall, although some work was required by the undertaking to meet full compliance, the inspector was satisfied that the areas for improvement did not pose a risk in relation to the radiation protection of service users at this facility.

Regulation 4: Referrers

Following review of radiation safety documentation, a sample of referrals for DXA procedures and by speaking with staff, the inspector was satisfied that GP Scans only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

After radiation safety document and imaging record review and by speaking with staff the inspector was assured that adequate systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

GP Scans Ltd was identified as the undertaking with overall responsibility for the protection of service users from medical exposures to ionising radiation. Based on the evidence gathered as part of this inspection, the inspector was assured that the undertaking had provided a clear allocation of responsibility for the protection of service users from medical exposures to ionising radiation. For example, where aspects of the medical radiological procedure were delegated by a practitioner to individuals registered with the Nursing and Midwifery Board of Ireland, formal records of the delegation were available. Also a service level agreement (SLA) established the undertakings allocation of responsibility to the MPE at GP Scans. Similarly, documents reviewed and communication with staff highlighted the clear communication pathways between the relevant staff at this facility.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of DXA referrals on the day of inspection.

The inspector was assured that processes were in place to ensure 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 on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Patient questionnaire forms supplied to the inspector provided service users with information relating to the benefits and risks associated with the radiation dose from DXA scanning.

Judgment: Compliant

Regulation 10: Responsibilities

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner.

Where aspects of the medical radiological procedure were delegated by a practitioner to individuals registered with the Nursing and Midwifery Board of Ireland, records of the delegation and associated professional registration was available and reviewed as part of the inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of DRLs, the inspector was satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility.

Judgment: Compliant

Regulation 13: Procedures

The inspector reviewed a sample of reports for DXA medical radiological procedures and found that information relating to the patient exposure formed part of the

report for all reports generated since the beginning of January 2024. However, it was noted that reports generated before this date did not include information relating to patient exposure.

The inspector was subsequently informed that this process had been adopted by the undertaking in January of 2024 and was now standard practice for all DXA reports generated at this facility.

Judgment: Substantially Compliant

Regulation 14: Equipment

Documentation reviewed and staff communication established that this facility's QA program included routine daily in-house testing, annual manufacturer preventative maintenance and annual MPE quality assurance testing. Records of daily QA and annual MPE equipment testing were provided and reviewed. However, a record of manufacturer preventive maintenance completed within the time line specified was not available during the course of the inspection. This was an area that needs to be addressed by the undertaking to ensure that records are available for all aspects of quality assurance specified by documentation as necessary for the strict surveillance of radiology equipment.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Following documentation and imaging record review and after speaking with staff, the inspector was assured that the undertaking had processes in place to ensure that all appropriate service users were asked about pregnancy status and the answer recorded in a manner satisfying the requirements of Regulation 16.

Multilingual posters were observed in the facility which increased awareness of individuals to whom Regulation 16 applies.

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 and the details were available in a service level agreement (SLA) reviewed as part of this inspection. All evidence supplied satisfied

the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the facility, the inspector was assured that the undertaking had arrangements in place to ensure the involvement and contribution of 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 staff 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

Regulation 22: Education, information and training in field of medical exposure

Regulation 22 specifies that those delegated the practical aspects of medical exposures have completed training as prescribed by the relevant professional body, in this case the NMBI's guidance on *Nurses Undertaking the Practical Aspects of Dual Energy X-Ray Absorptiometry (DXA) Scanning for Adults Standards and Requirements for Education Programmes* which outlines the requirements for nurses who are delegated practical aspects.

Training records of all individuals undertaking the practical aspects of DXA scanning were provided to the inspector. While initial training records were available for all staff completing the practical aspects of DXA scanning, records in relation to continuing education and training after qualification were only available for some staff completing the practical aspects of DXA scanning. This was noted as an area for improvement required by the undertaking to meet compliance with Regulation 22.

Judgment: Substantially 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	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	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
Regulation 22: Education, information and training in field of medical exposure	Substantially Compliant

Compliance Plan for GP Scans OSV-0007023

Inspection ID: MON-0042303

Date of inspection: 24/01/2024

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 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: As per the report, the above deficit in reporting the patient exposure has been rectified as of the 1st of January 2024.	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: The above documentation has been requested from the manufacturer and copies will be kept to be available for review in the future.	
Regulation 22: Education, information and training in field of medical exposure	Substantially Compliant
Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure: We have addressed the concern in continuing education by ensuring our staff will be partaking in regular CPD accredited course with an appropriate body such as the IOD, ISCD and the Irish DXA society moving forward.	

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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	01/01/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	22/03/2024
Regulation 22(4)	An undertaking shall ensure that the persons referred to in paragraph (1) undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques	Substantially Compliant	Yellow	01/05/2024

	and the relevant radiation protection requirements.			
Regulation 22(5)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	22/03/2024