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:	Dexascan & Bone Health Unit
Undertaking Name:	Dexascan & Bone Health Unit
Address of Ionising Radiation Installation:	Unit III, Lugh Medical Centre, College Height's, Dundalk, Louth
Type of inspection:	Announced
Date of inspection:	23 February 2022
Medical Radiological Installation Service ID:	OSV-0006883
Fieldwork ID:	MON-0034551

About the medical radiological installation:

Dexascan & Bone Health Unit provide a dual-energy X-ray absorptiometry (DXA) scanning service in Dundalk, Co. Louth. The DXA service commenced in March 2009 and provides DXA imaging procedures to local general practitioners (GP) and some local long-stay units.

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 23 February 2022	09:30hrs to 10:30hrs	Kirsten O'Brien	Lead

Summary of findings

An on-site inspection was carried out on the 23 February 2022 at Dexascan & Bone Health Unit to review measures put in place to achieve compliance with the regulations following a previous inspection carried out on the 26 May 2021.

From a review of documentation and speaking with staff and management, the inspector was satisfied that measures had been put in place to ensure that all referrals for dual-energy X-ray absorptiometry (DXA) radiological procedures were from referrers entitled to refer as per Regulation 5. A practitioner was found to take clinical responsibility for all medical exposures and carried out justification on each individual referral for DXA radiological procedures in advance.

On the day of inspection, written protocols relating to the conduct of DXA radiological procedures were available for review. Diagnostic reference levels (DRLs) had been established and compared to national DRLs for DXA radiological procedures carried out at Dexascan & Bone Health Unit. Similarly, information relating to the radiation dose of individual procedures was included on the report of DXA radiological procedures.

From speaking with staff and the review of this documentation, the inspector was satisfied that the DXA radiological equipment at the Unit is kept under strict surveillance regarding radiation protection. A medical physics expert (MPE) had been formally engaged by the undertaking and the inspector found that the MPE was appropriately involved, as appropriated, in the radiation protection of medical exposures to ionising radiation at Dexascan & Bone Health Unit. The inspector reviewed records of quality assurance (QA) carried out by the MPE and a report of servicing by the manufacturer which had been carried out since the last inspection.

Overall the inspector was assured that the undertaking had put measures in place to address the non-compliances with the regulations identified on the previous inspection of Dexascan & Bone Health Clinic.

Regulation 4: Referrers

From a review of documentation and speaking with staff on the day of inspection, the inspector were satisfied that only referrals for DXA procedures from individuals entitled to refer, as per Regulation 4, were carried out at the Unit.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only a practitioner, as defined in the regulations and registered with the appropriate professional regulator, took clinical responsibility for individual medical exposures at Dexascan & Bone Health Unit.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed documentation provided and spoke with staff and management on the day of inspection and was satisfied that a clear allocation of responsibility for the radiation protection of patients was now in place at Dexascan & Bone Health Unit.

The clinical director of the Unit was identified as the practitioner with clinical responsibility for all DXA imaging procedures carried out. Additionally, the undertaking had delegated the practical aspects of DXA imaging procedures to an appropriately registered individual. A formalised arrangement had also been put in place to ensure that an MPE was appropriately involved, as appropriate, for consultation and advice on matters relating to radiation protection of service users.

Judgment: Compliant

Regulation 8: Justification of medical exposures

A sample of records of DXA radiological procedures were reviewed during the on-site inspection. The inspector found that a practitioner, registered with the Medical Council, took clinical responsibility for justifying all individual procedures in advance. All referrals reviewed were in writing, stated the reason for requesting the radiological procedure in addition to containing sufficient medical data to allow the practitioner to carry out a justification assessment. The record of justification by the practitioner for each individual referral was also available for review on the day of inspection.

Judgment: Compliant

Regulation 10: Responsibilities

From speaking with management, and reviewing documents and other records, the inspector was satisfied that a registered medical practitioner took clinical responsibility for all DXA radiological procedures conducted at the Unit. Similarly, a referrer and practitioner were involved in the justification process. The inspector was also satisfied that the MPE, the practitioner and the individual delegated the practical aspects were involved in the optimisation process for all medical exposures conducted at Dexascan & Bone Health Unit.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for DXA radiological procedures conducted at Dexascan & Bone Health Unit by the MPE as part of the annual QA carried out on the equipment. The inspector found that these DRLs had been reviewed in relation to national DRLs to ensure the optimisation of DXA radiological procedures at the Unit.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection written protocols for the conduct of DXA radiological procedures were available at the console of the equipment. Additionally a sample of the reports of DXA procedures were reviewed by the inspector who found that information relating to the radiation dose of each individual procedure was included on the report.

Judgment: Compliant

Regulation 14: Equipment

On the day of inspection, records and documentation relating to QA and performance testing were reviewed. An appropriate QA programme had been implemented which included an assessment of radiation dose associated with DXA radiological procedures conducted at Dexascan & Bone Health Unit. Annual QA had been carried out by an MPE and preventative maintenance and servicing had also been conducted by the manufacturer since the last inspection.

From the evidence reviewed on the day of inspection, the inspector was satisfied that the DXA radiological equipment at Dexascan & Bone Health Unit is kept under

strict surveillance regarding radiation protection.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Dexascan & Bone Health Unit had formally engaged a recognised MPE and had appropriate access to medical physics expertise as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection the undertaking had ensured that an MPE was available to act and give specialist advice on matters relating to radiation protection of service users at Dexascan & Bone Health Unit. The MPE was found to contribute to optimisation, including the establishment of DRLs, evaluation of dose delivered to service users, and QA at the Unit.

Judgment: Compliant

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

The inspector found that an MPE was appropriately involved for consultation and advice on matters relating to radiation protection at the Unit.

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 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	Compliant
Regulation 14: Equipment	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 Dexascan & Bone Health Unit OSV-0006883

Inspection ID: MON-0034551

Date of inspection: 23/02/2022

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**
Outline how you are going to come into compliance with :	

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