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:	Dexa Protection
Undertaking Name:	Dexa protection
Address of Ionising Radiation Installation:	17 Fair Street, Drogheda, Louth
Type of inspection:	Announced
Date of inspection:	18 January 2024
Medical Radiological Installation Service ID:	OSV-0006061
Fieldwork ID:	MON-0042298

About the medical radiological installation:

Dexa Protection provides an osteoporosis screening service located in Drogheda, Co. Louth. The facility has one dual-energy X-ray absorptiometry (DXA) scanner. Dexa Protection is open Monday to Thursday between the hours of 9:00 and 17:00.

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
Thursday 18 January 2024	10:30hrs to 12:30hrs	Kirsten O'Brien	Lead

Summary of findings

An inspection of Dexa Protection was carried out by an inspector on the 18 January 2024 to assess compliance with the regulations. A sample of referrals, documentation and other records were reviewed by the inspector as part of the inspection process. The inspector also spoke with staff involved in the provision of the dual-energy X-ray absorptiometry (DXA) service.

On the day of inspection, only practitioners took clinical responsibility for individual medical exposures at Dexa Protection. The practitioner had delegated the practical aspects of DXA procedures conducted at the unit to appropriately registered individuals. The inspector found that the majority of referrals to the facility were from general practitioners (GPs) or consultants who were registered medical practitioners.

A medical physics expert (MPE) was found to be appropriately involved to provide specialist advice on matters relating to radiation protection at the practice. In addition, the DXA equipment was found to be kept under strict surveillance with regards to radiation protection as required by Regulation 14. The undertaking, Dexa Protection, had also ensured that diagnostic reference levels (DRLs) and written procedures were established and available to staff working at the practice.

However, while referrers were allocated responsibility for inquiring and recording the answer regarding the pregnancy status of applicable patients, the inspector was not satisfied that a record of this inquiry was available for all relevant patients. While noting that a self-declaration of pregnancy status was completed and reviewed by a registered nurse prior to completing DXA procedures for relevant patients, the inspector was not satisfied that the referrer or a practitioner had made the inquiry in all relevant cases, and documented the response, as required by the regulations.

The inspector reviewed documentation and spoke with staff and found that appropriate arrangements were in place for recording and analysing any accidental or unintended exposures. In addition, the inspector was assured that staff at Dexa Protection ensured the MPE contributed to the analysis of any accidental or unintended exposures which may occur and that arrangements were in place to notify HIQA should a significant event occur at the practice.

Overall on the day of inspection, from the evidence available, the inspector was satisfied that the management and staff at Dexa Protection were committed to the safe delivery of DXA procedures. Notwithstanding the area of improvement needed to achieve full compliance with Regulation 16, a high level of compliance with the regulations was found during the inspection.

Regulation 4: Referrers

The inspector was assured that DXA procedures were only performed based on referrals from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Only those entitled to act as practitioners were found to take clinical responsibility for DXA scans carried out at Dexa Protection.

Judgment: Compliant

Regulation 6: Undertaking

The governance and management arrangements to ensure the safe provision of the DXA screening service at Dexa Protection were reviewed on the day of inspection. Overall, the inspector found that there was a clear allocation of responsibility for the radiation protection of patients attending the practice.The inspector was assured that only appropriate individuals took clinical responsibility for medical exposures and that the practical aspects were only delegated to appropriately recognised persons by a practitioner.

A clinical nurse manager, who was also the designated manager, was the person responsible for the day-to-day operation of the practice. The clinical nurse manager was supported in the management of the DXA screening service by a radiation protection officer. The undertaking representative was the practitioner in charge of the screening service and the line manager of the clinical nurse manager. Staff informed the inspector that there were good lines of communication within the practice with regards to radiation protection.

In addition, the practice had a radiation safety committee (RSC) which met annually. The RSC was the official forum for discussing matters relating to radiation protection and included representation from the practitioner, staff, MPE and persons involved in the practical aspects. Minutes of past meetings were reviewed as part of this inspection process and the terms of reference of this committee were also provided to the inspector.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The sample of referrals reviewed by the inspector were found to be 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. Dexa Protection only accepted referrals from external referrers who were mainly GPs and met the requirements of the regulations.

All referrals were justified in advance by a practitioner. The record of justification of medical radiological procedures in advance by a practitioner was available for all medical radiological procedures reviewed over the course of the inspection. The inspector found evidence of where additional information was requested before a referral was justified and how this process was managed.

The inspector observed information about the benefits and risks associated with the radiation dose from DXA procedures available to patients in the form of leaflets in waiting areas at the practice and also online on the practice's website.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector found that a registered medical practitioner, who had completed additional education relating to DXA, was the practitioner with overall clinical responsibility for medical exposures conducted at the practice. Additionally, the clinical evaluation of the outcome in the form of a written report was completed by practitioners.

The inspector was satisfied from speaking with staff and reviewing a sample of records that the referrer and a practitioner were involved in the justification of all DXA procedures carried out at Dexa Protection. The practical aspects of carrying out the DXA imaging were delegated to individuals registered with the Nursing and Midwifery Board of Ireland who had completed training in the conduct of DXA procedures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for DXA procedures at the practice. The DRLs were found to have been compared to the national DRLs as required by the regulations. The inspector also observed the DRLs displayed in the DXA scan room.

Judgment: Compliant

Regulation 13: Procedures

The inspector found that written protocols were established for DXA procedures for standard radiological views. The inspector also found that information about the radiation dose was included on the sample of reports reviewed on the day of inspection.

Judgment: Compliant

Regulation 14: Equipment

The inspector found that appropriate quality assurance (QA) programmes, which included an assessment of dose, were in place to ensure that medical radiological equipment at Dexa Protection was kept under strict surveillance. An up-to-date inventory was provided to the inspector and documentation reviewed demonstrated that regular quality control, including equipment service by equipment vendors, was performed. As the DXA scanner at this practice had recently been replaced, the inspector also reviewed the record of acceptance testing by an MPE before first clinical use. The inspector also found that the DXA equipment transferred relevant parameters for assessing patient dose to the record of the examination.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in public places such as the waiting area.

The inspector reviewed documentation, including a sample of referral records, and spoke with staff at the practice. The undertaking had allocated responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, to the referrer. However, on the day of inspection, the inspector found that the record of this inquiry of pregnancy status was only available for certain types of referrals.

Consequently, following a review of the evidence available, the inspector was not assured that a record of the inquiry into pregnancy status by the referrer or a practitioner was available for every relevant patient.

Staff spoken with communicated, and provided examples of how the undertaking, had put an extra control in place for all relevant patients. These patients were provided with a pregnancy self-declaration form in advance of their appointment to ensure that where a patient may be pregnant, appropriate radiation protection measures, such as rescheduling the DXA procedure, were implemented. However, as this form was reviewed by staff delegated the practical aspects, rather than the referrer or a practitioners, a gap in compliance was found for some relevant patients.

Notwithstanding the efforts to ensure the radiation protection of patients who may be pregnant, to ensure full compliance with this regulation, the undertaking must ensure that a record of the inquiry of pregnancy status is documented, in line with the requirements of this regulation, by the referrer or a practitioner.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The systems in place for recording and analysing any accidental or unintended medical exposures was assessed on the day of inspection. From speaking with staff, and reviewing the records and other documentation, the inspector found that processes were in place to report any accidental or unintended exposures which may occur to management and the MPE. The inspector was also satisfied that measures to identify if any accidental or unintended exposure was reportable to HIQA as a significant event were in place at the practice.

The inspector also reviewed evidence which provided an assurance that where an accidental or unintended exposure took place, measures were implemented to minimise the probability of a similar incident reoccurring.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from communication with staff and a review of relevant policies and other records, that the practice had adequate processes in place to ensure the continuity of medical physics expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users at Dexa Protection. On the day of inspection, an MPE was found to take responsibility for dosimetry and contributed to QA and acceptance testing at the practice. An MPE was also involved in the establishment of DRLs, in the analysis of events involving, or potentially involving, accidental or unintended medical exposures and was also involved in providing training in the area of radiation protection.

Judgment: Compliant

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

On the day of inspection, the undertaking had mechanisms in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at the practice.

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 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 Dexa Protection OSV-0006061

Inspection ID: MON-0042298

Date of inspection: 18/01/2024

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 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: Our MPE has carried out a risk assessment for decision to discontinue asking the Pregnancy question as it not relevant for the radiological procedure concerned. I have attached this risk assessment and an amended copy of the local rules for Dexa protection. The decision was made to continue using the pregnancy self declaration form, for the purpose of correct interpretation of the DXA Procedure being carried out.	

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 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	29/02/2024
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	Not Compliant	Orange	29/02/2024

	Authority on request.			