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:	Lifford Health Centre
Undertaking Name:	Lifford Health Centre
Address of Ionising Radiation Installation:	Coneyburrow Road, Lifford, Donegal
Type of inspection:	Announced
Date of inspection:	08 February 2024
Medical Radiological Installation Service ID:	OSV-0007075
Fieldwork ID:	MON-0042305

About the medical radiological installation:

DXA Scans are performed in Lifford Health Centre.

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 8 February 2024	12:00hrs to 15:00hrs	Lee O'Hora	Lead

Summary of findings

An inspection of Lifford Health Centre was conducted by an inspector on the 08 February 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. 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 articulated to the inspector.

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 with 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 now commensurate with the services provided. However, it was noted that this relationship had been allowed to lapse between January 2022 and early 2024 causing some non compliances in relation to the continuity of MPE expertise, their associated contributions and the maintenance of a MPE quality assurance (QA) testing programme.

The inspector was assured that the undertaking had established and reviewed diagnostic reference levels (DRLs) at this facility and had ensured that detailed written protocols were available for every type of standard DXA scan provided at Lifford Health Centre. Also, systems and processes to ensure that the information relating to patient exposure formed part of the report had been established satisfying the requirements of Regulation 13(2).

The inspector was also assured that the undertaking had implemented a system to ensure that all appropriate service users were asked about pregnancy status by a practitioner, who subsequently recorded their answers satisfying the requirements of Regulation16.

Overall, although some areas of historical failure to comply with the provisions of the regulations were noted, the inspector was satisfied that these 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 referral documentation, a sample of referrals for DXA procedures and by speaking with staff, the inspector was satisfied that Lifford Health Centre only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Following review of radiation safety procedure documentation, a sample of referrals for DXA procedures and by speaking with staff and management, the inspector was assured that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Lifford Health Centre, a partnership undertaking, was identified as having overall responsibility for the protection of service users from medical exposures to ionising radiation. Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by Lifford Health Centre. The relevant responsibilities and lines of communication regarding the effective protection of service users was also clearly articulated to the inspector during the course of the inspection.

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 at the time of inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

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

The inspector observed that the undertaking provided service users with information relating to the benefits and risks associated with the radiation dose from DXA scans.

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.

The inspector was assured by the training records supplied that Lifford Health Centre had a system in place to ensure that all training requirements, as specified by the Nursing and Midwifery Board of Ireland, were satisfied. Training records were well maintained by the undertaking and staff and included initial training records, records in relation to continuing education after qualification and clinical instruction records.

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. While meeting the requirements of Regulation 11 in this instance, the consistent involvement of an MPE in the establishment and review of DRLs was highlighted as an area for improvement under Regulation 20.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for all standard medical radiological DXA procedures.

The inspector reviewed a sample of DXA reports and was assured that the undertaking had developed and implemented a system to ensure that information relating to patient exposure formed part of the report.

Judgment: Compliant

Regulation 14: Equipment

The inspector reviewed records of in-house, manufacturer and MPE QA testing of radiological equipment. While an appropriate QA program had been implemented by the undertaking, this had not been maintained due to the lapse in MPE involvement and subsequent lapse in MPE QA as mentioned under Regulation 19.

The inspector was satisfied that the undertaking had now implemented systems to address historical gaps seen in the MPE QA record.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and imaging records reviewed satisfied the inspector that the undertaking had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Multilingual posters were observed in the DXA room to increase awareness of individuals to whom Regulation 16 applies. The inspector was assured that the requirements of Regulaion16 were met by Lifford Health Centre.

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

supplied satisfied the inspector that Lifford Health Centre had the necessary arrangements in place to ensure continuity of MPE expertise at the time of inspection. However, this arrangement which was was established recently had been allowed to lapse between equipment acceptance testing in January 2022 and MPE QA completed in February 2024. To ensure full compliance with Regulation 19, undertakings must put in place the necessary arrangements to ensure continuity of this relationship.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the facility, the inspector was satisfied that the undertaking had arrangements in place to ensure the involvement and contribution of MPEs was now in line with the requirements of Regulation 20. However, due to the lapse of MPE service as mentioned in Regulation 19, DRLs established in November of 2023 were not contributed to by the MPE.

Judgment: Substantially 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 at Lifford Health Centre at the time of inspection.

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	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

Compliance Plan for Lifford Health Centre OSV-0007075

Inspection ID: MON-0042305

Date of inspection: 08/02/2024

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 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: To help fulfil requirements under SI 256 2018, Lifford Health Centre (the Undertaking) has put in place agreed arrangements with a named Medical Physics Expert (and RPA). The document Procedure for the involvement of MPE for DXA outlines these arrangements and the activities the MPE will be consulted and act upon.	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: To help fulfil requirements under SI 256 2018, Lifford Health Centre (the Undertaking) has put in place agreed arrangements with a named Medical Physics Expert (and RPA). The document Procedure for the involvement of MPE for DXA outlines these arrangements and the activities the MPE will be consulted and act upon.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:	

To help fulfil requirements under SI 256 2018, Lifford Health Centre (the Undertaking) has put in place agreed arrangements with a named Medical Physics Expert (and RPA). The document Procedure for the involvement of MPE for DXA outlines these arrangements and the activities the MPE will be consulted and act upon.

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 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	13/02/2024
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	13/02/2024
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of	Substantially Compliant	Yellow	13/02/2024

	the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in			

	relevant aspects of radiation protection.			