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:	Rowe Creavin Medical Practice
Undertaking Name:	Rowe Creavin Medical Practice
Address of Ionising Radiation Installation:	Waterford Health Park, Slievekeale Road, Waterford, Waterford
Type of inspection:	Announced
Date of inspection:	26 May 2022
Medical Radiological Installation Service ID:	OSV-0007470
Fieldwork ID:	MON-0036487

About the medical radiological installation:

We provide a DXA scanning service within our practice. All practitioners are qualified in providing this service. We are supported by a trained administration staff to ensure quality and safety of service. Our service is over seen by a clinically responsible GP.

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 26 May 2022	10:00hrs to 11:15hrs	Noelle Neville	Lead

Summary of findings

An on-site inspection was carried out on 26 May 2022 to verify the actions taken following an inspection on 6 December 2021. This inspection focused on regulations deemed substantially compliant or not compliant during the previous inspection. The inspector validated information provided by the undertaking in the compliance plan and it was noted that Rowe Creavin Medical Practice had made significant progress and implemented the required improvements to ensure compliance with the regulations. The inspector noted compliance across the regulations reviewed, namely Regulations 4, 5, 6, 8, 10, 11, 13 and 14.

The inspector was satisfied that all dual-energy X-ray absorptiometry (DXA) procedures were carried out on the basis of a referral from a referrer and only those entitled to act as practitioner had taken clinical responsibility for DXA procedures. Rowe Creavin Medical Practice had a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) and documentation reviewed reflected this. The inspector was satisfied that all DXA procedures were justified in advance and evidence of same was maintained as required by Regulations 8(8) and 8(15).

Local diagnostic reference levels (DRLs) were available for all DXA procedures and were regularly reviewed and used at Rowe Creavin Medical Practice as required by Regulation 11. In relation to Regulation 13, the practice had written protocols in place for all DXA procedures, together with inclusion criteria and referral guidelines. The inspector was also satisfied that information relating to patient exposure formed part of the report of DXA procedures conducted at the practice as required under Regulation 13(2).

Finally, the inspector was satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Rowe Creavin Medical Practice.

Regulation 4: Referrers

On the previous inspection, it was noted that some DXA procedures had been carried out in the absence of a referral from a person entitled to refer as per the regulations. The inspector was satisfied on this inspection that all DXA procedures were carried out on the basis of a referral from a person entitled to refer as defined in Regulation 4. This was evident from a sample of records of medical exposures to ionising radiation reviewed and from discussions with staff about the processes in place.

Judgment: Compliant

Regulation 5: Practitioners

On the previous inspection, it was noted that some aspects of clinical responsibility, namely, the justification of medical exposures were allocated to individuals who were not recognised within Regulation 5, including nursing and administrative staff. The inspector was satisfied on this inspection that only those entitled to act as practitioners, as defined in Regulation 5, had taken clinical responsibility for medical exposures, namely medical doctors at the practice.

Judgment: Compliant

Regulation 6: Undertaking

On the previous inspection, it was noted that Rowe Creavin Medical Practice had not clearly allocated responsibilities as required by Regulation 6(3). For example, justification in advance of DXA procedures was not allocated to a practitioner and there was an absence of a referral from a referrer for certain DXA procedures carried out. In addition, the allocation of practical aspects of medical exposures was not clearly outlined in documentation. The inspector was satisfied on this inspection that Rowe Creavin Medical Practice had a clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation as required by Regulation 6(3) and documentation reviewed reflected this.

Judgment: Compliant

Regulation 8: Justification of medical exposures

On the previous inspection, it was noted that there was an absence of a referral for some DXA procedures performed at the practice which were carried out on the basis of self-directed referrals, without the involvement of a referrer. The inspector was satisfied on this inspection, from a review of a sample of medical records and speaking with staff, that all DXA procedures had a referral from a referrer as required by Regulations 4 and 8(10).

It was also noted on the previous inspection that justification in advance of a procedure was not carried out by a practitioner at the practice. The inspector was satisfied on this inspection, from a review of a sample of medical records and speaking with staff, that all DXA procedures were justified in advance and a record

of same was maintained as required by Regulations 8(8) and 8(15).

Judgment: Compliant

Regulation 10: Responsibilities

On the previous inspection, it was noted that not all aspects of clinical responsibility were carried out by a practitioner. For example, a practitioner had not justified DXA procedures in advance of the exposure taking place and certain procedures were performed on the basis of self-directed referrals. The inspector was satisfied on this inspection that all aspects of clinical responsibility were held by practitioners as defined in Regulation 5 and a referrer was involved in all DXA procedures as required by Regulations 10(1) and 10(3).

It was noted on the previous inspection that the practical aspects of DXA procedures were carried out by nurses at Rowe Creavin Medical Practice. However, this delegation of practical aspects was not outlined in documentation and instead nurses were recognised as practitioners at this practice. The inspector was satisfied on this inspection that the delegation of practical aspects to nurses had been documented and the allocation of clinical responsibilities had been updated so that only those defined under Regulation 5, namely medical doctors at Rowe Creavin Medical Practice, could act as practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

On the previous inspection, a local DRL had not been established for some DXA procedures. The inspector was satisfied on this inspection, from documentation reviewed and discussions with staff that local DRLs had been established, regularly reviewed and used for all DXA procedures at Rowe Creavin Medical Practice as required by Regulation 11.

Judgment: Compliant

Regulation 13: Procedures

On the previous inspection, written protocols had not been established for all DXA procedures carried out at the practice. The inspector was satisfied on this inspection that written protocols were available for all DXA procedures carried out at the

practice. These protocols can provide assurance that DXA imaging procedures are carried out in a safe and consistent manner.

Information relating to patient exposure did not form part of the report of DXA procedures conducted at the practice on the previous inspection. However, the inspector was satisfied on this inspection, from a review of a sample of records and speaking with staff, that information relating to patient exposure formed part of the report of DXA procedures conducted at the practice as required under Regulation 13(2).

On the previous inspection, it was noted that improvements could be made to include inclusion criteria for all DXA procedures performed at the practice. In addition, referral guidelines which take into account radiation doses were not available to referrers for all DXA procedures performed at the practice as required by Regulation 13(3). The inspector was satisfied on this inspection that inclusion criteria for all DXA procedures performed at the practice were available together with relevant referrals guidelines as required by Regulation 13(3).

The inspector noted that Rowe Creavin Medical Practice had continued to carry out clinical audit since the previous inspection and the inspector reviewed a recent clinical audit in relation to the demographics of DXA procedures.

Judgment: Compliant

Regulation 14: Equipment

On the previous inspection, it was noted that annual quality assurance was due to be carried out at the time of inspection. It was also noted that the quality assurance programme could be better defined to ensure that equipment is kept under strict surveillance, including a clear outline of the frequency of quality assurance and performance testing and persons responsible. The inspector was satisfied on this inspection that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1) at Rowe Creavin Medical Practice. The programme of quality assurance had been clearly defined and documented. In addition, annual quality assurance, vendor servicing and regular quality control had been carried out on the DXA unit and records of this were available to the inspector for review.

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