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:	Farnham Medical Practice
Undertaking Name:	Zubair Ali Memon
Address of Ionising Radiation Installation:	Primary Care Centre, Connolly Street, Cavan, Cavan
Type of inspection:	Announced
Date of inspection:	08 February 2023
Medical Radiological Installation Service ID:	OSV-0008390
Fieldwork ID:	MON-0038775

About the medical radiological installation:

Farnham Medical Practice is a General Practitioner Practice offering a bone health programme for osteoporosis including bone densitometry scanning or dual-energy X-ray absorptiometry (DXA).

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 8 February 2023	12:30hrs to 15:00hrs	Lee O'Hora	Lead

Summary of findings

An on-site inspection was carried out on the 08 February 2023 of Zubair Ali Memon operating at Farnham Medical Practice which provided a dual-energy X-ray absorptiometry (DXA) service. On the day of the inspection, the inspector spoke with staff and management involved in the provision of the DXA imaging service and reviewed documentation and records. The undertaking representative who was a general practitioner (GP) had overall responsibility for the DXA service.

The undertaking had engaged the services of a medical physics expert (MPE) who had contributed to quality assurance (QA) and was available to advise the undertaking on matters relating to radiation protection. However the engagement of the MPE by the undertaking must be improved to ensure the strict surveillance of DXA equipment regarding radiation protection.

From a review of documentation and speaking with staff and management, the inspector was satisfied that measures were in place to ensure that all referrals for DXA radiological procedures were from referrers entitled to refer, included reason for the request and the associated medical data required by the Regulations.

On the day of inspection records reviewed and staff communication established that on certain occasions, the undertaking had not ensured that all medical exposures took place under the clinical responsibility of a practitioner. It is imperative that where aspects of clinical responsibility or practical aspects of medical radiological procedures are allocated or delegated to individuals that the undertaking ensures that these individuals are registered with the appropriate professional bodies and adequately trained in radiation safety.

Written protocols relating to the conduct of DXA radiological procedures were available for review and information relating to the radiation dose of individual procedures was included on the report of DXA radiological procedures. However, no evidence of public notices to increase awareness of service users in relation to special protection during pregnancy was observed during the inspection.

While a number of non-compliances with the regulations were highlighted on the day of inspection, the inspector was satisfied that these did not pose a current risk to the safety, health or welfare of service users.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for DXA imaging and by speaking with staff, the inspector was satisfied that Farnham Medical

Practice only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection the inspector established through staff communication and imaging record review that, in some limited cases, clinical responsibility was taken by a person not entitled to act as a practitioner. It is imperative that undertakings have systems in place to ensure that only appropriately qualified individuals, as per the regulations, take clinical responsibility for all aspects of individual medical exposures.

Judgment: Not Compliant

Regulation 6: Undertaking

The partnership Zubair Ali Memon was the undertaking with overall responsibility for the radiation protection of service users undergoing DXA scanning at Farnham Medical Practice.

The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection, However, records reviewed and staff communication established that on at least one occasion scanning was done by an individual for whom no professional registration or training records were available. Similarly, as discussed under Regulation 5, evidence reviewed indicated that aspects of clinical responsibility were also allocated to an individual not entitled to act as a practitioner.

In all cases where aspects of clinical responsibility or practical aspects of medical radiological procedures are delegated or allocated to individuals, it is imperative that the undertaking ensure that these individuals are appropriately qualified before they are allocated such responsibilities and the relevant professional registration and training records are retained and available for review.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

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 service user notes. For a sample of referrals reviewed on site the reason for the request and associated medical data was available for each individual referral.

Staff spoken with on the day were able to provide information relating to the benefits and risks associated with DXA scanning and were confident in the communication of this information to service users. While the inspector was satisfied that the undertaking met the requirements of the regulations in relation to risk benefit communication, there was no risk benefit information available to service users in the form of posters or pamphlets and this was noted as an area for improvement.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that the justification process of individual medical exposures involved the practitioner and the referrer and that the optimisation process involved the practitioner and the MPE. However, as discussed under Regulation 5 and 6, the inspector reviewed evidence that suggested the undertaking had not ensured that all aspects of medical exposures took place under the clinical responsibility of a practitioner.

Also the inspector reviewed DXA procedures which had been done by an individual for whom no professional registration or training records were available. In this case it is unclear if this individual was a practitioner or person delegated practical aspects. In either case, the necessary professional qualification records, radiation safety training records or formal record of delegation were not available.

Judgment: Not Compliant

Regulation 13: Procedures

Written protocols for DXA scanning procedures were supplied and articulated to the inspector on the day.

A number of DXA reports were reviewed on site and each report included information relating to patient exposure.

Judgment: Compliant

Regulation 14: Equipment

The inspector reviewed MPE equipment acceptance testing records as well as six monthly manufacturer service records. The undertaking also supplied records of daily quality assurance testing. Local documentation noted that annual MPE performance testing was to be maintained, however, at the time of inspection this testing was overdue. No records of associated scheduling or MPE communication to address the overdue MPE performance testing was available on the day of inspection and this was highlighted as a non-compliance that needed prompt action by the undertaking.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector was satisfied that the undertaking, as appropriate, employed a system to inquire and record if an individual was pregnant before the medical exposure. However, no measures to increase awareness of individuals to whom this regulation applies such as public notices in appropriate places were observed on the day of inspection.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the practice were described to the inspector by staff and the continuity of MPE service was established in documentation reviewed. 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 the inspector and was up to date. From reviewing documentation and records 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 the 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 the relevant staff members and following document review, the inspector was not assured that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided. As discussed under Regulation 14, the undertaking must enhance the involvement of the MPE particularly in relation to regular performance testing and the strict surveillance of medical radiological equipment.

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	Not Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially 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	Substantially Compliant

Compliance Plan for Farnham Medical Practice OSV-0008390

Inspection ID: MON-0038775

Date of inspection: 08/02/2023

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 5: Practitioners	Not Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: No one at Farnham Medical Practice will undertake any medical exposure in relation to DXA unless they are suitably qualified, are on the appropriate professional register and hold a radiation safety certificate. The copies of the above records will be held by the undertaking representative for 5 years after practitioner has left the practice. The practice has introduced a new recruitment protocol to ensure, going forward, all practitioners at the practice will furnish their qualification to the undertaking representative prior to commencing any work. All practitioners currently at the practice are fully compliant with all regulations.	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: All individuals shall be appropriately qualified as per the recruitment protocol for DXA at Farnham Medical Practice. The records of qualification and professional registration will be kept on file with the undertaking and retained for 5 years after practitioners has left the practice, and available for review if required. The training record and training protocol will be adhered to also.	
Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities: No one shall operate the DXA machine and undertake medical exposures or any aspect of clinical responsibility without suitable qualification and without holding their current certificate of registration with their relevant registration authority the qualification certificates will be reviewed by the undertaking representative prior to the practitioner commencing their work in the DXA unit. All records will be kept on file by the undertaking representative and kept for 5 years after the practitioner leaves the practice. The Recruitment Protocol will be strictly adhered to

Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: The Medical Physics Expert (MPE) will visit yearly and do quality assurance testing to ensure equipment is compliant with European safety standards. The MPE will discuss results with the equipment engineer to discuss any findings and rectify and issues found. The MPE will be contacted by the undertaking representative to schedule a visit at the beginning of every year to carry out the necessary inspection of the DXA equipment	
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: Multilingual posters regarding radiation safety during pregnancy have now been displayed prominently in the DXA waiting room and also in the DXA room. DXA specific pamphlets have been designed to help patients understand all aspects of DXA including radiation safety, radiation safety during pregnancy and breastfeeding, where the patients can access their report etc. This pamphlet will be given to every patient on arrival to the department prior to having a scan.	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: The Medical Physics Expert will be contacted yearly in advance of the time that he is expected, to schedule a date for testing of the equipment to ensure the equipment is operating efficiently and safely. He will liaise with the engineer to discuss any issues found in the equipment. The MPE came to Farnham Medical Practice and carried out a Bone Densitometer Equipment survey on the 13/03/2023. He will be contacted again next January to schedule another survey before March 2024. He can be contacted if any help or advice is need before then.	

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 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	20/03/2023
Regulation 5(c)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section	Not Compliant	Orange	20/03/2023

	36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).			
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	13/03/2023
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	20/03/2023
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council,	Not Compliant	Orange	20/03/2023

	(ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			
Regulation 10(5)	An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.	Not Compliant	Orange	20/03/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological	Substantially Compliant	Yellow	13/03/2023

	equipment in use by it is kept under strict surveillance regarding radiation protection.			
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	13/03/2023
Regulation 16(4)	Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to increase the awareness of individuals to whom this Regulation applies, through measures such as public notices in appropriate places.	Not Compliant	Orange	13/03/2023
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the	Substantially Compliant	Yellow	13/03/2023

	practice.			