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:	Vhi 360 Health Centre
Undertaking Name:	Vhi Health & Wellbeing DAC
Address of Ionising Radiation Installation:	Hampstead Building, Carrickmines Retail Park, Co. Dublin
Type of inspection:	Announced
Date of inspection:	15 February 2023
Medical Radiological Installation Service ID:	OSV-0008184
Fieldwork ID:	MON-0038989

About the medical radiological installation:

This Vhi 360 clinic Carrickmines is a multi-disciplinary service for Vhi clients. It includes diagnostic services, the provision of which is outsourced. The diagnostics offered include 1.5T MRI, Ultrasound, DXA and X-ray. There are two X-ray rooms within the facility – in the main imaging department, and in Urgent Care. All radiological services are on an out-patient basis, referred either internally by physicians or advanced nurse practitioners, or externally by GPs. Outsourced diagnostic services provide a complete radiology service to Vhi including provision of radiographic staff, management of services, RSC participation and radiological reporting. Outsourced diagnostic services also provide the RIS and PACS systems and associated functions. In addition to the above, Vhi 360 Health Centre in Carrickmines currently offers a comprehensive urgent dental care service for patients who have acute pain, infection or dental trauma.

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 and management 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 complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[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.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

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 15 February 2023	09:30hrs to 16:00hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation and visited the general X-ray, dual-energy X-ray absorptiometry (DXA) and dental departments and spoke with staff and management. On this inspection, the inspector found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures.

Vhi Health and Wellbeing DAC operated three similar facilities and was the undertaking with overall responsibility for the radiation protection of service users at Vhi 360 Health Centre Carrickmines. The undertaking engaged an external imaging company to provide a managed X-ray and DXA service across all sites. Local responsibility for the radiation protection of service users lay with the Managing Director of the Vhi group who chaired the radiation safety committee (RSC) and reported directly to the undertaking's Board. The RSC was used by Vhi Health and Wellbeing DAC to clarify and promote the requirements of all national radiation safety regulations and also served as one of many platforms for communication between the undertaking and the external imaging provider.

Following a review of documents and records, and speaking with staff, the inspector was assured 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.

The inspector reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Evidence of professional registration and arrangements to ensure continuity of MPE expertise was also supplied to the inspector. From the documentation reviewed, the inspector was assured that the level of involvement of the MPE was proportionate to the level of radiological risk at the installation and that the MPE took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, the inspector was satisfied that a clear and effective allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at Vhi 360 Health Centre Carrickmines.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that

Vhi 360 Health Centre Carrickmines only accepted referrals from appropriately recognised referrers.

In line with the regulations, radiographers and advanced nurse practitioners were also considered referrers in this facility and the specific circumstances in which each profession could act as referrers were clearly outlined in local policies and articulated to the inspector by staff.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of professional registration records, radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by Vhi Health and Wellbeing DAC operating at Vhi 360 Health Centre Carrickmines. Vhi Health and Wellbeing DAC was the undertaking with overall responsibility for the protection of service users from medical exposures to ionising radiation.

The Vhi 360 Health Centre was supported by a RSC, which met twice yearly and reported to the undertaking's board through the undertaking representative who was the managing director of the Vhi group and chair of the RSC. The inspector also reviewed minutes of the newly established radiation protection unit (RPU) and was informed that this group provided further opportunities for the timely consideration and communication of all radiation safety issues as they occurred.

Vhi Health and Wellbeing DAC engaged a third party imaging provider to deliver a managed X-Ray and DXA service at Vhi 360 Health Centre Carrickmines. Radiation safety documentation, radiation safety meeting minutes and staff interaction satisfied the inspector that the relevant responsibilities and lines of communication were well defined and understood. The inspector was assured that the RSC and RPU provided platforms for the consideration and communication between the undertaking and the third party imaging provider. The inspector was also informed that this relationship was well defined in a service level agreement (SLA) and

enhanced by annual executive management meetings, quarterly contract management meetings and monthly quality meetings. This SLA was provided to, and reviewed by, the inspector on the day of inspection.

The dental service at Vhi 360 Health Centre Carrickmines was managed and run directly by the undertaking. The documentation reviewed and staff interaction satisfied the inspector that the relevant responsibilities and lines of communication for the radiation safety of service users undergoing dental procedures were well defined and understood.

It was noted that the MPE played an important role across all services. The undertaking directly engaged the MPE and an SLA was available and reviewed on site by the inspector. After document review, radiation safety meeting minutes review and staff and management communication the inspector was assured that the undertaking had taken the necessary steps to ensure the appropriate involvement and contribution of the MPE for the protection of service users across the entire service. The inspector was also satisfied that communication pathways and platforms between the MPE and the third party imaging provider were well defined and understood facilitating the necessary involvement and contribution of the MPE to the managed X-ray and DXA service as needed.

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.

Judgment: Compliant

Regulation 10: Responsibilities

Following the review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner at Vhi 360 Health Centre Carrickmines.

The inspector was assured that the optimisation process involved the practitioner and the medical physics expert (MPE). Similarly, following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer .

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of MPE expertise at the facility were described to the inspector by staff and management and the details were available in a SLA reviewed as part of this inspection. 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 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 in line with the requirements of Regulation 20. For example, the inspector was satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing and the analysis of accidental or unintended exposures.

Judgment: Compliant

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

From speaking with the relevant staff members 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 Vhi 360 Health Centre Carrickmines.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this facility.

Following a review of a sample of referrals for general X-ray, DXA and dental procedures the inspector was satisfied that the undertaking had processes in place

to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded.

The inspector was satisfied that diagnostic reference levels (DRLs) were established and routinely compared to national levels. However, where local facility DRLs exceeded national levels, not all records of corrective actions were available on the day of inspection. One other area for improvement noted by the inspector related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of all patients' reports as required. However, the inspector was informed by staff and management that the undertaking had taken steps to procure a dose management system that would ensure regulatory compliance in relation to Regulation 13(2).

Records of acceptance and performance testing for all radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained a comprehensive QA programme. The inspector was satisfied that the undertaking had systems in place to ensure that all medical radiological equipment was kept under strict surveillance.

The inspector reviewed documentation and records of accidental and unintended exposures and near misses. The undertaking demonstrated a comprehensive approach to the investigation and mitigation of risk from such events and the systems and platforms to ensure appropriate record keeping and analysis were well described on the day. The inspector also noted that practical equipment performance improvements were delivered through the effective use of local incident management structures used by the undertaking as described under Regulation 17.

Overall, while some areas for improvement were noted, the inspector was assured that the undertaking had appropriate systems in place to support the safe delivery of medical exposures at Vhi 360 Health Centre Carrickmines.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure that all medical exposures were justified in advance and that justification by a practitioner was recorded. The record of justification was also audited by the undertaking which was noted as a positive measure to help ensure regulatory compliance.

In line with Regulation 8, all referrals reviewed by the inspector on the day of inspection 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 visited the DXA, general radiography and dental clinical areas and observed multiple posters, both general

and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of local facility DRLs and associated documentation, the inspector was satisfied that DRLs had been established and were compared to national levels. Dental DRLs established in February 2022 were above national DRLs. Evidence of associated dental procedure reviews and corrective actions were supplied during the course of the inspection. Similarly, some radiography and DXA DRLs recently established by the undertaking were above national levels. However, while the inspector was informed that reviews and tentative corrective actions had been discussed by the appropriate staff members, no record of these reviews or corrective actions were available at the time of inspection. It is imperative that undertakings have systems in place to ensure that all DRL reviews and corrective actions are formally recorded to satisfy the requirements of Regulation 11.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for standard medical radiological procedures. A sample of these were reviewed in the clinical areas visited by the inspector. Staff spoken with in the clinical areas clearly articulated how these protocols were made available to them.

The inspector spoke with staff and reviewed a sample of imaging reports from all clinical areas on the day of inspection. The inspector observed and was informed by staff and management that information relating to patient exposure did not form part of the report for medical imaging procedures at the time of inspection. However, the inspector was informed by staff and management that the undertaking had taken steps to procure a dose management system that would ensure regulatory compliance in relation to Regulation 13(2) for X-ray and DXA. The inspector also observed that information relating to patient dose in the dental service was recorded in a dose log book. While a dose log book is not considered part of the report and is not sufficient to meet compliance, staff spoken with on the day did suggest that this information could routinely be recorded in the record of the evaluation of the outcome of the medical radiological procedure or service user report.

Inspectors reviewed a number of examples of radiation safety related clinical audits completed by Vhi 360 Health Centre Carrickmines. These included audits of procedure justification, practitioner justification records, pregnancy policy compliance, dental image quality and patient identification records. In the clinical area, results and learning from audits were available to all staff. The inspector also noted that audit was a standing agenda point of the RSC.

Judgment: Substantially Compliant

Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. Records of manufacturer, radiographer and MPE performance testing were reviewed as part of the inspection. The inspector was also provided with an up-to-date radiology equipment inventory which was verified on site.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspector that the Vhi 360 Health Centre Carrickmines had processes in place to ensure that all services users, where appropriate, were asked about pregnancy status by a practitioner. This included the use of a Pregnancy Status Declaration Form to record the answer to pregnancy inquiries. However, the inspector was informed and observed that not all inquiries were subsequently recorded. For example, during a review of the record of a pelvic radiological procedure of a female patient, determined by the undertaking to be of child bearing age, no associated record of inquiry was available. Staff informed the inspector that while the inquiry was made the answer was not recorded.

The policy document *Patient Last Menstrual Period & Pregnancy Policy – VHI 360 Health Centres Carrickmines, Swords & Cork* dictated that the scope of the policy applied to 'any ionizing radiation examinations involving irradiation between the diaphragm and symphysis pubis' and pregnancy declaration forms were to be completed for the lumbar spine X-ray only. Therefore pregnancy enquires were made for a number of procedures but only recorded for one of these procedures, the lumbar spine. In order to satisfy the requirements of the Regulations, the undertaking must ensure that, as appropriate, the referrer or practitioner records the answer to all pregnancy inquires and that all records are retained.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility.

The inspector was satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Vhi 360 Health Centre Carrickmines and that effective communication and shared incident management resources between the undertaking and the managed X-Ray and DXA service provider strengthened the undertaking's ability to effectively minimise the probability and magnitude of accidental or unintended exposures.

Radiation incidents were a standing agenda point of the RSC and the inspector reviewed evidence detailing the use of a small number of non-reportable incidents to highlight and address equipment reliability concerns subsequently resulting in equipment upgrades eliminating similar incidents. This was seen as a practical demonstration of the effective use of local incident management structures used by the undertaking to mitigate risk for the service user.

At the time of inspection the undertaking had not reported any incidents to HIQA. The inspector was satisfied that this did not represent a failure to identify, record or report such events.

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially 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

Compliance Plan for Vhi 360 Health Centre OSV-0008184

Inspection ID: MON-0038989

Date of inspection: 15/02/2023

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 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Further analysis has been undertaken by the Medical Physics Expert (MPE). Local DRLs have been reviewed and approved as justified by both the Practitioner Radiologist and the Medical Physics Expert. Local DRLs are approved at the Radiation Safety Meetings, held biannually. Discussions on preliminary data and any associated amendments to LDRL methodology or clinical protocols will be discussed and minuted at the quarterly Radiation Protection Unit (RPU) meetings. The next meeting is scheduled for 17th April. The recommendations of the RPU are brought to the Radiation Safety Committee meetings (RSC) for sign off.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: We have now completed scoping and analysis of available software options and have moved into development, testing and integration phases. This is managed by our Project and Planning Manager and our Solutions Architect and is a Priority 1 project. Projected completion date is August 2023. The project involves upgrading our PACS to enable automation of accurate dose recording within the report and implementing a dose management solution to facilitate the provision of required dose data. This will also mean we have a complete dose profile across sites, modalities, and patients.	

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:
The policy has been amended to include plain film pelvic examinations as a procedure within the Low Dose category such that pregnancy status is queried, the response recorded, and examination re-justified if the patient is uncertain as to the possibility of pregnancy. This amendment will be reviewed after the implementation of the dose monitoring software which will enable a more detailed analysis of examinations with additional views and the effect of patient BMI on uterus dose.

This updated policy will be brought to the RSC for review and approval for implementation on the 17th April 2023.

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 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Substantially Compliant	Yellow	17/04/2023
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide	Substantially Compliant	Yellow	17/04/2023

	such records to the Authority on request.			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/08/2023
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 Authority on request.	Not Compliant	Orange	17/04/2023