



Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Vhi Swiftcare Clinic Swords
Undertaking Name:	Vhi Health & Wellbeing DAC
Address of Ionising Radiation Installation:	Vhi Swiftcare Clinic, Columbia House, Airside Retail Park, Swords, Co. Dublin
Type of inspection:	Announced
Date of inspection:	08 April 2024
Medical Radiological Installation Service ID:	OSV-0008345
Fieldwork ID:	MON-0043112

About the medical radiological installation:

Vhi Swiftcare Clinic Swords is an urgent care service for Vhi clients. It includes a diagnostic X-ray service. There is one X-ray room within the facility. All radiological services are on an out-patient basis, and are referred internally by Vhi physicians and approved Vhi nurse referrers. Outsourced diagnostic services provide a complete radiology service to Vhi Health and Wellbeing DAC, including the provision of radiographic staff, management of diagnostic imaging services, radiology equipment management, clinical audit, RSC participation and radiological reporting. Outsourced diagnostic services also provide the RIS and PACS systems and associated functions.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Monday 8 April 2024	09:55hrs to 14:00hrs	Margaret Keaveney	Lead

Governance and management arrangements for medical exposures

On 08 April 2024, the inspector completed an inspection of the radiological service at the Vhi Swiftcare Clinic Swords, in order to monitor the undertaking's compliance with the regulations. On the day of inspection, the inspector visited the service's single X-ray unit, spoke with staff and the management team, and reviewed documentation pertaining to radiation protection matters and also service user records. The inspector found that there was a good culture of radiation protection in Vhi Swiftcare Clinic Swords, and during this inspection the undertaking was found to be compliant with all regulations assessed.

The inspector was informed that the undertaking, Vhi Health and Wellbeing DAC, had engaged an external imaging company to provide the radiological service in Vhi Swiftcare Clinic Swords, which included the provision of radiography staff, and overseeing day-to-day operations within the radiology service. From discussions with the management teams of both parties and a review of a documentation, the inspector was assured that overall responsibility for the radiation protection of service users remained with the undertaking, Vhi Health and Wellbeing DAC, and that each party was aware of their responsibilities in providing a safe service to service users. The inspector was also satisfied that there were appropriate governance and management arrangements in place, with good communication between the undertaking and external company engaged to provide the radiological service. From speaking with staff in the clinical areas, the inspector noted that the arrangements in place were understood by all involved.

The undertaking also has three other facilities across Ireland. The inspector noted that the learning and compliance actions from an inspection in February 2023 of one of these facilities had been applied to this service, which was noted as an effective and safe management approach to the service.

During the inspection, the inspector reviewed a sample of patients' radiological records and noted that only appropriate persons as per the regulations were involved in referring for exposures completed at the service. The inspector was also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service. The inspector also noted that both the referrer and practitioner were involved in the justification of medical exposures carried out in the service, and that the medical physics expert (MPE) and practitioner completed a number of optimisation processes for these exposures. The roles and responsibilities of both referrers and practitioners were known to staff in the service, however, the inspector noted that the documentation to support these allocations could undergo a minor review to enhance their clarity.

On the day of the inspection, the inspector spoke with one of the MPEs involved in the service. From this discussion and a review of documentation, the inspector noted the MPE's involvement in the service was proportionate to the radiological risk

in the service. The inspector also determined that the undertaking had arrangements in place to ensure the continuity of their service.

Overall, the inspector was assured that service users were receiving a safe radiological service in Vhi Swiftcare Clinic Swords.

Regulation 4: Referrers

The inspector was satisfied that referrals for ionising radiation examinations in Vhi Swiftcare Clinic Swords were made only from persons as defined in Regulation 4.

The management team had developed a *Referrals Policy* which clearly stated that the role of referrer had been allocated to Vhi medical practitioners and to Vhi approved nurses with appropriate registrations. The policy also outlined the specific circumstances in which radiographers could adapt referrals, while a document titled *Nurse Authority to Refer for Radiological Procedures* outlined the specific circumstances in which approved nurses could refer.

Judgment: Compliant

Regulation 5: Practitioners

From discussions with staff, the inspector was informed that radiologists and radiographers were allocated the role of practitioner in the service.

A review of a sample of medical exposure records verified that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in Vhi Swiftcare Clinic Swords.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed a governance structure organogram (organisation chart), that was submitted prior to the inspection, and saw that it provided a clear allocation of the governance and management arrangements for the radiation protection of service users. The organogram also clearly outlined the roles and responsibilities of both the undertaking and the external imaging company at an operational level. From a review of policies and procedures and discussions with staff, the inspector was satisfied that there was an allocation of roles and

responsibilities at individual, team and organisational level so that all staff working in the service were aware of their responsibilities and who they are accountable to.

The undertaking had established radiation safety committee (RSC) which was scheduled to meet twice yearly, and the inspector noted that it had done so in the previous 12 months. From a review of the RSC's terms of reference, the inspector noted that it had a multi-disciplinary membership, comprising of both the undertaking's staff and staff from the external imaging company. This allowed the RSC to serve as a communication pathway, on radiation protection matters, between both parties. A review of a sample of meeting minutes showed that matters such as equipment quality assurance (QA), dosimetry, incidents, clinical audit and diagnostic reference levels were discussed and actions agreed upon as required. The RSC meetings were chaired by the Managing Director of Vhi Health and Wellbeing DAC, who was also the undertaking representative, and reported directly to the Vhi Board.

The undertaking had also established a number of other forums, through which they and the external imaging company discussed and shared radiation protection matters. For example, they met through a radiation protection unit, which met quarterly and was essentially the working group for the RSC. A Quality, Safety and Risk Group also discussed radiation incidents and clinical audits at their monthly meetings.

Overall, the inspector was satisfied that there were effective management structures in place for the delivery of medical exposures to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of the inspection, the inspector was satisfied that all individual medical exposures took place under the clinical responsibility of a practitioner, and that only those recognised as practitioners conducted medical exposures in Vhi Swiftcare Clinic Swords.

There was also evidence that practitioners and MPEs were involved in the optimisation of medical exposures.

From discussions with staff and a review of medical records, the inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from discussions with staff and a review of documentation, including a service level agreement, that the undertaking had arrangements in place to ensure access to and continuity of medical physics expertise in the service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector was satisfied that the involvement of and contribution by the MPE in the service met the requirements of this regulation. The MPE had been assigned the role of Radiation Protection Advisor in the service, and attended the biannual RSC meetings.

It was noted that the MPE gave advice on the medical radiological equipment in use in the service. A review of documentation and discussions with staff demonstrated that the MPE team were involved in the quality assurance and regular performance testing of medical radiological equipment, and in patient dosimetry, dose calculations and advising on radiation incidents. They were also involved in dose optimisation, for example by the review and sign off of annual diagnostic reference levels (DRLs).

The MPE was also involved in staff training on radiation protection, for example, they had reviewed and approved an online QA training tutorial for radiographers.

Judgment: Compliant

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

From discussions with the MPE and management staff, and a review of documentation, the inspector was satisfied that the level of MPE involvement in medical radiological practices in Vhi Swiftcare Clinic Swords was commensurate with the radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, the inspector noted that since declaring as the undertaking in August 2022, the management team had put in place measures to assure the radiation protection of service users. For example, through the implementation of support documentation on optimisation and on the equipment quality assurance programme, and by establishing systems for the use and review of diagnostic reference levels (DRLs).

The inspector reviewed a sample of referrals, and saw that each was in writing, stated the reason for the request and was accompanied by sufficient medical data to enable the practitioner to consider the benefits and the risk of these medical exposures. The justification of these medical exposures in advance, by the referrer and practitioner, was also evident in the sample reviewed by the inspector. The inspector also noted that a flowchart on the justification process was on display in the console area for easy reference by staff, and this was identified as positive practice in the service.

The management team in Vhi Swiftcare Clinic Swords monitored compliance with the justification process through an audit programme, and had applied audit learning to improve the radiation protection of service users. For example, an audit of knee exposures had been completed to ensure that referrals for the medical exposure type adhered to international best practice referral guidelines, and through a multidisciplinary approach, repeat auditing and staff education, the compliance levels with referral guidelines had significantly increased in the previous 12 months.

Other processes and procedures, in relation to the radiation protection of service users, had also been clinically audited by staff in the service, such as incorrect referrals and adherence to the pregnancy policy. Overall, the management team placed good emphasis on the use of clinical audit as a tool in identifying areas for improvement and of good practice in the service. The inspector also noted that they had initiated the development of a clinical audit strategy to align the local clinical audit programme with the national procedures on clinical audit published by HIQA.

The inspector saw that staff in the service had established and reviewed local DRLs for medical exposures that were frequently completed for both adult and paediatric service users. This data was reviewed by the MPE, approved by the practitioner in charge and then discussed at the RSC. The inspector noted that this data was colour-coded for ease of use and prominently displayed in the console area and from discussions with staff, the inspector was satisfied that DRLs were referred to when completing medical exposures.

From a review of documentation, the inspector was satisfied that there was an established QA programme for radiological equipment in the service. The inspector was assured that the undertaking's management team had good oversight that this programme was performed as scheduled, with the day-to-day programme overseen by the radiation services manager (RSM) and the overall programme discussed at the RSC. Staff also informed the inspector of the action and communication pathway to be followed in the event of an equipment fault occurring. The inspector noted

that when the Vhi Health and Wellbeing DAC acquired the radiological equipment from the previous undertaking in August 2022, they had commissioned the MPE to complete a safety report on the equipment. This was identified as good diligence by the undertaking to the safety of service users.

The undertaking had a safe and effective process in place to determine the pregnancy status of service users, where relevant, and staff spoken with demonstrated good knowledge of this process. The inspector also reviewed documentation that evidenced good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Overall, the inspector was satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

During the inspection, the inspector reviewed a sample of written referrals which showed that ionising radiation exposures were justified in advance by practitioners. The inspector also spoke with radiographers conducting medical exposures who demonstrated a good understanding of their role in the justification process.

Information in relation to the benefits and risks associated with radiation was widely available to service users undergoing medical exposures on posters in service user waiting areas and in clinical areas. The inspector also noted that the management team had made good efforts to ensure that service users could make decisions on ionising radiation examinations, through the development and distribution of information leaflets on the benefits and risks.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed a document titled *Diagnostics Reference Levels (DRLs) for Medical Radiological Procedures Policy*, which set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and approving local DRLs. The inspector observed that both adult and paediatric DRLs, based on 2023 data, had been established, compared to national DRLs and were in use in Vhi Swiftcare Swords. This information had been discussed and approved at a RSC meeting, and was displayed in colour-coded posters in the clinical area. Staff who spoke to the inspector demonstrated a good awareness of how to use the DRLs when carrying out medical exposures to ionising radiation.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector reviewed written protocols available for standard adult and paediatric medical radiological procedures carried out in the service, and noted that these protocols were accessible to staff in the clinical area. Staff who spoke with the inspector were familiar with the protocols and demonstrated how they guided them in optimising service user positioning and exposure parameters for different medical exposures. The inspector also noted that appropriate referral guidelines were available to staff.

The inspector noted that a number of clinical audits had been completed in the service, such as audits on incorrect referrals, image quality, adherence to checking pregnancy status and clinical justification of medical exposures.

The inspector also reviewed a sample of reports on medical exposures carried out in the service, and found that information relating to patient exposure formed part of the report as required by Regulation 13(2).

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Vhi Swiftcare Clinic Swords as required by Regulation 14(1). The management team had developed an *Equipment Maintenance and Quality Assurance Policy*, which outlined staff responsibilities in relation to quality assurance and there was evidence that an appropriate quality assurance programme had been implemented in the service.

From a review of records the inspector noted that regular performance testing was carried out as required by Regulation 14(3). Daily and monthly quality assurance (QA) testing was completed by radiography staff, who had received appropriate training by the radiation safety officer (RSO) and MPE, with a support video developed by the RSO to support this training. This was identified as an area of good practice in the service. QA records also showed that annual QA and servicing was performed by the MPE and manufacturer, in line with documented schedules.

There was a process in place to report any equipment faults or issues, if needed. A review of records demonstrated that this process was adhered to, and appropriately overseen by the management team, as and when required. The records also showed that when a fault or issue was identified, appropriate internal and external personnel were called upon to address the issue in a timely and effective manner.

The inspector also noted that the undertaking had engaged the MPE to complete supplementary testing of the equipment to provide assurances that it was fit for clinical use, prior to taking ownership of it in August 2022. This was identified by the inspector as responsible and safe practice by the undertaking. In addition, the inspector was also informed that discussions to replace the medical radiological equipment in Vhi Swiftcare Clinic Swords had taken place at the RSC, to ensure that the equipment continued to meet the criteria of acceptability. Again this demonstrated good awareness by the undertaking's management team of ensuring that the equipment in use in the service contributed to dose optimisation.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

There was an effective process in place in Vhi Swiftcare Clinic Swords to determine the pregnancy status of service users, where relevant. This process was documented in both the local *Radiation Safety Procedures* and *Patient Last Menstrual Period & Pregnancy Policy*.

Practitioners were allocated responsibility for inquiring on patients' pregnancy status, where relevant, and during a review of a sample of service user records the inspector saw that practitioners had inquired on, and recorded in writing, the pregnancy status of patients, where relevant. The inspector also noted that where there was any uncertainty on pregnancy status, the pregnancy policy in such a scenario had been adhered to and a re-justification form completed, with dose information included.

The inspector observed that a number of multi-lingual notices were displayed in service user waiting areas and clinical areas, to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From discussions with staff and a review of documents, the inspector was satisfied that the undertaking's management team had ensured that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented in the service. The incident management process and structures were outlined in the *Incident Reporting Policy*

and in the *Radiation Safety Procedures*, and included information on the requirement to notify HIQA of certain reportable incidents.

The inspector was informed that when an actual or potential radiation incident occurred, it was recorded by staff on an online system, managed by the external imaging company. The undertaking's management team was then informed by phone or email, and the incident recorded on their incident management system. Both management teams met monthly at a Quality, Safety and Risk meeting to discuss all incidents, and to ensure that investigations were underway and actions agreed where necessary. These arrangements satisfied the inspector that incidents were appropriately managed and that learning from such incidents was used to improve the quality and safety of the service, and to prevent future such incidents occurring.

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	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant