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:	St Vincent's University Hospital
Undertaking Name:	St Vincent's University Hospital
Address of Ionising Radiation Installation:	Elm Park, Merrion Road, Dublin 4
Type of inspection:	Announced
Date of inspection:	08 April 2025
Medical Radiological Installation Service ID:	OSV-0007407
Fieldwork ID:	MON-0044591

About the medical radiological installation (the following information was provided by the undertaking):

SVUH is a Level 4, leading academic teaching hospital, providing front line, acute, chronic and emergency care for over 50 different medical specialities. SVUH is the largest hospital in the HSE Dublin and South East region. This region has a population of almost one million people. SVUH's comprehensive range of services, including trauma, oncology, and cardiac care means the hospital plays a crucial role in the healthcare system for a significant portion of the population at regional and national level. SVUH's Emergency Department (ED) is the major regional referral centre for patients with strokes and major trauma, providing front line 24/7 Emergency Services and national, supra-regional and regional medical care on an inpatient and outpatient basis. At full capacity SVUH has 614 beds incorporating 7-day; 5-day and day care facilities and provides in excess of forty medical and surgical specialities.

SVUH has a commitment to provide Radiology support to regional Cardiology, GIT, Respiratory, Neurology, Renal, Metabolic, Dermatology, Rheumatology, Endocrinology, Orthopaedics, Urology, Vascular, Plastics, ENT, Ophthalmology and tertiary Hepatobiliary, Pancreatic, Neuroendocrine, Sarcoma, Cystic Fibrosis referral units within the hospital. In addition, SVUH has an ever expanding Oncology workload, having been designated as the national surgical centre for pancreatic cancer and a regional centre for breast, colorectal, lung and prostate cancer by the National Cancer Control Programme (NCCP). SVUH is also a designated HSE NCCP National Sarcoma MDT. In October2023, SVUH, supported by the NCCP introduced Peptide Receptor Radionuclide Therapy (PRRT) for patients with neuroendocrine tumours.

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, as amended. 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] 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.

1. Governance and management arrangements for medical exposures:

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
Tuesday 8 April 2025	09:10hrs to 14:25hrs	Kay Sugrue	Lead
Tuesday 8 April 2025	09:10hrs to 14:25hrs	Emma O'Brien	Support
Tuesday 8 April 2025	09:10hrs to 14:25hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

An inspection of St Vincent's University Hospital (SVUH) was carried out on the 8 April 2025 to assess compliance with the regulations. Inspectors visited the computed tomography (CT), nuclear medicine, positron emission tomography computed tomography (PET CT), interventional radiology and interventional cardiology services during this inspection. Inspectors spoke with staff in each area inspected, and reviewed documentation including records from completed medical radiological procedures across all modalities within the service to inform the findings of this report. In addition, corrective actions from the compliance plan submitted following the previous HIQA inspection in 2023, were followed up to determine if the measures implemented had achieved their goal of regulatory compliance. Inspectors noted that specific findings in relation to gaps in compliance previously identified in the dual-energy X-ray absorptiometry (DXA) service had been addressed.

Governance arrangements were reviewed by the inspection team which were found to be similar to those in place during previous inspections in 2022 and 2023. The designated manager for radiation protection of service users was the interim chief executive officer (CEO) who also acted as the undertaking representative for the undertaking, St Vincent's' University Hospital (SVUH). The designated manager was a member of the radiation safety committee (RSC) which had operational and regulatory oversight of radiation protection at the hospital. Inspectors found there were appropriate communication pathways through the CEO and hospital committee reporting structures up to the St Vincent's Hospital Group (SVHG) Board of Directors and the undertaking.

The allocation of responsibility for the radiation protection of service users at the hospital was reviewed in available documentation and also described by staff in discussions with inspectors in the areas visited. The evidence gathered from these discussions and documentation reviewed satisfied inspectors that medical physics experts (MPEs) were engaged for the radiology service and continuity arrangements were in place. There was sufficient evidence to show that MPE involvement in medical radiological procedures was proportionate to the radiological risk associated with the practices at SVUH, thereby demonstrating compliance with Regulations 19(9), 20 and 21. Inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Inspectors found that the electronic system utilised by referrers within the hospital to request a medical radiological procedure was effective to ensure the referral came from an individual entitled to refer under Regulation 4. However, compliance with hospital policy that outlines the process for identifying referrers on externally sourced referrals needs to improve to provide greater assurance for the undertaking with this regard, and to meet requirements of Regulation10(3)(b). In addition, the delegation of the practical aspects for nuclear medicine procedures must be reviewed by the undertaking to ensure that individuals allocated this responsibility have met the necessary radiation safety training requirements

prescribed by their relevant professional body, to meet compliance with Regulation 10(4).

Although some gaps in compliance were found, inspectors determined that staff at SVUH demonstrated a strong commitment to the radiation protection of service users attending the hospital for medical exposures. In an environment that has high activity levels and delivers higher dose, complex procedures on a daily basis, several examples of good practices were seen, particularly, in the area of optimising protocols to reduce radiation doses to service users.

Regulation 4: Referrers

Inspectors reviewed a sample of referrals that originated from within the hospital and referrals from external referrers. Hospital generated referrals were submitted via an electronic portal system by approved referrers with unique log in details. This system provided assurance that referrals for medical radiological procedures originating from within the hospital were from individuals entitled to refer, as per Regulation 4. However, as discussed under Regulation 10(3)(b), greater assurance is required to ensure that local procedures are followed in verifying the referrer for externally sourced referrals.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors found from a review of documentation and discussion with staff that clinical responsibility for individual medical exposures was taken by an individual entitled to act as a practitioner, as per Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Governance, management and oversight arrangements for the radiation protection of service users at SVUH were reviewed on the day of inspection. Inspectors spoke with management and staff at the hospital who consistently articulated the arrangements and lines of communication in place within the management structure. A multidisciplinary radiation safety committee (RSC) had oversight of the radiation safety and protection of service users subject to medical exposures at the hospital. The interim CEO was the undertaking representative and designated manager for the undertaking, St Vincent's University Hospital, and was also a

member of the RSC. The reporting pathways to the St. Vincent's Hospital Group (SVHG) Board of Directors and undertaking was through the established directorate and hospital committee structures via the CEO.

Since the last inspection in February 2023, staff at the hospital had implemented measures to improve the allocation of responsibility in relation to ensuring reports of medical exposures conducted in the DXA service were reviewed by a practitioner, as per the regulations. While noting the actions taken by the undertaking to improve compliance, further gaps relating to the allocation of responsibilities required under Regulation 6(3) were again identified during the course of this inspection. For example, more assurance was required in relation to adherence with hospital policy on the identification of referrers for all external referrals processed at the hospital. Furthermore, the allocation of responsibility to individuals delegated with the practical aspects of nuclear medicine procedures must meet the requirements set out under Regulation 10(4) pursuant to Regulation 22(3).

Inspectors found that while the hospital had engaged with HIQA and submitted applications for the generic justification of new types of practices, there was scope to expand information provided in local policy to detail the review and approval process applied, as described by staff and management to inspectors. These gaps in compliance, in addition to those identified under Regulations 13(2) and Regulation 8 of this report, require further action by the undertaking to attain and maintain compliance in line with regulatory requirements.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that medical exposures took place under the clinical responsibility of a practitioner and evidence gathered demonstrated that practitioners and MPEs were involved in the optimisation process. Similarly, referrers and practitioners were involved in the justification process for individual medical exposures in the majority of records viewed for referrals originating within the hospital.

For externally sourced referrals, the hospital procedure named *'Radiology: Standard Operational Procedure'* required the referrer to include their professional registration number and contact details. However, in a small sample of external referrals viewed by inspectors, the professional registration number of the referrer was not provided to verify the individual making the referral was a recognised referrer. Therefore, greater assurance is required to ensure adherence to hospital policy for the identification of referrers submitting referrals from outside the hospital, to comply with the requirements of Regulation 10(3)(b).

In addition, under Regulation 10(4), practical aspects of medical radiological procedures can only be delegated to professionals who have completed a course in radiation safety as prescribed by an appropriate body, as per Regulation 22(3). On

the day of inspection, inspectors found that individuals were carrying out the practical aspects for nuclear medicine procedures in the absence of training requirements for nuclear medicine procedures been set by the relevant professional body. Although local training had been provided, the undertaking must review and update the delegation of practical aspects to achieve regulatory compliance.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Similar to the findings of previous inspections in 2022 and 2023, inspectors were satisfied that SVUH had the necessary arrangements in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users at SVUH and found evidence to demonstrate compliance with the requirements of this regulation. For example, an MPE was found to take responsibility for dosimetry and contributed to quality assurance (QA), acceptance testing and preparation of technical specifications of medical radiological equipment at the hospital. There was evidence to show the involvement of an MPE in the establishment and review of facility diagnostic reference levels (DRLs) across all modalities within the service, and MPEs were involved in several projects to optimise protocols to achieve lower doses, as required. Inspectors were satisfied that an MPE contributed to the analysis and dose calculations of incidents relating to medical exposures and contributed to staff training on radiation protection.

Judgment: Compliant

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

Inspectors were satisfied that MPEs were appropriately involved at SVUH. From discussions with staff in each area visited and members of the medical physics team, inspectors found that MPE resources were assigned to each modality with specific focus on medical radiological practices associated with higher radiological risk, in line with regulatory requirements. The evidence gathered demonstrated that the

contribution and involvement of an MPE was proportionate to the radiological risk posed by practices delivered at this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes implemented to ensure the radiation protection of service users undergoing medical exposures at the hospital during this inspection. Inspectors visited a range of radiology services provided at this facility, spoke with staff and management, and reviewed documentation to assess the safe delivery of medical exposures at SVUH. The evidence viewed showed compliance with Regulations 9, 11, 14, 15 and 16, while corrective actions were required to meet full compliance with Regulations 8, 13 and 17.

Inspectors identified several examples of good practices under this domain for the safe delivery of medical exposures. Inspectors noted the proactive approach taken by staff at the facility to optimise protocols to reduce doses to service users as discussed under Regulation 9. The systems, processes and oversight for the review and establishment of DRLs ensured that facility DRLs were established annually, compared with national DRLs, and where doses were found to consistently exceed national DRLs, appropriate investigation was initiated and corrective actions implemented. Optimisation of radiation doses was achieved through multidisciplinary input for the review of protocols and theoretical and practical training with demonstrations targeted at improving techniques used by staff during the practical aspects of a medical exposure. This approach resulted in a reduction of doses to service users across a range of modalities. Furthermore, the process for review and establishment of DRLs was used as a tool to identify potential areas to be included in clinical audit and quality improvement of the service.

Good practices were also evident in clinical audit of medical radiological procedures, which inspectors found were carried out in line with HIQA's national procedures, as per Regulation 13(4). The provision of information on the risks and benefits for patients undergoing treatment with radionuclides in nuclear medicine therapeutic procedures was also considered by inspectors to exemplify good practice.

Inspectors were satisfied that strict surveillance of medical radiological equipment met the requirements set out under Regulation 14. QA and quality control checks were monitored by the RSC, using key performance indicators (KPIs), to ensure performance testing was completed in line with the hospital QA programme. Other good practices were noted in practices involving higher dose procedures. For example, there was a process in place to monitor doses delivered during interventional radiology and interventional cardiology procedures and where necessary, follow up patients that were exposed to dose thresholds with the potential to cause skin damage.

Nothwithstanding these examples of good practice, inspectors found that the process of recording justification in advance for all medical radiological procedures requires improvement in some services to comply with Regulation 8. In addition, a gap in compliance in relation to Regulation 13(2), first identified during the 2022 inspection, remains an outstanding issue at the time of this inspection. Inspectors were informed that an upgrade to the radiology information system (RIS) and picture archiving communication system (PACS) system was due to be implemented in July 2025 and is expected to provide a solution to address this issue. Finally, the tracking, trending and analysis of near misses and potential incidents was another area that required improvement to ensure full compliance with Regulation 17.

Regulation 8: Justification of medical exposures

SVUH had a procedure that detailed the practitioner responsible for justifying individual medical exposures within the radiology service. Justification in advance of each medical exposure was recorded on the radiology information system.

Inspectors reviewed a sample of medical radiological procedure records across a range of modalities and found that the record of justification in advance of the procedure was evident in the majority of records viewed. However, not all medical radiological procedures carried out in the mammography and theatre services had a record to show that justification in advance had taken place. Inspectors were informed that these weaknesses in the justification process had already been identified at the hospital before this inspection and corrective actions had been implemented to improve compliance with the recording of justification by a practitioner.

In addition, inspectors were informed that medical exposures justified by a practitioner well in advance of the scheduled medical exposure was subject to a further review by a practitioner to ensure it was still justified. However, staff informed inspectors that there was no system in place to record the outcome of these reviews. Inspectors concluded that the process for justification in advance should be strengthened further to ensure the requirements of Regulation 8(15) are met for all medical exposures carried out at the hospital.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors viewed the procedures and processes to ensure that doses resulting from medical exposures were kept as low as reasonably achievable (ALARA). The hospital policy *Optimisation of Medical Exposures in the Radiology Department* outlined standard approaches for the optimisation of medical radiological procedures carried

out across all modalities within the radiology service. This document also outlined the processes to be applied for the optimisation of medical exposures involving minors, carers and comforters, and individuals subject to medical exposures undertaken as part of a research project, in addition to measures to be taken for the protection of the unborn child.

Inspectors noted multiple examples of good practice in relation to optimisation. For example, there were effective processes in place with strong oversight by hospital management of these processes. Doses found to exceed national DRLs by more that 20% in general X-ray prompted an investigation and corrective action to be taken. In the interventional radiology service, an upward drift was seen in facility DRLs for one procedure. To address this, a two-tiered approach to training was taken in which staff first completed an online training module and then attended a multidisciplinary clinical-based simulation of the procedure carried out under different circumstances. Inspectors were informed that the practical demonstration and review of the technique in conducting the practical aspects of this procedure, with real time assessment of dose demonstrated to staff, resulted in a significant drop in doses delivered to service users. Inspectors were also informed of a number of other optimisation projects ongoing or completed at the facility which also saw the reduction in doses in CT colongraphy, lumbar puncture procedures in interventional radiography and general X-ray.

In the nuclear medicine service, a forum called the 'Dose Optimisation for Radiological Equipment Nuclear Medicine Optimisation Group' was in place. This group considered optimisation of protocols and dosimetry through a multidisciplinary collaboration and close involvement between practitioners and medical physics for therapeutic nuclear medicine procedures. Inspectors were informed that this group took a step-by-step approach through each protocol with the aim of further optimising scan times and doses to service users.

Staff informed inspectors that radiological dose assessments were carried out in advance of each therapeutic nuclear medicine medical exposure. Patients undergoing treatment with radionuclides are routinely provided with information on the risks of ionising radiation and appropriate written instructions to restrict doses of persons in contact with the patient. In Peptide Receptor Radionuclide Therapy (PRRP) treatment with Lutetium-177 (lu-177) for instance, a three phase approach is taken for the provision of this information, and includes verbal and short condensed written reminder on the day of the medical exposure. In addition, detailed written documentation is also provided during an in-person consultation with the practitioner with responsibility for the medical exposure.

Inspectors found that staff at the hospital took a proactive approach to the optimisation of medical exposures which was underpinned by optimisation focused clinical audit practices. Examples of good practice in optimisation were evident across multiple areas within the radiology service which was similar to the findings and compliance level identified during the 2022 inspection. The collective approach taken by staff emphasised an organisational and service wide commitment to the radiation protection of services users undergoing medical exposures at SVUH.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were provided with facility DRLs established in 2024 for each area within the radiology service and DRLs were overseen and monitored by management as a key performance indicator (KPI), the progress of which was reviewed in RSC meetings. Facility DRLs were compared with national DRLs and a proactive multidisciplinary approach was taken to reviewing and optimising protocols to ensure doses were kept as low as reasonably achievable, if and when needed. Inspectors noted that facility DRLs were displayed in the control room of each area visited.

Judgment: Compliant

Regulation 13: Procedures

A sample of written protocols for standard radiological procedures were viewed by inspectors in each of the areas visited which provided evidence of compliance with Regulation 13(1).

The corrective action noted in the compliance plan submitted by the undertaking following the 2022 inspection by HIQA identified that a new RIS/PACS system, once implemented, would enable compliance with Regulation 13(2). However, the installation date was delayed. To address the gap in compliance, staff at the hospital had put in place an interim solution which inspectors found did not meet the requirements of this regulation in the reports of medical radiological procedures viewed. Inspectors were informed that the new RIS/PACS system will connect SVUH to the National Integrated Medical Imaging System (NIMIS) and is due to be installed in July 2025.

Referral guidelines were available to staff on desktops at work stations located in each clinical area as per regulations.

Inspectors reviewed a programme of clinical audit and a sample of audit reports related to radiological practices carried out at the facility. A clinical audit strategy was in place which was found to align with the principles and criteria detailed in HIQA's *National procedures for clinical audit of radiological procedures* published in November 2023. Inspectors viewed the 2024 and 2025 clinical audit programme for the radiology service and were informed of several examples of clinical audit which had resulted in the optimisation of protocols and reduction of doses to services users. Inspectors were satisfied that the approach taken incorporated audits of

structures, processes and outcomes in line with the national procedures, therefore, meeting the requirements of Regulation 13(4).

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory provided in advance of this inspection was reviewed and verified on site by inspectors. From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking as required under Regulation 14(1).

Inspectors found that a QA programme was established, implemented and maintained. Compliance with the QA programme and quality control checks was monitored as a KPI and updates discussed at the RSC. Records reviewed demonstrated that appropriate acceptance testing had been completed as required under Regulation 14(3)(a) and regular performance testing had been completed in line with frequencies detailed in the QA programme. The overall findings and compliance levels were consistent with the previous inspection carried out by HIQA in 2022.

Judgment: Compliant

Regulation 15: Special practices

Inspectors visited areas within the radiology service considered to be associated with higher doses such as interventional cardiology, interventional radiology, PET CT and nuclear medicine services and spoke with staff involved in carrying out procedures there. In all areas visited, staff described the measures in place to monitor dose levels to service users undergoing medical exposures in these services. Staff informed inspectors that a practitioner was present to optimise and monitor radiation doses throughout each procedure which provided assurance that potentially high doses to the skin were identified and followed up as required.

Overall, inspectors were satisfied from reviewing the systems in place, and discussions with staff, that special attention was given to optimising medical exposures involving high doses to the patient as per Regulation 15.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, inspectors observed multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation in public areas of the radiology department.

Documentation and imaging records reviewed throughout this inspection demonstrated compliance with this regulation. Inspectors saw evidence that demonstrated a practitioner had carried out the inquiry regarding the pregnancy or breast feeding status of all relevant service users and the answer was recorded and maintained under the service user record on the hospital radiology information system. Records showed that special attention was also paid to the re-justification of a medical radiological procedure by the referrer and practitioner in situations where pregnancy could not be ruled out.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following a review of documentation and discussion with staff, inspectors found that significant events that met the threshold for reporting to HIQA were managed appropriately and reported in line with the timelines in HIQA guidance. There was also evidence in minutes of meetings viewed to show that radiation incidents were regularly discussed at committees within the radiology governance structures.

Inspectors were informed that an electronic system was available to staff to record and analyse radiation incidents and potential incidents. Inspectors were provided with analysis and reports of radiation incidents which had occurred in 2024, however, the same trending and analysis for potential incidents and near misses was not available to view during the inspection. From discussions with staff and management regarding the types of events and incidents that were routinely reported, inspectors found that reporting of potential incidents and near misses could be improved to comply with Regulation 17(1)(c).

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, as amended. 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	Substantially Compliant
Regulation 10: Responsibilities	Not 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	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for St Vincent's University Hospital OSV-0007407

Inspection ID: MON-0044591

Date of inspection: 08/04/2025

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, as amended.

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 6: Undertaking	Substantially Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:
Identification of external referrers
On 18 June 2025, SVUH adopted Healthlink as our electronic GP referral pathway. External hospitals referrals will continue to be accepted in writing and referring hospitals will be sent a communication through the CEO's office in August 2025 detailing the minimum requirements for all referrals and stating that inappropriate referrals will not be accepted.

Practical aspects delegation in nuclear medicine
For diagnostic imaging procedures in nuclear medicine the practice of individually trained and signed off nursing staff administering radiopharmaceuticals prepared and approved for administration to the patient by a radiographer has been discontinued as of June 2025. SVUH will engage in discussion with the NMBI, as the relevant professional body, to explore the possibility of the development of training requirements for delegation of radiopharmaceutical administration in nuclear medicine for diagnostic applications to RGNs. SVUH's training program will be shared with them.

For therapeutic intravenous administration of Lutathera in Nuclear Medicine, the Nurse no longer commences or progresses the infusion of the drug. The Consultant Radiologist or Nuclear Medicine Physician carries out these duties. In the future, other practitioners will possibly be also trained to carry out these duties in accordance with the regulation.

Generic justification
The radiation safety procedures shall be amended to include further detail about how new proposed practices must be communicated up through the clinical directors to the CEO and be communicated and approved to commence by the RSC.

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
Identification of external referrers
On 18 June 2025, SVUH adopted Healthlink as our electronic GP referral pathway. External hospitals referrals will continue to be accepted in writing and referring hospitals will be sent a communication through the CEO's office in August 2025 detailing the minimum requirements for all referrals and stating that inappropriate referrals will not be accepted.

Practical aspects delegation in nuclear medicine
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Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Records of justification
Audits of compliance with recording of justification in advance were completed in April 2025 and further audits will be completed in July 2025 and October 2025 (across all modalities) and thereafter will remain part of the audit schedule.

Where justification has occurred "well in advance" and an additional justification is carried out by a practitioner on the day of exposure, the current RIS/PACS system only allows storage of a single time stap. Multiple records of justification will be possible on the new RIS/PACS.

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Dose information on report The new RIS/PACS will connect SVUH to NIMIS and this has a go live date of Nov 2025. We have engaged with the national NIMIS team and will adopt the recommendation of the HSE National Radiation Protection Committee.	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: Near misses Previously near misses were reported and were dealt with in the same way as incidents reported. From June 2025 near misses are flagged as near misses and trending and analysis will be possible from now on. There will be staff education in July 2025 to highlight how to report near misses.	

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 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.	Substantially Compliant	Yellow	30/08/2025
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical	Substantially Compliant	Yellow	30/10/2025

	exposure, and shall provide such records to the Authority on request.			
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Substantially Compliant	Yellow	30/08/2025
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, (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	Not Compliant	Orange	30/06/2025

	in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			
Regulation 10(4)(b)	Practical aspects of a medical radiological procedure may be delegated by the practitioner as appropriate, to one or more individuals, (i) registered by the Dental Council, (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.	Not Compliant	Orange	30/06/2025

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	31/12/2025
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	30/06/2025