



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:	28 June 2022
Medical Radiological Installation Service ID:	OSV-0007407
Fieldwork ID:	MON-0032795

About the medical radiological installation:

St. Vincent's University Hospital (SVUH) is a large academic teaching hospital and part of the St. Vincent's Healthcare Group. The Emergency Department is a referral centre for stroke and major trauma presentations for the region. SVUH is also the location of a number of national centres including the National Centre for Cystic Fibrosis, National Cancer Control Programme (NCCP), National Liver Transplant Programme and National Pancreas Transplant Programme.

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
Tuesday 28 June 2022	09:00hrs to 16:00hrs	Kirsten O'Brien	Lead
Tuesday 28 June 2022	09:00hrs to 16:00hrs	Maeve McGarry	Support

Governance and management arrangements for medical exposures

An inspection of St Vincent's University Hospital (SVUH) was carried out on the 28 June 2022 to assess compliance with the regulations. As part of the inspection, inspectors visited areas in the hospital where medical radiological procedures were conducted, in particular, computed tomography (CT), nuclear medicine, positron emission tomography computed tomography (PET CT) and the two dual-energy X-ray absorptiometry (DXA) scanners which are located in the Radiology Department and Bone and Joint Unit.

On the day of inspection a clear overarching governance structure was found to be in place at SVUH. The interim chief executive officer (CEO) was the designated manager and the person responsible for the radiation protection of service users at the hospital. The designated manager was a member of the Radiation Safety Committee (RSC) which was the main forum for providing oversight of radiation protection at the hospital. Terms of reference and minutes as well as annual and quarterly reports for the RSC were also reviewed by inspectors in addition to speaking with staff and management. The RSC met four times a year and its membership included representation from individuals involved in the conduct of medical exposures at the hospital, as well as other relevant departments. The RSC had a reporting relationship to the Quality and Patient Safety Executive Committee as well as representation on other committees in the hospital such as the Clinical Audit Committee.

Documentation reviewed by inspectors outlined the allocation of responsibility for the radiation protection of service users at the hospital. Inspectors noted the policies and procedures, and in particular a chart which depicted the professional groups allocated clinical responsibility for medical exposures at the hospital, provided a good visual representation of the allocated responsibilities locally.

On the day of inspection, the hospital had appropriate mechanisms in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at SVUH. Inspectors also identified that a programme for the training and education of medical physics personnel was in place at the hospital which had a positive impact on the overall service.

The practical aspects of medical exposures at the hospital were only carried out by those recognised as practitioners in the regulations or individuals delegated the practical aspects by SVUH. Inspectors reviewed a sample of referrals in the Radiology Department for nuclear medicine, PET CT and CT radiological procedures and found that both the referrer and a practitioner were involved in the justification process for individual medical exposures in these areas. Additionally, in the Radiology Department, practitioners, MPEs and those entitled to carry out the practical aspects of medical radiological procedures were involved in the optimisation process for all medical radiological procedures at the hospital.

However, notwithstanding the examples of good practice found on the day of inspection, areas of non-compliance were also identified by inspectors. Individuals that were not recognised in the regulations as a referrer or practitioner had been allocated responsibility by SVUH for inquiring and recording information about the pregnancy and breastfeeding status of patients for nuclear medicine and PET CT procedures.

In the DXA service located in the Bone and Joint Unit inspectors found that clinical responsibility had been allocated to persons that are not recognised to act as a practitioner in the regulations. From a review of documentation and other records and from speaking with staff, inspectors found that responsibility for justification had been delegated to staff not entitled to act as practitioners as per the regulations. Furthermore, although the lead practitioner for the DXA service of the Bone and Joint Clinic was found to have oversight of aspects of optimisation for the service, such as by approving the diagnostic reference levels (DRLs) for the service, documentation reviewed showed that responsibility for optimisation had been delegated from the lead practitioner to staff not entitled to act as a practitioner.

While inspectors were satisfied that the non-compliances with the regulations found over the course of the inspection regarding the involvement of a practitioner in the Bone and Joint Unit's DXA service presented a low radiation risk to the service user, the undertaking was required to submit an urgent compliance plan to address the non-compliances identified regarding the Bone and Joint Unit's DXA service at SVUH. The undertaking's response provided assurance that the risk was adequately addressed.

Regulation 4: Referrers

A sample of referrals were reviewed by inspectors who also spoke with staff at the hospital. Inspectors were satisfied that only referrals for medical radiological procedures from individuals entitled to refer as per Regulation 4 were carried out at SVUH.

Judgment: Compliant

Regulation 5: Practitioners

Documentation submitted in advance of the inspection was reviewed by inspectors who also spoke with staff involved in the conduct of medical exposures. While clinical responsibility for individual medical exposures was found to be taken by an individual entitled to act as a practitioner in most areas in the hospital, inspectors found that clinical responsibility for medical exposures in the DXA service located in the Bone and Joint Unit at SVUH had been taken by individuals not recognised to act

as a practitioner in the regulations. Actions to come into immediate compliance were taken by management at the hospital following the inspection.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at SVUH were reviewed by inspectors. Management at the hospital outlined the overarching allocation of responsibility for the radiation protection of service users at the hospital. The interim CEO was the designated manager and undertaking representative for SVUH. The interim CEO reported upwards to the board of St. Vincent's Hospital Group which provided oversight for the provision of services at SVUH. A directorate-based management structure was in place at the hospital, with the lead of each directorate reporting to the interim CEO.

The RSC was the main forum for radiation protection at the hospital. The designated manager was the person responsible for the radiation protection of service users at the hospital and a member of the RSC. The RSC was chaired by a consultant radiologist. Inspectors found that the membership of the RSC included representation from all areas where medical exposures were conducted at the hospital, including non-radiology consultants, for example a consultant cardiologist, which was noted as a positive measure for the undertaking to ensure oversight of radiation protection at the hospital. The RSC met four times a year and provided an annual report in addition to quarterly reports to the Quality and Patient Safety Executive Committee. RSC representation was also present on the Health and Safety Committee, the Clinical Audit Committee and the Positive Patient Identification Committee.

Documentation reviewed by inspectors outlined the allocation of responsibility for the radiation protection for service users at the hospital. Inspectors noted the policies and procedures, and in particular a chart which depicted the professional groups allocated clinical responsibility for medical exposures at the hospital, provided a representation of the allocation of responsibility for radiation protection at the hospital.

However, following a review of this documentation and speaking with staff inspectors found that clinical responsibility for medical radiological procedures had been allocated to individuals not entitled to take clinical responsibility under Regulation 5. In particular, inspectors found that responsibility for justification had been delegated to staff not entitled to act as practitioners as per the regulations.

Furthermore, although the lead practitioner for the DXA service of the Bone and Joint Unit was found to have oversight of aspects of optimisation for the service, such as by approving the DRLs, documentation reviewed showed that responsibility for optimisation had been delegated from the lead practitioner to staff not entitled to act as a practitioner. Additionally, individuals that were not recognised in the regulations as a referrer or practitioner had been allocated responsibility by SVUH for inquiring and recording information about pregnancy and breastfeeding in nuclear medicine and PET CT. This allocation of responsibility to individuals not entitled to act as a practitioner or referrer contributed to non-compliances with other regulations on the day of inspection.

Overall, while inspectors were satisfied that overarching governance and management structures were in place at the hospital, measures to come into compliance immediately were sought on the day of inspection in respect of the allocation of responsibility for radiation protection to persons not recognised to act as a practitioner in the regulations. An assurance was provided to inspectors on the day of inspection that immediate measures had been taken by the hospital on the day of inspection to come into compliance with Regulation 16.

Furthermore, inspectors were informed by management at the hospital that a review of the DXA service would be carried out following the inspection. However, to provide assurance that the risk was adequately addressed, the undertaking was required to submit an urgent compliance plan to address the non-compliances identified over the course of the inspection regarding the DXA service at SVUH. The undertaking's response did provide assurance that the risk was addressed.

Judgment: Not Compliant

Regulation 10: Responsibilities

The practical aspects of medical exposures at SVUH were carried out by persons recognised as practitioners or by persons delegated the practical aspects by SVUH. A record of delegation of the practical aspects was provided to inspectors on the day of inspection. The practical aspects of DXA imaging procedures in the Bone and Joint Unit were delegated to individuals who were registered with the Nursing and Midwifery Board of Ireland. For nuclear medicine and PET CT procedures the practical aspects were delegated to individuals who were registered with the Nursing and Midwifery Board of Ireland and individuals recognised as MPEs by the Irish College of Physicists in Medicine.

However, on the day of inspection, inspectors were not satisfied that SVUH had measures in place to ensure that all aspects of clinical responsibility were carried out by a practitioner for all medical radiological procedures conducted at the hospital. Inspectors found that while the individual elements of clinical responsibility for medical exposures were allocated to different professional groups at the hospital, in some instances the allocation of clinical responsibility was to a person who was not

recognised as a practitioner in the regulations.

Inspectors reviewed a sample of referrals in the Radiology Department for nuclear medicine, PET CT and CT radiological procedures and found that both the referrer and a practitioner were involved in the justification process for individual medical exposures. Additionally, in the Radiology Department a practitioner, an MPE and those entitled to carry out the practical aspects of medical radiological procedures were involved in the optimisation process for all medical radiological procedures at the hospital.

However, following a review of records and documentation and communication with staff, inspectors found that a practitioner did not take responsibility for all aspects of clinical responsibility for all individual DXA imaging procedures carried out at the Bone and Joint Unit in the hospital. For example, a practitioner did not justify individual DXA imaging referrals in advance of the exposure taking place, as required by the regulations. All medical exposures to ionising radiation require a practitioner to justify each individual medical radiological procedure in advance of the exposure being carried out to determine that the medical exposure provides a sufficient net benefit to the patient. Additionally, responsibility for optimisation of DXA procedures had been delegated to individuals that are not recognised to take clinical responsibility as a practitioner as per Regulation 5.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk found on inspection relating to the justification of DXA imaging procedures by a practitioner. The undertaking's response provided an assurance that the risk was adequately addressed.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

SVUH had the necessary arrangements in place to ensure the continuity of medical physics expertise at the hospital. Inspectors noted that the hospital had established a programme for the training and education of medical physics personal at SVUH. Inspectors spoke with physics staff and were informed that medical physics staff were rotated through different areas and provided with mentoring by an MPE as they worked to attain required competencies as part of training requirements for recognition as an MPE. This was seen as an example of good practice in ensuring the ongoing provision of medical physics expertise at SVUH.

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. The roles and responsibilities of MPEs at the hospital were clearly documented with a responsible MPE for particular modalities at the hospital clearly allocated and understood by all staff spoken with on the day of inspection.

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. An MPE was also involved in the analysis of events involving, or potentially involving, accidental or unintended medical exposures and as part of a comprehensive multidisciplinary team in optimising medical exposures at the hospital. Multiple research projects were being carried out at the hospital which had a positive impact in driving optimisation in high dose areas such as PET CT.

An MPE provided training in the area of radiation protection to staff at the hospital and had developed a training programme for radiation protection that included both a theoretical and practical component. The practical component was also seen as a good example of informing non-radiology staff about the impact of different imaging parameters on the radiation dose so as to promote good practice regarding the optimisation of medical exposures in areas such as theatre. Inspectors also found that radiation protection training for staff involved in the use of ionising radiation was a key performance indicator (KPI) that was monitored by the hospital.

Judgment: Compliant

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

On the day of inspection, the hospital had appropriate mechanisms in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at SVUH. In particular, dedicated MPEs were found to be appropriately involved in therapeutic nuclear medicine and PET CT practices as required by the regulations.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at SVUH. Staff at the hospital demonstrated a good reporting culture with management at the hospital

identifying and promoting the importance of reporting near-miss events in order to analyse these to identify trends or patterns. Another example of good practice was the involvement of radiography management on the Positive Patient Identification Committee and RSC representation on the Quality and Patient Safety Executive Committee.

A programme of clinical audit for medical radiological procedures was found to be in place with multidisciplinary involvement from all staff grades. Additionally, staff involved in the conduct of medical radiological procedures were also represented on the hospital's Clinical Audit Committee. However, on the day of inspection, information about the radiation dose did not form part of the report of the medical exposures.

Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters in waiting areas. Additional information was also provided as part of patient information leaflets provided to patients undergoing certain procedures, such as PET CT imaging and interventional radiology procedures. For therapeutic nuclear medicine procedures information about the risks associated with ionising radiation and written instructions regarding the reduction of dose to persons in contact with the patient which was provided to the patient before they left the hospital. Inspectors reviewed a sample of documentation for individuals participating in research involving medical exposures and were satisfied that these individuals participated voluntarily and were informed in advance about the risks of the exposure.

On the day of inspection multiple examples of optimisation were found to be in place to ensure adherence to the as low as reasonably achievable (ALARA) principle at SVUH. In particular, inspectors noted that diagnostic reference levels (DRLs) were used in the optimisation process across a number of modalities. Of particular note was the use of DRLs to identify where the radiation dose associated with a procedure exceeded the relevant national DRL in order to optimise the imaging procedures and protocols used and identify the need for supplementary education to staff.

Furthermore, quality assurance of medical radiological equipment was a hospital KPI. The clear allocation of responsibility to individual MPEs and staff at the hospital for specific equipment meant that all medical radiological equipment at SVUH was found to be kept under strict surveillance regarding radiation protection. Inspectors also were satisfied that SVUH gave additional attention to special practices in areas involving high doses to the patient such as PET CT.

A non-compliance was found on the day of inspection regarding the DXA imaging service as part of the Bone and Joint Unit regarding the justification of DXA imaging procedures in advance. The undertaking was required to submit an urgent compliance plan under Regulation 8 to address this non-compliance identified on inspection. The undertaking's response provided an assurance that the risk was adequately addressed.

In areas of the Radiology Department visited on the day, inspectors found that a practitioner had satisfied themselves that each individual medical exposure was

justified in advance of carrying out the medical radiological procedure. A sample of referrals reviewed were in writing, stated the reason for the request and were accompanied by medical data. The record of justification of medical radiological procedures in advance by a practitioner in the Radiology Department was also available on the hospital's radiology information system.

Inspectors also identified a non-compliance relating to Regulation 16 at the hospital. This non-compliance related to nuclear medicine and PET CT procedures where the inquiry and recording of the answer of pregnancy or breastfeeding status was sometimes carried out by persons not recognised as referrers or practitioners in the regulations. This finding was identified to staff and management on the day of inspection and inspectors were provided with an assurance that a change in practice had been put in place on the day of inspection to come into compliance with the requirements of the regulation.

Notwithstanding the areas of non-compliance identified over the course of the inspection, inspectors were satisfied that appropriate governance and management arrangements were in place to ensure the safe delivery of medical exposures at SVUH. Inspectors also noted the assurances of management on the day, and through the response to the urgent compliance plan, that good oversight mechanisms were in place and appropriate actions taken to ensure the radiation protection of service users attending the hospital.

Regulation 8: Justification of medical exposures

Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters in waiting areas. Additional information was also provided as part of patient information leaflets for service users undergoing medical radiological procedures, for example, inspectors reviewed a sample of leaflets available to individuals attending SVUH for PET CT imaging or fluoroscopically-guided interventional procedures.

For patients undergoing therapeutic nuclear medicine procedures, staff communicated to inspectors the process in place to ensure that information about the benefits and risks associated with the radiation dose from the medical exposure were comprehensively communicated to patients, or their representative in advance of attending the hospital. This involved contacting the individual by phone or email and providing the patient with an opportunity to discuss the medical exposure as required. As part of this process, a risk assessment was conducted to ensure that any medical exposure to a carer or comforter as a result of a therapeutic nuclear medicine exposure to a patient was considered including if there was a sufficient benefit when the risks as a result of the medical exposure to were considered.

On the day of inspection, inspectors spoke with staff in the DXA imaging service provided as part of the Bone and Joint Unit who explained the process in place for accepting referrals for DXA imaging procedures. From a review of the documentation received in advance of the inspection, inspectors found that

justification was not carried out in advance of the medical exposure by a practitioner. Inspectors found that referrals were routinely justified by staff not entitled to act as a practitioner, based on a list of criteria as per the hospital's DXA guidelines and procedures. Where the clinical indications for the medical exposure did not meet the specific criteria, staff would bring the request to the attention of a medical practitioner registered with the medical council for a decision on justification. Noting that justification by a person entitled to act as a practitioner under Regulation 5 only occurred by exception, inspectors brought this non-compliance with the regulations to the attention of personnel working in the DXA service on the day of inspection and also identified this issue to the designated manager and other management at the hospital.

Aside from this non-compliance regarding the DXA imaging service in the Bone and Joint Unit, inspectors were satisfied that a practitioner had satisfied themselves that each individual medical exposure was justified in advance of carrying out the medical radiological procedure in all other areas visited on the day. A sample of referrals were reviewed by inspectors and were found to be in writing, stated the reason for the request and were accompanied by medical data in order to allow a practitioner to consider the benefits and risks of the individual medical exposure. The record of justification of medical radiological procedures in advance by a practitioner was available for the sample of medical radiological procedures reviewed over the course of the inspection.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk on inspection relating to the justification of DXA imaging procedures by a practitioner. The undertaking's response provided assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff to determine the processes and procedures in place at SVUH to ensure that all doses due to medical exposures were kept as low as reasonably achievable while still obtaining the required information or intended therapeutic outcome. For example inspectors found that following the installation of a new CT scanner, staff identified procedures that would benefit from the technological advances available to them in order to achieve lower doses while obtaining the required medical and diagnostic information. Specific clinical tasks were prioritised as a result of the establishment and review of local facility and national CT DRLs. New CT imaging protocols were developed by a multidisciplinary collaboration at the hospital which included radiographers, radiologists and the MPE assigned to CT. Furthermore, in addition to standard anatomical site protocols, additional lower dose protocols were developed such as a specific protocol for cystic fibrosis patients and acute appendicitis in line with the

ALARA principle.

Additionally, other opportunities to ensure optimisation were also found to be in place. For example, in the general X-ray department a feedback mechanism was in place using a dedicated email account to identify opportunities to improve on imaging techniques to ensure the consistent production of adequate diagnostic information.

Furthermore, staff also provided information to inspectors about the processes in place for medical or biomedical research involving medical exposures at the hospital. This information included how SVUH ensured that all individuals participated voluntarily in the research projects and were informed in advance about the risks of the exposure. A sample of patient information leaflets and consent forms developed for individuals participating in research were reviewed and found to contain information about the medical exposure including the potential risks.

Inspectors reviewed the patient information leaflets for radioiodine therapy procedures carried out at SVUH. These leaflets included information about the risks associated with ionising radiation and written instructions regarding the reduction of dose to persons in contact with the patient. Inspectors also spoke with staff involved in carrying out therapeutic nuclear medicine procedures who explained how this written information was provided to the patient in advance of their treatment.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established and were reviewed annually for all modalities at SVUH. Inspectors observed DRL values displayed in the control areas of general X-ray, CT and PET CT and were satisfied that DRLs were used to optimise medical exposures carried out at the hospital.

Additionally, inspectors found an example of good practice where a review had been carried out at the hospital following the identification of a local DRL exceeding the relevant national DRL. Consequently, a number of corrective actions were carried out, including optimising the imaging protocol by a multidisciplinary team. The use of DRLs as a mechanism to identify opportunities for the optimisation of medical exposures at the hospital was a positive finding on the day of inspection.

Judgment: Compliant

Regulation 12: Dose constraints for medical exposures

From speaking with staff and reviewing documentation and other information

inspectors were satisfied that relevant dose constraints were used by SVUH to ensure the optimisation of medical exposures for comforters and carers and individuals involved in research involving the use of ionising radiation.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection written protocols for standard medical radiological procedures for each type of equipment were found to be in place at the hospital. Referral guidelines, which take into account the radiation doses, were identified in the hospital's policies and procedures and were available to referrers.

Inspectors also noted that an extensive programme of clinical audit was in place relating to medical exposures at SVUH. Staff involved in the conduct of medical radiological procedures were represented on the hospital's Clinical Audit Committee which provided a mechanism for shared learning and service improvements as a result of clinical audit findings across all areas in SVUH. An additional example of good practice and staff involvement in quality improvements was a radiology clinical audit day which involved all staff grades and roles in the department. The inclusion of all radiology staff members including administrative staff in audit was noted as an example of the hospital's recognition of the importance of clinical audit for the entire patient pathway. These efforts ensured that audit was both used as a tool for demonstrating compliance with the regulations and also a commitment to quality improvement which inspectors found was commendable.

However, inspectors reviewed a sample of records for medical radiological procedures and found that, with the exception of nuclear medicine and PET CT procedures, information about the radiation dose was not included on the report of the medical exposures. To ensure compliance with Regulation 13(2) the undertaking needs to implement measures to ensure that information relating to patient exposure forms part of the report of all medical radiological procedures carried out at SVUH.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before the inspection. Over the course of the inspection processes and procedures were found to be in place at SVUH to ensure that all medical radiological equipment was kept under strict surveillance regarding radiation protection. Inspectors found that annual QA was a hospital KPI which was an added assurance

that a QA programme had been implemented and maintained at the hospital.

A programme was in place to ensure the assessment of dose or verification of administered activity for medical radiological procedures. For example, residual dose measurements were taken and recorded for PET CT procedures and consideration was given to the time elapsed from when the radionuclide was drawn up to when it was administered to the patient. Inspectors also reviewed a sample of records of performance and acceptance testing.

The hospital had a medical radiological equipment replacement programme in place for equipment that had passed its nominal replacement date. This was seen as a positive approach by inspectors and examples of how technological advancements can be used to further optimise medical exposures were noted by inspectors, for example in CT and PET CT as described in Regulations 9 and 15.

Judgment: Compliant

Regulation 15: Special practices

Inspectors spoke with staff and reviewed documentation and other records which provided examples of compliance regarding special practices in areas involving high doses to the patient. In particular, a proactive approach to optimisation was identified in PET CT where research was ongoing to identify methods of ensuring that the radiation doses received by patients and other service users were optimised. For example, a multidisciplinary team was involved in ensuring that the administered activity as part of Gallium PET CT scans was kept as low as reasonable achievable consistent with obtaining the required medical information. Additionally, studies involving the calculation of residual dose to ensure that administered activity was appropriately verified for patients in PET CT were also carried out.

Special attention was also given to the assessment of the radiation dose received by patients undergoing fluoroscopically-guided interventional procedures in radiology and cardiology. SVUH had also measures in place to identify and ensure appropriate follow up for patients where a pre-defined radiation dose threshold is reached during a procedure. This follow-up included MPE involvement in calculating the exact skin dose received.

Additionally, inspectors were informed that due to the newer medical radiological equipment and technology available in some areas, extra optimisation measures were available to staff to assist them in assuring doses were kept as low as reasonable achievable. For example, methods such as incorporating iterative reconstruction techniques in CT and similarly using a detector with increased sensitivity to detect radiation when generating an image in PET CT.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in public places such as changing rooms and waiting areas. Additionally, inspectors noted a flow-chart, outlining the steps to follow to establish pregnancy status, was available as a memory aid for radiographers in the general X-ray control area.

On the day of inspection, radiographers were found to be responsible for carrying out the inquiry of patients' pregnancy status where relevant in line with the regulations for most medical exposures at the hospital. However, inspectors found that in nuclear medicine and PET CT the inquiry and recording of the answer of pregnancy or breastfeeding status was sometimes carried out by persons not recognised as referrers or practitioners in the regulations. This finding was identified to staff and management on the day of inspection and inspectors were provided with an assurance that a change in practice had been put in place to come into compliance with the requirements of the regulation immediately following this inspection.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

On the day of inspection, SVUH had an appropriate system in place for recording and analysing events involving, or potentially involving an unintentional or accidental exposure to ionising radiation. Inspectors were satisfied that a good culture of reporting was proactively encouraged by management at the hospital. Management at the hospital had also ensured that a formal process was now in place to ensure that a summary of the investigation into any significant event and corrective actions were signed off by senior management at the hospital and submitted to HIQA within the required time frame.

Inspectors were also satisfied that the hospital had a system in place to share information and corrective actions regarding incidents involving medical exposures to all staff members. For example, a member of radiography management was a member of the Positive Patient Identification Committee for SVUH. This hospital-wide and multidisciplinary focus on ensuring correct patient identification and procedures was identified by inspectors as an example of good practice.

Additionally, inspectors also found that technological advancements were also incorporated into work flows in order to reduce and minimise the probability of an event occurring involving an accidental or unintended exposure. For example, as an extra measure to ensure that the correct patient receives the correct medical exposure the patient's name and medical radiological procedure are now displayed

in the CT room. This was possible due to the additional capabilities of the new medical radiological equipment which had been identified as a measure to reduce the likelihood of the incorrect patient receiving a medical exposure.

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	Not Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 12: Dose constraints for medical exposures	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

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

Inspection ID: MON-0032795

Date of inspection: 28/06/2022

Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 5: Practitioners	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 5: Practitioners: A change in practice was implemented immediately after notification by HIQA to ensure that every Bone and Joint DXA scan is individually justified by a Consultant Endocrinologist. The Consultant Endocrinologist now receives hardcopies of referrals, checks the clinical indications on the referral against those listed in the protocol, therefore providing individual justification in advance of the DXA examination. The Consultant Endocrinologist signs and dates each referral, which is subsequently scanned and added to the patient's file on the Radiology Information System (RIS). The referral criteria used are based on those published by the International Society for Clinical Densitometry. At the time of imaging, the trained DXA nurses will continue to check that the patient's imaging is justified. Prior to proceeding with the exposure, they will continue to check imaging history and will double check that the correct imaging protocol is used as per departmental protocol. The radiation safety procedures and relevant clinical procedures have been amended accordingly to reflect this change in workflow.</p> <p>The Bone and Joint DEXA service accounts for approximately 1% of SVUH patients undergoing medical exposures a year.</p>	
Regulation 6: Undertaking	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Relating to the issue of non-compliance identified in Bone and Joint DEXA service:</p> <p>A change in practice was implemented immediately after notification by HIQA to ensure that every Bone and Joint DXA scan is individually justified by a Consultant Endocrinologist. The Consultant Endocrinologist now receives hardcopies of referrals,</p>	

checks the clinical indications on the referral against those listed in the protocol, therefore providing individual justification in advance of the DXA examination. The Consultant Endocrinologist now signs and dates each referral, which is subsequently scanned and added to the patient's file on the Radiology Information System (RIS). The referral criteria used are based on those published by the International Society for Clinical Densitometry. At the time of imaging, the trained DXA nurses will continue to check that the patient's imaging is justified. Prior proceeding with the exposure, they will continue to check imaging history and will double check that the correct imaging protocol is used as per departmental protocol. The radiation safety procedures and relevant clinical procedures have been amended accordingly to reflect this change in workflow.

Relating to the issue of non-compliance identified for a subset of patients attending for PET CT and Nuclear Medicine procedures (<0.5% of patients undergoing medical exposures in SVUH) whose pregnancy status check was carried out by the nurse or MPE performing their medical exposure.

A change in practice was implemented immediately after notification by HIQA, to ensure that nurses and MPEs were removed from the list of staff authorised to carry out the documented procedure in place for determination of the pregnancy status for women of child-bearing age. Practitioners are now the only professional group authorised to perform this function. The hospital will continue to provide training and assessment to new practitioners before they take on this responsibility with the aim of ensuring that the zero incident rate in relation to women of child-bearing age undergoing Nuclear Medicine and PET CT is maintained. Periodic audits will continue to monitor compliance of the procedure. Both MPE and nurse carrying out the medical exposure will need to satisfy themselves that the pregnancy status declaration form has been completed correctly before proceeding with the exposure.

The relevant policies and documentation are under revision and will be signed off at the radiation safety committee meeting on 14/09/2022.

Regulation 10: Responsibilities	Substantially Compliant
---------------------------------	-------------------------

Outline how you are going to come into compliance with Regulation 10: Responsibilities: Relating to the issue of non-compliance identified in Bone and Joint DEXA service (<1% service users annually):

A change in practice was implemented immediately after notification by HIQA to ensure that every Bone and Joint DXA scan is individually justified by a Consultant Endocrinologist. The Consultant Endocrinologist now receives hardcopies of referrals, checks the clinical indications on the referral against those listed in the protocol, therefore providing individual justification in advance of the DXA examination. The Consultant Endocrinologist now signs and dates each referral, which is subsequently scanned and added to the patient's file on the Radiology Information System (RIS). The

referral criteria used are based on those published by the International Society for Clinical Densitometry. At the time of imaging, the trained DEXA nurses will continue to check that the patient's imaging is justified. Prior proceeding with the exposure, they will continue to check imaging history and will double check that the correct imaging protocol is used as per departmental protocol. The radiation safety procedures and relevant clinical procedures have been amended accordingly to reflect this change in workflow.

Relating to the issue of non-compliance identified for a subset of patients attending for PET/CT and Nuclear Medicine procedures (<0.5% of patients undergoing medical exposures in SVUH) whose pregnancy status check was carried out by the nurse or MPE performing their medical exposure.

A change in practice was implemented immediately after notification by HIQA, to ensure that nurses and MPEs were removed from the list of staff authorised to carry out the documented procedure in place for determination of the pregnancy status for women of child-bearing age. Practitioners are now the only professional group authorised to perform this function. The hospital will continue to provide training and assessment to new practitioners before they take on this responsibility with the aim of ensuring that the zero incident rate in relation to women of child-bearing age undergoing Nuclear Medicine and PET CT is maintained. Periodic audits will continue to monitor compliance of the procedure. Both MPE and nurse carrying out the medical exposure will need to satisfy themselves that the pregnancy status declaration form has been completed correctly before proceeding with the exposure.

The relevant policies and documentation are under revision and will be signed off at the radiation safety committee meeting on 14/09/2022.

Regulation 8: Justification of medical exposures	Not Compliant
--	---------------

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
 A change in practice was implemented immediately after notification by HIQA to ensure that every Bone and Joint DXA scan is individually justified by a Consultant Endocrinologist. The Consultant Endocrinologist now receives hardcopies of referrals, checks the clinical indications on the referral against those listed in the protocol, therefore providing individual justification in advance of the DXA examination. The Consultant Endocrinologist now signs and dates each referral, which is subsequently scanned and added to the patient's file on the Radiology Information System (RIS). The referral criteria used are based on those published by the International Society for Clinical Densitometry. At the time of imaging, the trained DXA nurses will continue to check that the patient's imaging is justified. Prior proceeding with the exposure, they will continue to check imaging history and will double check that the correct imaging protocol is used as per departmental protocol. The radiation safety procedures and relevant

clinical procedures have been amended accordingly to reflect this change in workflow.

The Bone and Joint DEXA service accounts for approximately 1% of SVUH patients undergoing medical exposures.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
We have explored options of providing dose information on the radiology with our current RIS provider and this is considered not viable. However, this system is at end of life and the hospital is currently out to tender for a RIS/PACs solution. The capacity to input dose information directly into the radiology report has been stipulated as mandatory in the tender specifications.

As at 11 August 2022 the tender has closed and responses are being evaluated. Once the new RIS/PACS is installed and commissioned, the inclusion of medical exposure metric on the report will be comprehensively tested for all systems prior to implementation. The target date for full implementation is 28/05/2023.

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:
Relating to the issue of non-compliance identified for a subset of patients attending for PET/CT and Nuclear Medicine procedures (<0.5% of patients undergoing medical exposures in SVUH) whose pregnancy status check was carried out by the nurse or MPE performing their medical exposure.

A change in practice was implemented immediately after notification by HIQA, to ensure that nurses and MPEs were removed from the list of staff authorised to carry out the documented procedure in place for determination of the pregnancy status for women of child-bearing age. Practitioners are now the only professional group authorised to perform this function. The hospital will continue to provide training and assessment to new practitioners before they take on this responsibility with the aim of ensuring that the zero incident rate in relation to women of child-bearing age undergoing Nuclear Medicine and PET CT is maintained. Periodic audits will continue to monitor compliance of the procedure. Both MPE and nurse carrying out the medical exposure will need to satisfy themselves that the pregnancy status declaration form has been completed correctly

before proceeding with the exposure.

The relevant policies and documentation are under revision and will be signed off at the radiation safety committee meeting on 14/09/2022.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Not Compliant	Orange	01/07/2022
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	01/07/2022
Regulation 5(c)	A person shall not take clinical responsibility for	Not Compliant	Orange	01/07/2022

	<p>an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).</p>			
Regulation 6(3)	<p>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.</p>	Not Compliant	Orange	14/09/2022
Regulation 8(8)	<p>An undertaking shall ensure that all individual medical exposures carried out on its</p>	Not Compliant	Orange	01/07/2022

	behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.			
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 exposure, and shall provide such records to the Authority on request.	Not Compliant	Orange	14/09/2022
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	14/09/2022
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Not Compliant	Orange	14/09/2022
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Orange	01/07/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient	Not Compliant	Orange	28/05/2023

	exposure forms part of the report of the medical radiological procedure.			
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Not Compliant	Red	01/07/2022
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	Red	01/07/2022