



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:	07 February 2023
Medical Radiological Installation Service ID:	OSV-0007407
Fieldwork ID:	MON-0037872

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 7 February 2023	10:00hrs to 15:30hrs	Kirsten O'Brien	Lead
Tuesday 7 February 2023	10:00hrs to 15:30hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

A short-notice announced inspection was carried out at St Vincent's University Hospital (SVUH) by inspectors on the 7 February 2023 to assess compliance with the regulations and follow up on the outcomes of a previous inspection. On the day of inspection, inspectors visited the following areas in the hospital where medical exposures to ionising radiation were conducted; positron emission tomography computed tomography (PET CT), nuclear medicine, and the dual-energy X-ray absorptiometry (DXA) scanner located in the Bone and Joint Unit.

Inspectors found evidence on the day of inspection that measures had been put in place by the hospital to address gaps previously identified. SVUH had also implemented additional measures to strengthen the governance and management arrangements for medical exposures in the hospital. For example, the terms of reference of the radiation safety committee (RSC) and agenda had been updated to increase and promote the involvement of all departments and professions in the hospital that were involved in the conduct of medical radiological procedures.

Additionally, the hospital had ensured that the justification process for individual medical exposures involved the practitioner. However, inspectors identified an area of improvement relating to the allocation of clinical responsibility for the evaluation of the outcome which must be addressed by the hospital to come into full compliance with the regulations.

Overall, and based on the evidence reviewed on the day of inspection, inspectors were satisfied that SVUH had governance and management arrangements in place to address the findings identified previously and to ensure the continued safe delivery of medical exposures to ionising radiation.

Regulation 6: Undertaking

The overarching governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at SVUH were reviewed on the day of inspection. Inspectors spoke with management at SVUH who communicated the allocation of responsibility for the radiation protection of service users at the hospital. Documentation and other records were also reviewed by inspectors.

The hospital had identified and implemented measures to strengthen its governance and management arrangements in relation to radiation protection. This included a review and update of the membership of the RSC. In addition, inspectors noted that the RSC agenda was amended to facilitate and encourage the attendance of clinical representatives at the meeting. This was noted as a positive measure which demonstrated SVUH's commitment to ensuring oversight of medical exposures at

the hospital.

Inspectors also found evidence that the allocation of practitioners' clinical responsibility to different professional cohorts had been reviewed and updated as required by the regulations. This update had been documented in the *Radiation Safety Procedures (X-ray Procedures)* and this policy was subsequently approved by the RSC, the Medical Executive and the Executive Management Team which assured inspectors that SVUH had oversight of the allocation of responsibility for the radiation protection of service users. However, the *DXA guidelines and procedures*, while reflective of day-to-day practice, was found to not fully align with the overarching hospital's allocation of clinical responsibility for medical exposures to ionising radiation. To ensure full compliance with this regulation, SVUH must ensure that all medical exposures conducted are aligned with the hospital's overarching delegation of responsibility and aligned with the requirements of the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors spoke with staff and management at the hospital on the day of inspection. Documentation submitted to HIQA in advance of the inspection was also reviewed. Inspectors found evidence that SVUH had put measures in place to ensure that a practitioner was involved in the justification process for individual medical exposures and, as per the regulations, the hospital had ensured that all aspects of clinical responsibility were allocated to a practitioner for most procedures. However, inspectors found evidence that SVUH had not ensured that clinical responsibility for the evaluation of the outcome of the medical radiological procedure had been delegated to a person recognised as a practitioner in the regulations for a small cohort of patients in one area of the hospital.

While there has been progress with compliance since the previous inspection, SVUH must ensure that all aspects of each individual medical exposure are conducted under the clinical responsibility of a person entitled to act as a practitioner in line with requirements of the regulations.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff. The arrangements put in place at SVUH to ensure the safe delivery of medical exposures, specifically Regulations 8 and 16, were assessed by inspectors. On the

day of inspection, inspectors were satisfied that the measures identified following the previous inspection had been successfully implemented by the hospital.

Staff informed inspectors that practitioners justified all medical exposures in advance and a sample of written records of justification in advance of medical radiological procedures were available for review on the day of inspection. The measures put in place by the hospital to ensure full compliance with the requirements of this regulation were reviewed by inspectors over the course of the inspection and inspectors were satisfied that these measures had addressed the previously identified issue with Regulation 8 for all medical exposures conducted at the hospital.

Furthermore, inspectors assessed the pathway for conducting an inquiry regarding patients' pregnancy or breastfeeding statuses in advance of nuclear medicine or PET CT procedures. From speaking with staff and reviewing documentation and other records, inspectors were satisfied that only an individual entitled to act as a practitioner carried out an inquiry regarding pregnancy or breastfeeding status.

From the evidence on the day of inspection, inspectors were satisfied that appropriate governance and management arrangements were in place to ensure the safe delivery of medical exposures at SVUH and noted the swift measures implemented by the hospital to address the gaps previously identified in relation to Regulations 8 and 16.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff involved in the conduct of medical exposures in the areas visited on the day of inspection and staff communicated the justification process for individual medical exposures at the hospital. A sample of patient records and documentation from PET CT and nuclear medicine were also reviewed as part of the inspection. From the evidence reviewed on the day of inspection, inspectors were assured that SVUH had implemented measures to ensure that justification in advance was carried out by a practitioner for individual medical exposures conducted at the hospital. Inspectors acknowledged the additional measures put in place and subsequent effort by those involved in the conduct of medical radiological procedures in the Bone and Joint Unit to ensure that SVUH were compliant with this regulation on the day of inspection.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

As part of this inspection, inspectors visited the PET CT and Nuclear Medicine departments and spoke with staff and reviewed a sample of patient records.

Inspectors also reviewed policies and other documentation. For nuclear medicine and PET CT procedures, inspectors found that radiographers and radiologists were responsible for carrying out the inquiry of a patient's pregnancy status. Inspectors also observed notices to raise awareness of the special protection required during pregnancy in public places such as changing rooms and waiting rooms. A sample of audits relating to compliance with the hospital's pregnancy policy were also reviewed by inspectors and provided an assurance that SVUH was monitoring its own compliance with the requirements of this regulation.

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 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant

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

Inspection ID: MON-0037872

Date of inspection: 07/02/2023

Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The DXA guidelines and procedures have been revised to align with the overarching hospital's allocation of clinical responsibility for medical exposures to ionising radiation. These guidelines and procedures have been circulated for review at the Radiation Safety Committee meeting scheduled to take place on 8th March 2023 and for final approval at the Radiation Safety Committee meeting scheduled to take place on 21st June, 2023.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: As and from 7th February, 2023 (and documented in hospital records), all DXA scan machine reports are individually reviewed by the practitioner and receive a review comment from the practitioner which is saved on the report along with the practitioners name and date/time stamp. This includes the small number of reports (between 0.02% - 0.18% of SVUH patients undergoing medical exposures per year) referred to in the finding above. The DXA guidelines and procedures have been revised to reflect this change as outlined in the previous section.</p>	

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	21/06/2023
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	07/02/2023

