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 Private Hospital
Undertaking Name:	St Vincent's Private Hospital
Address of Ionising Radiation Installation:	Merrion Road, Dublin 4
Type of inspection:	Announced
Date of inspection:	23 July 2020
Medical Radiological Installation Service ID:	OSV-0006462
Fieldwork ID:	MON-0028257

About the medical radiological installation:

St. Vincent's Private Hospital is a member of St Vincent's Healthcare Group, which also includes St. Vincent's University Hospital and St. Michael's Hospital, Dun Laoghaire. The hospital has 236 inpatient beds, 31 general and 23 oncology day care beds, 12 consulting suites, operating theatres for major and minor surgery, endoscopy, radiotherapy, cardiology and diagnostic imaging facilities.
Radiology operates Monday to Friday from 8am - 6pm. An emergency out-of-hours service is available outside of these times. Services provided by the radiology department include:

- general radiography and fluoroscopy,
- mobile radiography, theatre, wards and day surgery,
- computed tomography (CT),
- magnetic resonance imaging,
- ultrasound,
- DEXA scanning,
- mammography,
- interventional radiology,
- radiography support for the interventional cardiology department.

The radiotherapy services provided include CT simulation, treatment planning and treatment delivery, for patients undergoing external beam radiotherapy.
Brachytherapy services are also provided by the radiotherapy department.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 23 July 2020	09:30hrs to 15:00hrs	Agnella Craig	Lead
Thursday 23 July 2020	09:30hrs to 15:00hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

From the evidence gathered, inspectors found that there was effective leadership, governance and management arrangements in place with systems and processes detailing the allocation of responsibility for the radiation protection of service users within St Vincent's Private Hospital (SVPH). The Chief Executive Officer was the designated person responsible for radiation protection for the hospital and sits on the Radiation Safety Committee (RSC). The hospital's RSC, chaired by a consultant radiologist report to the Board of Directors through the Quality Improvement and Safety Committee and the Leadership Team. Based on the membership of the RSC, the terms of reference of the RSC, and the minutes of the RSC meetings reviewed by inspectors, this committee provides an effective mechanism to ensure appropriate oversight in this installation.

On this inspection, inspectors reviewed documentation from both the radiology and the radiotherapy department at SVPH. Inspectors visited both departments and spoke with staff in both areas. Six of the regulations included in this dimension were considered on this inspection.

From the documents and records reviewed, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures, in both the radiotherapy and radiology department. Similarly, inspectors were assured that clinical responsibility for medical exposures was taken by personnel entitled to act as practitioners as per the regulations.

Inspectors were informed of the process in place to ensure involvement and continuity of medical physics expertise. From the documentation reviewed, inspectors were assured that the level of involvement of the Medical Physics Expert (MPE) was proportionate to the level of risk in this installation, and that the MPEs take responsibility for all aspects of medical exposures including liaising with the radiation protection adviser as per the regulations.

Although the overarching governance structures provided assurance of the protection of service users, and staff were aware of their roles and responsibilities, documentation and local policy should be updated and communicated to staff to clearly specify the personnel involved in the day to day aspects of medical exposure delivery and outline their specific roles and responsibilities. However, overall, from the systems and processes in place in both departments in this installation, inspectors were assured of the oversight and management of this medical radiological installation in ensuring a quality, effective, and safe service when conducting medical exposures.

Regulation 4: Referrers

The hospital currently receives referrals from both internal and external sources. The policies outlined who is entitled to refer patients for medical exposures, and this was in line with the regulations. However, the documentation could be updated to make it more specific to this installation to include a definitive list of types of referrers for which referrals are accepted locally. Although compliant with this regulation, updating the documentation to reflect the local situation would provide further assurance to the undertaking that the documentation is consistent with the day to day referral processes in place in this installation.

Judgment: Compliant

Regulation 5: Practitioners

The policies viewed by inspectors in advance of the inspection outlined who is entitled to act as practitioner as per the regulations. For example, in addition to radiologists and radiation oncologists, radiographers and radiation therapists were identified in these policies as practitioners. From the records reviewed on the day of inspection in both the radiology and the radiotherapy department, inspectors were assured that medical exposures were conducted by those entitled to act as practitioners, as per the regulations.

Judgment: Compliant

Regulation 6: Undertaking

From the documentation provided in advance of inspection, and the documents and information reviewed on the day of inspection, inspectors were assured of the structures in place to ensure good oversight by the undertaking of all medical exposures conducted within this installation. However, a clear allocation of responsibilities for the day to day practices was less evident in the documentation reviewed.

Staff who spoke with inspectors on the day of inspection were able to articulate both their own specific responsibilities, and the responsibilities of others, but in order to be fully assured, the undertaking should update the policy documents to outline each staff member's responsibilities by procedure type. For example, the documentation reviewed outlined that radiographers and radiation therapists are viewed as practitioners within this installation, which is in line with the regulations,

however, staff who spoke with inspectors on the day of inspection viewed the radiologists and radiation oncologists as practitioners.

Inspectors were informed by management that the specific breakdown of responsibilities per procedure type is an area that is evolving and that the scope of practice identified by the radiographers' and radiation therapists' professional body will facilitate this. Updating the documentation to clearly identify the allocation of roles and responsibilities to match the day to day practice and communication of relevant responsibilities to staff will assist the undertaking in coming into full compliance with Regulation 6(3).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

A number of MPEs were available to ensure the continuity of expertise in both the radiology and radiotherapy department within this installation.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From documents reviewed prior to, and on the day of inspection, and from speaking with staff, it was evident that the MPEs in both the radiology and the radiotherapy department take responsibility as detailed in the regulations. These responsibilities include: optimisation, dosimetry, reviewing diagnostic reference levels (DRLs), quality assurance (QA) and acceptance testing, analysing events involving or potentially involving ionising radiation, and training and education of staff.

Judgment: Compliant

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

From the documentation reviewed, and meetings with staff, inspectors were assured that the MPEs were involved in all medical radiological practices, including all radiotherapeutic practices as per the regulations, and their level of involvement was in line with the level of risk posed by this installation.

Judgment: Compliant

Safe Delivery of Medical Exposures

On this inspection of the radiotherapy and radiology department, inspectors found evidence that SVPH had appropriate systems and processes in place to ensure that safe and effective medical exposures are provided to service users. This included evidence of appropriate processes to ensure the optimisation of radiology and radiotherapy procedures, the use of diagnostic reference levels in the radiology department and written protocols for different types of procedures. Evidence that exposures were justified in advance and a record kept of justification was also seen, and inspectors were assured of the processes in place for reporting accidental and unintended exposures in both the radiology and radiotherapy department. Documentation on the QA programme in place and records of the maintenance of equipment used to perform medical radiological procedures also provided assurance of the safe delivery of ionising radiation in this installation. However, as information relating to patient exposure was not included on the radiology report, this installation was not compliant with Regulation 13(2).

Notwithstanding regulation 13(2), from the seven regulations within this dimension considered during this inspection, overall, inspectors were assured by the arrangements in place that this service was providing safe medical exposures to ionising radiation in both the radiology and the radiotherapy department. This included the appropriate technical arrangements to ensure that medical exposures to ionising radiation are carried out safely and having specific systems and processes to ensure service users undergo medical exposures when justified by appropriate individuals.

Regulation 8: Justification of medical exposures

Before inspection, inspectors reviewed the justification policy available for procedures in the radiology department which detailed how justification in advance of medical exposures is conducted by the appropriate individuals as defined in Regulation 5. On the day of inspection, inspectors spoke with radiographers and radiation therapists who explained how they justify a medical exposure in advance of conducting the exposure. The information provided was in line with the justification policy viewed in advance of inspection and the information about justification contained in the Radiation Safety Procedures document applicable to both radiology and radiotherapy procedures.

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the benefits versus the risk of exposures to be considered by the practitioner.

Practitioners in both the radiotherapy and radiology department described how they would seek previous diagnostic information or medical records and consider this information when justifying a medical exposure. Referral guidelines were available to staff and staff in radiology explained that they would either consult these guidelines or discuss issues with a colleague should they have concerns about justifying a referral. Inspectors noted that a record of justification was documented and an audit of the justification of radiology requests showed high levels of compliance.

Inspectors reviewed information about radiotherapy available for patients and were informed that the radiation oncologists provide information to all patients on the benefits and risks of treatment as part of the consent process.

From the information provided and the meetings with staff, inspectors were assured of the undertakings compliance with this regulation.

Judgment: Compliant

Regulation 9: Optimisation

Information relating to the optimisation of radiology procedures included in the policy- "Procedure for establishing Diagnostic reference levels and performing optimisation of all diagnostic procedures in SVPH" was reviewed by inspectors in advance of the inspection. This outlined the role of the MPE in optimisation, and the role of the RSC in reviewing reports relating to optimisation. Inspectors were assured that doses are kept as low as reasonably achievable while obtaining the required medical information.

The optimisation of medical exposures for patients undergoing radiotherapy was discussed with staff on the day of inspection, and further documentation relevant to the optimisation process of radiotherapeutic procedures was reviewed by inspectors, including documentation about the QA testing and the process for assessing and verifying patient doses. Documentation specific to the optimisation process for patients undergoing treatment for breast cancer was also reviewed. Inspectors were assured that treatments are optimised by individually planning all exposures to the required area, verifying the dose to this area while reducing the dose to nearby organs as much as possible and ensuring the dose is consistently delivered.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Diagnostic reference levels (DRLs) have been established for radiological procedures in this hospital and were compared to national levels. Staff who spoke with

inspectors described the actions taken if a DRL is higher than expected and this process was in line with the process detailed in the policy. An example of the investigation and report produced for one particular DRL found to be outside the expected range was provided to inspectors. Evidence that DRLs are discussed at the RSC was also seen in minutes of previous meetings reviewed by inspectors.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written protocols for routine examinations conducted in the radiology department, and noted that referral guidelines were available to staff.

A positive culture towards conducting clinical audit was noted by inspectors, and good compliance was seen in the audits reviewed by inspectors. These included audits of the timeout process in CT and that CT Request Cards were completed correctly, an audit of justification on radiology requests, and an audit of the triple check of charts in radiotherapy. The specific processes for following up on recommendations and implementing quality improvement plans was not as evident in all of the audits reviewed but inspectors were informed that the clinical audit committee reviews all audit reports and discuss and implement the recommendations as appropriate.

In order for the undertaking to be compliant with Regulation 13(2), a system to record information relating to patient exposure needs to be included in the patients' reports. Inspectors were informed that information relating to the overall treatment dose received in radiotherapy is included in letters sent to the referring team. In the radiology department, inspectors observed that information relating to patient exposure is currently not available on reports, however, a statement that information relating to dose is available on request is included on the reports. Inspectors were informed by management that an upgrade to existing software should facilitate this requirement in the future. A system or process to record information relating to patient dose for all procedures needs to be implemented in order to come into compliance with this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection and noted, from the details provided, that equipment was kept under strict surveillance regarding radiation protection. Inspectors were

informed that equipment is discussed at both the RSC and at the Medical Equipment Management Committee meetings, thus providing the undertaking with oversight of the radiological equipment. Evidence of the discussion on equipment at the RSC was seen in the minutes of the RSC meetings reviewed in advance of this inspection.

From the documentation reviewed and from speaking with staff, inspectors were satisfied that appropriate QA and quality control programmes were implemented and maintained for each piece of medical radiological equipment in the radiology and radiotherapy department. This documentation included the policies associated with QA, for example, the quality control programme for the linear accelerators (equipment used in radiotherapy treatments), and the records of initial acceptance testing and regular performance testing carried out in this installation. The role of the MPEs in relation to equipment was also evident in the policies and records reviewed. All QA testing was up-to-date and none of the equipment had passed their nominal replacement date.

From the documentation reviewed and the discussions with staff, inspectors were assured that the undertaking has strict oversight of the surveillance of all radiological equipment in this installation and is in compliance with this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From the documentation reviewed and the information obtained from staff on the day of inspection, inspectors were assured of the radiation safety of service users by the systems, processes and procedures in place in both the radiology and the radiotherapy department.

Before the inspection, inspectors reviewed the radiation incident reporting policy which detailed the categories of incidents, the roles and responsibilities of personnel, and the processes in place if an incident should occur within this facility. This document also included the specific reporting structures in place for incidents in radiology and radiotherapy. The template incident reporting forms for radiology and radiotherapy were also reviewed, in addition to the log of incidents and near misses in both radiotherapy and radiology. When discussing with staff the low number of near misses reported in radiology, inspectors were informed of the system in place to report near misses through a different system- the hospital incident management system, but staff recognised the value in highlighting near misses through the system in place in radiology. The staff who spoke with inspectors on the day of the inspection demonstrated a knowledge and understanding of the incident reporting processes as detailed in the hospital policy and members of management who met with inspectors detailed the specific governance arrangements in place to ensure the undertaking has oversight of accidental and unintended exposures and significant events.

The process followed if an incident or near miss occurs in the radiotherapy department includes a review by a multidisciplinary team comprised of the MPE, the radiotherapy services manager and the oncologist. To educate staff and give advice on the follow up recommendations, staff are informed of incidents through the weekly planning meetings. A summary of incidents including the actions to reduce or prevent reoccurrence is also presented to the RSC and incidents are documented, analysed for trends and presented to staff annually. A similar process is followed for incidents occurring in the radiology department.

From the evidence gathered during this inspection, inspectors were assured of the measures taken within this facility to minimise the probability of accidental or unintended exposures. Oversight from senior management within this hospital was also evident during this inspection and all reportable significant events were reported to HIQA in a timely manner.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	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	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for St Vincent's Private Hospital OSV-0006462

Inspection ID: MON-0028257

Date of inspection: 23/07/2020

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: The Radiotherapy and Radiology Departments are updating their pre-existing policy on the scope of practice for staff employed by SVPH. This policy will be aligned with current legalisation and the IIRRT guidelines and will reflect the current local practice for staff within the Radiology and Radiotherapy Departments at SVPH. All new staff who are employed by SVPH go through a comprehensive hospital induction process and local departmental induction into which this policy will be incorporated.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Both departments will establish a new bi-annual working group to review departmental audits. These groups will ensure that the audit PDCA (Plan, Do, Check, Act) cycle is followed and completed. This information will then be presented to the Quality Department and at the relevant Radiation Governance Group meeting (Radiation Protection and/or Radiation Services) and forwarded to the Radiation Safety Committee where appropriate. Recording of patient dose information relating to all procedures: We are currently consulting with our RIS/ PACS vendor for an upgrade to our system that will include patient dose on each examination report.	

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	30/10/2020
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Substantially Compliant	Yellow	28/05/2021

	radiological procedure.			