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:	Saint Vincent's Hospital Group
Address of Ionising Radiation Installation:	Merrion Road, Dublin 4
Type of inspection:	Announced
Date of inspection:	22 November 2023
Medical Radiological Installation Service ID:	OSV-0006462
Fieldwork ID:	MON-0037699

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 department at St Vincent's Private Hospital has two state of the art Elekta Linear Accelerators, a GE CT scanner and a brachytherapy HDR unit. The department provides treatment planning, treatment delivery for patients undergoing external beam radiotherapy and brachytherapy. The department was Ireland's first tattoo-less department with the use of Surface Guided Radiotherapy (AlignRT). The department also supports a LDR I 125 seed implant 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 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
Wednesday 22 November 2023	09:00hrs to 16:30hrs	Margaret Keaveney	Lead
Wednesday 22 November 2023	09:00hrs to 16:30hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiotherapy services at St. Vincent's Private Hospital on 22nd November 2023, during which they also followed up on a number of compliance plan actions from a previous inspection of the radiology department in July 2020. It was evident that since the previous inspection, St. Vincent's Hospital Group, as the undertaking, had taken action to achieve compliance with the regulations, although the management team informed inspectors that work to comply with Regulation 13(2) was ongoing.

During a tour of the radiotherapy department, inspectors met with staff in the computed tomography (CT) unit and at one of two treatment units to discuss the radiation protection measures in place for patients receiving radiotherapy treatment. Inspectors did not visit the brachytherapy unit (a high dose treatment unit) or the theatre where prostate seed implants were performed, however, they spoke with the staff working in these areas and the management team on the safety measures in place for patients attending these services. Overall, inspectors were assured that there were appropriate measures in place to facilitate the safe delivery of medical exposures along the patient pathway.

Inspectors reviewed documentation prior to and during the inspection. From these reviews and discussions with staff and the management team, inspectors noted that the undertaking had established effective governance and management arrangements, to provide good oversight of radiation protection in the service. Inspectors found that local oversight was provided by the Radiation Services Governance Group (RSGG), which in turn reported to the Radiation Safety Committee (RSC). The RSGG met every two months, and was attended by, among others, a Clinical Lead in Radiotherapy or Radiology, the radiation therapy services manager (RTSM) and a medical physics expert (MPE).

Meetings of the RSC were held quarterly each year with representation from the hospital management team, such as the chief executive officer (CEO), Quality Manager, RTSM and MPE, evident in the minutes reviewed. The meeting minutes also showed that the committee routinely discussed a range of radiation protection matters, which included incidents, clinical audit and diagnostic reference levels (DRLs), and also approved new or revised policies and procedures. Inspectors also reviewed other documentation that showed that there were established lines of communication from the RSC upwards, via the Quality Improvement and Safety Committee and CEO, to the St. Vincent's Hospital Group's Board of Directors.

Following the previous inspection of St. Vincent's Private Hospital in July 2020, inspectors saw that the undertaking's management team had developed a document titled '*Scope of Service for Radiotherapy Department and Staff*' which clearly outlined the roles and day-to-day responsibilities of radiation therapists in the

radiotherapy department. Inspectors were informed that a similar document had been developed for radiographers in the radiology department.

The management team had recently revised the service's '*Radiation Safety Procedure*' document to ensure that it met the requirements of the regulations. The aim of this policy was to define the responsibilities of and direct staff, working with medical exposures of ionising radiation, on the safety procedures required to ensure the radiation protection of patients. However, inspectors noted that this procedure document required further review to ensure that all staff involved in the planning and delivery of radiotherapy treatment were clearly aware of their responsibilities in the radiation protection of patients attending the service. This is further discussed under Regulation 6 below.

During the inspection, a sample of electronic records for patients, undergoing radiotherapy medical exposures, were reviewed by inspectors and showed that appropriate persons as per the regulations were involved in referring for medical exposures completed at the service. Inspectors were also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

The inspectors reviewed documentation and spoke with the management team regarding MPE involvement in the safe delivery of medical exposures, and were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall, notwithstanding the minor areas for improvement identified over the course of the inspection, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at St. Vincent's Private Hospital.

Regulation 4: Referrers

From discussions with staff in the radiotherapy department of St. Vincent's Private Hospital and from the sample of records reviewed, inspectors were satisfied that only referrals for medical radiological procedures from persons defined in Regulation 4 were carried out at this facility.

Inspectors were informed that consultant radiation oncologists and radiation oncology registrars were the primary referrers for radiotherapy procedures, and that radiation therapists could act as secondary or adaptive referral in particular circumstances, such as referring for additional imaging within protocol or for a CT planning rescan if required.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the radiotherapy department, namely radiation oncologists and radiation therapists.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors observed that the undertaking had effective governance and management arrangements in place, to provide appropriate oversight of radiation protection measures in the radiotherapy department at St. Vincent's Private Hospital. Overall, from a review of documentation and speaking with staff, inspectors were also assured that the undertaking had allocated the roles and responsibilities for the radiation protection of service users.

Inspectors also note that the management team had recently updated the local '*Radiation Safety Procedure*' with the roles and responsibilities of referrers and practitioners in the radiotherapy department. However, inspectors noted that although this update, and local practice, aligned with the regulations, further updates to the '*Radiation Safety Procedure*' and other documents that allocated roles and responsibilities were required. For example;

- the updated '*Radiation Safety Procedure*' included groups of professionals that had not been allocated the roles of referrers and practitioners in the radiotherapy department. For example, it stated that registered dentists and nurses could act as referrers in the department, when in practice referrals were not accepted from these groups of professionals
- As stated, the '*Radiation Safety Procedure*' outlined the roles and responsibilities of key staff groups involved in the radiation protection of radiotherapy patients, however it did not include the roles and responsibilities of the dosimetrist. Inspectors also noted that their delegated roles and responsibilities were not documented in any other relevant policy or procedure provided to the inspectors. The clear allocation of their roles and responsibilities is a key part of the overall radiation protection of patients in the radiotherapy department
- The MPE team had developed a number of documents on their day-to day practices around their roles and responsibilities. However, inspectors noted that these documents required further review to ensure that they accurately reflected all tasks and practices completed by MPEs in carrying out their responsibilities as per the regulations. For example, there was no documented procedure to clearly outline the frequency and quality assurance (QA) tests performed by the MPE team on the treatment planning system

- Inspectors also reviewed the hospital's '*Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures*' and saw that it required review to ensure that it aligned with the safe practices observed in the department. For example, the policy stated that after initial consent the pregnancy status of relevant patients is not checked. Inspectors observed that prior to the planning CT, radiation therapists enquired on and recorded the pregnancy status, and therefore the policy did not align with the safe practices observed in the department.

Inspectors also noted that improvements were required by the undertaking in the oversight of radiation protection in other areas of the radiotherapy department. For example, on the day of the inspection, inspectors noted that many of the policies and procedures adhered to by the MPE team were stored locally and were not available on the undertaking's document quality management system. Therefore the undertaking's management team could not be assured that they were reviewed and or updated as and when required.

While some improvements were required in the documentation and allocation of roles and responsibilities, inspectors were satisfied that overall there were effective arrangements in place to ensure the radiation protection of service users in the radiotherapy department.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all external beam radiotherapy medical exposures carried out in the service were found to take place under the clinical responsibility of a practitioner as defined in the regulations, with practitioner status allocated to the radiation oncologists and radiation therapists in this service. Inspectors were also informed that brachytherapy procedures were performed by radiation oncologists, with MPEs carrying out certain practical aspects of the procedure.

Similarly, from discussions with staff and from reviewing a sample of patient records and other documents, inspectors were satisfied that the optimisation of radiotherapy treatment, and associated imaging along the radiotherapy treatment pathway, involved the radiation oncologists, radiation therapists and the MPE team.

There was also sufficient evidence to satisfy inspectors that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were assured that St. Vincent's Private Hospital had adequate arrangements in place to ensure the continuity of medical physics expertise in the service. A team of MPEs were employed directly by the hospital, and inspectors were informed of arrangements to cover the service during the normal working day and out-of-hours.

The up-to-date professional registration certificates for each of the MPE team members were also reviewed on the day of inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions with staff, including the MPE team, and documentation viewed, inspectors were satisfied that the hospital had arrangements in place to ensure that there was appropriate MPE involvement in and contribution to medical exposure to ionising radiation in the radiotherapy department. Inspectors were satisfied that an MPE was involved in all aspects of medical exposures as per the regulations. This included overall responsibility for the QA programme for medical radiological equipment and its implementation. In addition, inspectors noted their involvement in dosimetry and the analysis of accidental and unintended exposures.

A review of RSC meeting minutes showed that there was MPE representation on this committee, and on other departmental committees tasked with the radiation protection of service users. Inspectors were also assured that an MPE was involved in the analysis of significant events, and that they provided radiation protection training for staff.

Although compliant with this regulation, the undertaking's management team should update relevant documentation to ensure the responsibilities of the MPE are clearly outlined as distinct from other staff, such as general physicists, working in the service.

Judgment: Compliant

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

From discussions with MPEs and other staff in the service, inspectors were satisfied that the undertaking was compliant with this regulation. Inspectors saw that MPEs were involved in radiotherapy practices as outlined under Regulation 20, and that

the level of involvement provided was commensurate with the radiological risk posed by the practices.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors noted many good practices in the radiotherapy department that ensured the radiation protection of patients and the safe delivery of medical exposures to ionising radiation.

From speaking with staff and a review of a sample of referrals in the radiotherapy service at St. Vincent's Private Hospital, inspectors were assured that all referrals for medical exposures were in writing, contained the reason for the requests and were accompanied by sufficient additional data. From this review, inspectors were also satisfied that radiotherapy procedures were justified in advance, by a person entitled, as per the regulations, to take clinical responsibility for justification. In St. Vincent's Private Hospital, this responsibility had been allocated to radiation oncologists and radiation therapists only.

Inspectors noted a strong multidisciplinary approach to the radiation protection of radiotherapy patients. This included good efforts in optimisation of medical radiological procedures. For example, inspectors were informed that new planning software had recently been introduced to assist in the optimisation of treatment plans and that a recent imaging audit and study by a multidisciplinary team had resulted in the refinement of an imaging protocol and schedule for one cohort of patients. Inspectors also noted that the radiotherapy team had developed written protocols for the standard examinations carried out in the department, and had completed a number of clinical audits to monitor the safety of the service being provided.

Inspectors found that a QA programme for ionising radiation equipment was in place in the radiotherapy department. This programme included a range of comprehensive tests that were performed daily, monthly and annually by both radiation therapists and the MPE team. However, inspectors observed that action was required to strengthen assurances that the MPE team had appropriate oversight of the QA programme. This is further discussed under Regulation 14 below.

The management at the St. Vincent's Private Hospital had good processes in place regarding the inquiring and recording of patients' pregnancy and breastfeeding status at the hospital. However, as discussed under Regulation 6 above, the documented procedure to support these practices required review to ensure that the safety measures completed by practitioners were clearly documented to support and guide staff.

There was an effective system in place for recording and reviewing incidents involving, or potentially involving, accidental or unintended exposures to ionising radiation. Inspectors noted that incidents and potential incidents were discussed and actioned at a weekly risk grading committee meeting, and later at the RSGG and RSC meetings, which provided the undertaking's management team with good oversight of potential and actual incident details and actions.

Overall, inspectors were satisfied that systems were in place to support the safe delivery of medical exposures, although some areas for improvement to ensure full compliance with the regulations were identified as part of this inspection.

Regulation 8: Justification of medical exposures

On the day of the inspection, inspectors reviewed a sample of referrals in the radiotherapy department and saw that they were available in writing and stated the reason for the request. From this sample review, and a review of other documents, inspectors were assured that practitioners had access to sufficient medical data that was used, during the justification process, to consider the risks and benefits of the medical exposure, as stated in the referral.

Throughout the inspection day, inspectors spoke to a radiation oncologist and a number of radiation therapists, and from these discussions were assured that staff were aware of their responsibilities to justify radiotherapy medical exposures in advance. Inspectors were informed that by approving a treatment request form, the radiation oncologist justifies in advance the patient's radiotherapy CT planning scan. Similarly, by reviewing and approving the final treatment plan, the radiation oncologist justifies in advance the medical exposures that are carried out along the radiotherapy treatment course..

Inspectors also observed that, over a course of radiotherapy treatment, radiation therapists are involved in the justification of daily medical exposures of radiotherapy treatment and noted that they indicate these justification decisions by electronically completing quality checklists in patient records. For example, inspectors observed that radiation therapists perform verification imaging, according to site-specific imaging protocols and clinically assessing these images before proceeding with delivering the treatment.

The management team had developed documents such as '*Radiation Safety Procedures for the Use and Application of Ionising Radiation at Saint Vincent's Private Hospital*' and '*Scope of Practice for Radiotherapy Department and Staff*' which outlined the personnel assigned to the roles and responsibilities of justification, and met the requirements of this regulation. However, as justification takes places for numerous medical exposures along the radiotherapy patient pathway, an area of improvement, to ensure full clarity for staff, could be to align these roles and responsibilities with the patient pathway in radiotherapy.

Inspectors reviewed a '*Radiotherapy Patient and Family Education Policy*', which outlined the roles and responsibilities of staff in providing radiotherapy patients with adequate information about the risks and benefits relevant to their medical exposure procedures. Inspectors observed that treatment site-specific information leaflets had been developed and were regularly reviewed by radiotherapy staff. These leaflets were available to patients and their families throughout the department, and inspectors were also informed that patients had frequent opportunities to discuss this information with practitioner staff throughout their treatment course.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, inspectors reviewed documentation and spoke with staff about the optimisation processes for medical exposures in the department. Inspectors reviewed policies, procedures and guidelines followed at treatment booking, CT scanning, and treatment planning and delivery stages, which outlined these optimisation processes along the patient pathway. In addition, the '*Radiation Safety Procedures for the Use and Application of Ionising Radiation at Saint Vincent's Private Hospital*' contained an overview of optimisation considerations for radiotherapy panning and treatment delivery and the responsible personnel. For example, treatment planning and verification imaging were outlined as areas to be considered for optimisation.

During a tour of the radiotherapy CT unit, inspectors were informed by staff that the dose length product (DLP), for each CT scan completed, was manually recorded. Senior staff in this area had reviewed the data, and calculated an optimal DLP range for different CT examinations. This information was used to identify any deviations from the normal range, which would alert staff to investigate reasons for such a deviation. This information was also used to drive the refinement of CT protocols or practices. For example, staff reported a reduction in scanning doses since the start of this optimisation project.

Inspectors also met with staff working in the treatment planning area to discuss how treatment plans were optimised. Inspectors were informed that target volumes were individually planned, and that doses to non-target volumes were kept as low as achievable. From a review of a sample of plans, inspectors noted that site-specific planning protocols had been developed to guide staff on planning aims and restrictions. Inspectors were informed that these protocols have been developed based on international evidence. However, they were also informed that these protocols were not systemically reviewed in the department, and although inspectors did not identify any concerns with the protocols, a regular review system was identified as an area for improvement to ensure that they continued to adhere to best practice.

In radiotherapy, verification imaging is used to guide and verify the delivery of medical exposure treatment procedures. This verification process is necessary to ensure the safe and accurate delivery of medical exposures. The radiotherapy management team had developed a '*Pre-Treatment Image Verification Policy*' that outlined treatment site-specific imaging protocols, including imaging frequency, tolerances, action levels and how to complete a trend analysis on imaging results. For example, it contained a protocol and flowchart for imaging patients with lung cancer and a separate protocol for imaging prostate cancer patients.

Inspectors also reviewed a number of policies which outlined the routine quality control checks performed by radiation therapists along the patient pathway, and from a review of patient's electronic records saw that these frequent checks were documented as completed.

Overall, it was evident to inspectors that there were good optimisation practices implemented along patient's radiotherapy pathway.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors noted that a number of the written protocols for the standard examinations carried out in the radiotherapy departments had been developed by the radiotherapy team. For example, procedures for the treatment of lung, chest, brain and breast cancer were reviewed.

During a review of patient records in the radiotherapy department, inspectors saw that the radiation dose received by the patient was included in a discharge letter which was generated for each patient after they finish their treatment.

Prior to the inspection, a sample of clinical audits conducted in the radiotherapy department were reviewed by inspectors. These included a justification of radiotherapy treatment audit and verification imaging audits. Inspectors also noted that these clinical audits had been used to drive service improvements with the radiotherapy department. For example, rescan audits completed in 2020 and 2022, had led to the revision of '*Procedure to be followed in the event of having to rescan a patient*', and that refinement of a scan preparation protocol was underway with the aim of reducing the number of CT rescans for a cohort of patients. The use of clinical audit information to improve radiation protection of service users was identified as an area of good practice in the service.

Judgment: Compliant

Regulation 14: Equipment

Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection.

According to the '*Radiation Safety Procedures for the Use and Application of Ionising Radiation at Saint Vincent's Private Hospital*', the MPE team were responsible for the QA programme, and inspectors noted that a comprehensive QA programme had been established by the team. The daily, monthly and annual testing to be performed by radiation therapists, physicists and MPEs was documented in a '*Quality Assurance (QA) Policy for Radiotherapy CPQR*' policy. From a review of this policy, inspectors were assured that this programme of performance testing was appropriate to the radiological risk associated with each individual piece of equipment in use in the department.

From discussions with staff, inspectors were also assured that staff had implemented the QA programme, and were aware of their responsibilities in completing testing and of how to appropriately escalate any test results that were outside the expected tolerances. From a review of QA records, inspectors were assured that all equipment testing was taking place in the department. Inspectors also noted that the MPE team was proactive in ensuring that any equipment issues were promptly addressed. For example, inspectors were informed that one piece of equipment had reported faults, and that although these faults did not present any risk to the patient, the equipment had recently been upgraded which had resolved the issues.

However, inspectors were not satisfied that the undertaking had appropriate oversight arrangements in place, to provide assurances that all medical radiological equipment in use in the radiotherapy department was kept under strict surveillance. For example, inspectors were informed that, as part of the QA programme, the daily and monthly QA test results were reviewed by the MPE team. However, when reviewed by inspectors, the reports did not include a signature or date to indicate that the reports had been reviewed by the MPE team. The documenting of such overview of test results was identified as an area for improvement in the service.

Judgment: Substantially Compliant

Regulation 15: Special practices

On the day of the inspection, inspectors observed that there was good cooperation between the various disciplines involved in the planning and delivery of radiotherapy medical exposures in the radiotherapy service. Inspectors were informed that a 'huddle' meeting was held daily in the department, at which the multidisciplinary radiotherapy team discussed any expected or actual points on the radiotherapy treatment courses completed in the department. This meeting was attended by radiation oncologists, radiation therapists from the CT and treatment units and by medical physics experts. This multidisciplinary approach and opportunity to discuss

radiation protection matters was acknowledged as an area of good practice in the department.

A contouring software system had been newly introduced into the planning department, and inspectors were informed that the system automatically outlined the non-target structures located close to the treatment target. These outlines, or contours, were used by the planning system to avoid or limit the dose to these non-target structures. Staff reported that this auto-contouring system had improved the optimised contouring of these structures, which overall resulted in improved radiation protection in treatment planning. Also in treatment planning, inspectors were informed that a new planning protocol had recently been introduced for a certain cohort of patients. When used, the protocol provided key information that assisted in additional treatment planning, if required.

Inspectors also observed that ancillary equipment was in use in the department, which detected the patients position on the treatment couch, compared it to their position during CT planning and subsequently corrected any variations. Inspectors were informed that the use of this equipment had reduced the number of verification images, and the associated dose to patients. Other ancillary equipment used in the department included immobilisation devices, such as head and neck masks and individualised positioning aids for thoracic treatments.

As a result of the analysis of the head and neck DLP audit and the introduction of DLP monitoring software in CT, inspectors were informed that the dose from this CT examination type had reduced and was now comparable with international levels. Inspectors were also informed that similar analysis had been completed on other CT examinations, in an effort to optimise the doses from CT planning scans.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

In the radiotherapy department, inspectors observed that notices were displayed in patient waiting areas, to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. These notices displayed the information in a number of different languages, which was identified as an area of good practice in the department. Inspectors also observed that flowcharts were displayed in the staff areas of the CT scanner to guide and support them in when and how to enquire on pregnancy status, when relevant.

For patients undergoing external beam radiotherapy, the radiation oncologists was involved in enquiring during the consent process and the radiation therapist again enquired and also documented the patient's pregnancy status prior to the CT scanning procedure. From speaking with staff, inspectors were satisfied that this process of enquiring was known by staff. However, as previously discussed under Regulation 6, the hospital's `*Policy for the protection of the unborn child arising from*

ionising radiation received during medical diagnostic or therapeutic procedures' required review to ensure that it aligned with the safe practices observed in the department.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors observed that there were arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

The management team had developed a local procedure '*The reporting of incidents, near misses and non-conformances involving radiation at SVPH*', and inspectors noted that it outlined the process for the management of accidental and unintended exposures and significant events. All incidents and potential incidents were recorded using an in-house incident management system, and as recorded, the management team, radiation protection officer and MPE were notified by email. All reported radiation incidents were subsequently discussed and actioned at a weekly risk grading committee meeting, and later at the bi-monthly Radiation Services Governance Group (RSGG) meeting. Inspectors also noted that reported incidents were discussed, as a standard agenda item, at the quarterly RSC meetings.

Inspectors noted that, overall, there was a good culture of incident reporting in the department, which included reporting and analysing potential accidental and unintentional exposures. From discussions with radiation therapists, inspectors were informed that near misses and non-conformances were regularly recorded. Inspectors were also informed that non-conformances detected by physics staff were discussed within the team, however they were not regularly recorded on the incident management system. The recording of potential and actual incidents facilitates trending, analysis and the implementation of corrective actions to improve the radiation protection of service users, and should be encouraged across the department. This was identified as an area for improvement within the service.

Inspectors were satisfied that the management team in St. Vincent's Private Hospital had arrangements in place to ensure that HIQA is notified of the occurrence of a significant event and had implemented measures to minimise the probability of re-occurrence of significant events, where necessary, as required by the regulations. The comprehensive investigation reports received by HIQA demonstrated a multi-disciplinary approach to incident management, which was identified as an area of good practice in the department.

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 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

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

Inspection ID: MON-0037699

Date of inspection: 22/11/2023

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: Outline how you are going to come into compliance with Regulation 6: Undertaking: 1 Specific: The RSP definition of referrer and Practitioner are taken from the statute instrument per say and cover the entire hospital as opposed to RT department only in relation to referring patients for medical exposure. The RSPs have been amended to include a section indicating the only accepted groups that may refer patients in SVPH. Measurable: The revised policy will be uploaded on QPulse upon completion and distributed to all relevant people for acknowledgment. Achievable and Realistic: The RPA can update the policy. It will be approved by the Radiation Safety Committee and then uploaded to QPulse through the Quality department. Time-bound: Update to policy must be completed by January 31, 2024. 2 Specific: The roles and responsibilities of the dosimetrist and general physicist must be included in the RSPs. Measurable: The revised policy will be uploaded on QPulse upon completion. Achievable and Realistic: The roles and responsibilities of the dosimetrist/non MPE will be included in Appendix 1 of the RSPs. Time-bound: Update to policy must be completed by January 31, 2024. 3 Specific: Create a QA procedure document for the treatment planning system in Radiotherapy (outline the frequency and QA tests performed). Measurable: The new procedure will be developed. It will require approval from the Radiation Safety Committee before being uploaded to QPulse. Achievable and Realistic: The department's MPEs are actively writing the QA procedure for the treatment planning system. Time-bound: Finalise the QA procedure document by January 31, 2024. 4	

Specific: Revise the SVHG "Policy on the protection of the unborn child.." to align with current practice of including the Radiation Therapist's role in checking and recording pregnancy status prior to the CT planning scan.
Measurable: Upload the updated policy with revised wording to QPulse once compete.
Achievable and Realistic: The Radiation Therapist Service Manager (RTSM) will oversee the policy review and ensure the updated policy will get uploaded to QPulse.
Time-bound: Update to policy must be completed by January 31, 2024.

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Specific: Upload all Medical Physics department policies and procedures to QPulse.
Measurable: Compare the number of locally stored documents with those uploaded on QPulse once uploaded.
Achievable and Realistic: The department's policies are in three categories- Radiotherapy, Radiation Protection, and Diagnostic Radiology. An MPE, the RPO, and the RPA were assigned ownership of each category, respectively. The Quality department was informed of the new ownership, and owners will get sent alerts when policies are up for review.
Time-bound: Ensure all Medical Physics department policies and procedures are on QPulse by March 31st, 2024.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
Specific: Revise the Radiotherapy department's QA programme to include method for recording the signature and date indicating that the reports have been reviewed by an MPE.
Measurable: Once review is complete, the updated procedure document will require approval from the Radiation Safety Committee before uploading to QPulse.
Achievable and Realistic: The department's MPEs are actively reviewing the QA programme, aligning it with AAPM Task Group 142 standards.
Time-bound: Update to policy must be completed by January 31, 2024.

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	31/01/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance	Substantially Compliant	Yellow	31/01/2024

	regarding radiation protection.			