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:	South Infirmary Victoria University Hospital
Undertaking Name:	South Infirmary Victoria University Hospital
Address of Ionising Radiation Installation:	Old Blackrock Road, Cork
Type of inspection:	Announced
Date of inspection:	05 July 2022
Medical Radiological Installation Service ID:	OSV-0007405
Fieldwork ID:	MON-0036812

About the medical radiological installation:

The South Infirmary-Victoria University Hospital (SIVUH), has 192 beds and caters for approximately 38,400 admissions and 72,500 outpatient attendances each year. The Radiology Department provides diagnostic services to cater for patient referrals from the hospital's main specialities (Ear, Nose and Throat (ENT), Elective Orthopaedic, Chronic Pain services, Rheumatology, Endocrinology, Plastic Surgery, Oral and Maxillofacial Surgery, and Elective Gynaecology). The Radiology department has 2 general digital X-ray rooms, 1 computed tomography (CT) scanner, 1 fluoroscopy room, 1 dual-energy X-ray absorptiometry (DXA) room, 2 ultrasound rooms, 1 orthopantomography (OPG) unit, and has 2 digital mobile X-ray units for use in the hospital. The hospital also has 2 mobile C-arms for use in the 2 orthopaedic theatres and 1 mobile C-arm for use in the pain medicine unit. The hospital provides a radiographer led service for functional swallowing assessment (video-fluoroscopy) in the department. The hospital provides a general X-ray service for Cork city GPs. SIVUH accommodates students from the MSc in Radiography course, UCC, in the department for tuition. The hospital is the only hospital in Cork that is on the National Picture Archiving and Communication system (PACS) National Integrated Medical Imaging System (NIMIS, therefore we share and view other referring hospitals' imaging via CD's/desktop applications. SIVUH carries out approximately 29,600 exams per year involving radiation.

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
Tuesday 5 July 2022	09:30hrs to 16:12hrs	Maeve McGarry	Lead
Tuesday 5 July 2022	09:30hrs to 16:12hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection of South Infirmary Victoria University Hospital (SIVUH) was carried out on the 5 July 2022 to assess compliance with the regulations. As part of the inspection, inspectors visited areas in the hospital where medical radiological procedures were conducted including dual-energy X-ray absorptiometry (DXA), computed tomography (CT), fluoroscopy and general X-ray.

The governance structures for radiation protection of service users undergoing medical exposures to ionising radiation were outlined to inspectors on the day of inspection. The chief executive officer (CEO) had overall responsibility for the radiation protection of service users and was a member of the hospital's Radiation Safety Committee (RSC) and Executive Management Board (EMB). The RSC was incorporated into local governance structures, reporting to the hospital board via a clinical governance committee. Inspectors found that the RSC's terms of reference should be reviewed to accurately reflect the current chairperson of this committee as per minutes reviewed by inspectors. While departments outside radiology were represented on the RSC by nursing staff, inspectors found that the hospital should consider the membership to also include appropriate representation from other relevant disciplines.

Inspectors identified that policy development, oversight and approval was an area of potential improvement in relation to radiation protection at the hospital. Some policies reviewed by inspectors were not version controlled and various formats were in use, and in some cases there was a lack of evidence that these had been formally approved for use. Inspectors were informed that a new document management system was being implemented by the radiology department but was delayed due to constraints placed by the COVID-19 pandemic.

From the records reviewed and discussions with management and staff, 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. The practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations. As an additional assurance SIVUH had also retained the presence of radiographers for all medical radiological procedures carried out at the hospital in the absence of new training requirements being implemented by professional bodies listed under Regulation 22. However, while clinical responsibility for most medical exposures at SIVUH was under the responsibility of a practitioner, a non-compliance was identified for a particular fluoroscopy guided procedure, whereby clinical evaluation of the outcome was carried out by a person not entitled to act as practitioner in these regulations.

Medical physics expertise was provided by an external, off-site medical physics expert (MPE) who was also the hospital's radiation protection advisor (RPA). Inspectors found from discussions with staff and from reviewing the service level

agreement (SLA) in place with the MPE, that on-site presence was limited and that the role was primarily focused on quality assurance of equipment. Inspectors also found that the MPE was not involved in the training of practitioners or the optimisation of medical exposures. Also, the MPE's role in the diagnostic reference level (DRL) process was not well defined and the MPE's contribution to the definition of the QA programme needed to be improved. In addition, inspectors found that the SLA should be updated to formalise arrangements to ensure the continuity of medical physics expertise. Although the level of involvement of the MPE was limited and should be reviewed by the undertaking, inspectors found that radiography staff, particularly the radiation safety officers, demonstrated a strong commitment to radiation safety within the service which provided assurance regarding the radiation protection of service users.

Notwithstanding the areas for improvement identified over the course of the inspection, inspectors found that SIVUH demonstrated a commitment to ensuring the radiation protection of service users undergoing medical radiological procedures at the hospital.

Regulation 4: Referrers

All referrals reviewed by inspectors were from referrers as defined in the regulations. Staff were familiar with, and could describe who was entitled to refer individuals for medical radiological procedures in line with local policies. Referrals for certain procedures were accepted from advanced nurse practitioners (ANPs) and the role of the radiographer to adapt and perform secondary referrals was outlined in policy and described by staff.

Judgment: Compliant

Regulation 5: Practitioners

While clinical responsibility for individual medical exposures was found to be taken by an individual entitled to act as a practitioner in most areas in the hospital, inspectors found that for a particular procedure type in fluoroscopy, clinical evaluation of the outcome of the procedures, which is an aspect of clinical responsibility, was carried out by persons not recognised to act as a practitioner in this regulation. This finding is discussed further in Regulation 10.

Judgment: Not Compliant

Regulation 6: Undertaking

The governance arrangements in place for radiation protection at SIVUH were outlined in documentation and communicated by staff and management to inspectors. An organogram outlined that the CEO was the designated manager with overall day-to-day responsibility for the radiation protection of service users. The CEO was a member of the local RSC and the EMB. The RSC communicated upwards to the EMB and the hospital's board via a clinical governance committee. Management informed inspectors that meetings of the clinical governance committee were suspended due to staffing issues and COVID-19 but the meetings were due to recommence shortly. Inspectors were informed that the CEO acted as a conduit up to the EMB in the absence of these meetings occurring and an example of how the oversight arrangements worked in practice from RSC to the board were outlined to inspectors.

The RSC met twice per year and was the main forum for oversight of radiation safety at the hospital. The terms of reference of the RSC outlined that the committee was chaired by the CEO. However, minutes of meetings indicated that a radiologist chaired the meetings and hence, the terms of reference should be updated by the hospital**.** Inspectors found that areas outside radiology where medical exposures were carried out were represented on the RSC by nursing staff and a radiologist was the only medical representative on the committee. The hospital should consider the membership of the committee to ensure appropriate representation from all relevant multidisciplinary teams.

While an MPE was available to give advice to this hospital, the level of involvement was limited and this allocation of responsibility should be addressed by the undertaking to ensure that all regulatory requirements are met, as outlined under Regulations 20 of this report.

Furthermore, inspectors identified that policy development, review and approval was an area for improvement at the hospital. In some cases the format of policies was inconsistent and the ratification process was not fully evident. Inspectors were informed that a new document management system is currently being implemented by the radiology team. The hospital should progress the implementation of this system to ensure that protocols are managed in a controlled manner to reflect version history, approval, updated changes and the involvement of appropriate staff. Furthermore, the undertaking should ensure that policies are aligned to day-to-day practices and clearly outline the allocation of responsibilities for the radiation protection of service users, including the justification of medical exposures.

While inspectors were satisfied that governance and management arrangements are in place to ensure the safe delivery of medical radiological procedures at SIVUH, the composite of findings from this inspection indicated that greater assurance was needed in relation to oversight of radiation protection at the hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The practical aspects of medical exposures were only carried out by practitioners at the hospital. Furthermore, the hospital had retained the presence of radiographers in areas where medical exposures were conducted outside the radiology department, typically theatre and in the pain management service. In the absence of new training requirements being implemented, as per Regulation 22, this is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation.

Staff who spoke with inspectors outlined their role in the justification of medical radiological procedures. The justification of medical exposures was found to involve the referrer and practitioner. Inspectors found that documentation outlining responsibilities for justification should be updated to clearly reflect the day-to-day practices described to inspectors. For example, the allocation of responsibility for justification in general X-ray did not fully align to documentation reviewed by inspectors.

Inspectors were satisfied that in most cases, individual medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. However, clinical evaluation of the outcome of medical exposures, which is an aspect of clinical responsibility under this regulation, was being carried out for certain fluoroscopy procedures by a person not recognised under these regulations as a practitioner. In addition, while there was evidence that radiologists and radiographers were involved in the optimisation process, an MPE was not found to be involved. These non-compliances should be addressed by the undertaking to ensure regulatory requirements.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that MPE services were provided by an external off-site MPE through a formal arrangement. In discussions with this MPE, inspectors were informed that the MPE was supported by a physicist to carry out quality assurance of equipment at the hospital. The MPE outlined the informal contingency arrangements in place to access MPE cover from a colleague at another hospital should the need arise. However, the SLA did not have any detail of this arrangement and therefore should be updated to outline and formalise the contingency arrangements as outlined to inspectors and to provide greater assurance that access to medical physics expertise is maintained.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, inspectors reviewed documentation and spoke with the MPE and staff about the role and responsibilities of the MPE at the hospital. The 'Radiation Safety Procedures' document outlined that the MPE also carried out the separate role of (RPA) to the hospital. Overall, inspectors found that the documented responsibilities, including the SLA, were weighted towards the RPA role and that MPE responsibilities under these regulations should be more clearly delineated to provide assurance around regulatory compliance.

There was evidence that the MPE had contributed to certain aspects of this regulation including performing quality assurance of medical radiological equipment and incident analysis. Also, inspectors were informed that the MPE gave advice on the selection of equipment and preparation of technical specification for medical radiological equipment. However, overall inspectors were not satisfied that the undertaking had ensured the appropriate engagement of an MPE in line with the types of medical radiological procedures conducted at this hospital. Inspectors were informed by staff that an MPE was not involved in the optimisation of protocols and training of practitioners. Further gaps were identified in relation to the MPE's contribution to the application and use of DRLs and inspectors were not satisfied that the undertaking had ensured the adequate contribution of an MPE to the definition of the QA programme. Inspectors determined that management at the hospital should review the existing MPE arrangements to ensure that an MPE is engaged with this service, as appropriate, to address the identified deficiencies in compliance with this regulation.

Judgment: Not Compliant

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

Overall, inspectors were not satisfied that the undertaking had ensured that a medical physics expert was appropriately involved in medical radiological practices at the hospital. Inspectors found that the input of an MPE should be further developed by the undertaking to ensure that involvement is commensurate with the radiological risk posed by the service and to address areas for improvement as outlined in Regulation 20. Discussions with staff and management also identified that an increased level of on-site MPE presence would be of benefit to the hospital, particularly in relation to DRLs, optimisation and training. Furthermore, relevant documentation should be updated to clearly outline the involvement of the MPE in the service as per these regulations, to provide assurance of the undertaking's compliance.

Judgment: Not Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff to assess the safe delivery of medical exposures at SIVUH. Inspectors found that the hospital had a good reporting culture of actual and near-miss events. The system in place for trending and analysing of events was found to be comprehensive and was used to identify trends or patterns to minimise the probability of actual and potential incidents. The trending of near-miss events and incidents included considerations such as time of the event, service user demographics and severity rating.

Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters in waiting areas. Also, inspectors acknowledged the positive work which had been done in relation to clinical audit at SIVUH. Inspectors reviewed evidence of how clinical audit was used as a tool to monitor compliance with local policy and to identify opportunities for improvement.

The hospital also demonstrated a proactive approach to the use of diagnostic reference levels which had been established and regularly reviewed at the hospital. Staff outlined to inspectors how reviews had taken place where DRLs exceeded national levels and how the decision making around optimisation considered both dose and the required medical information given the specialised services carried out at the hospital. However, from discussions with staff, inspectors identified an inconsistency in the grouping of paediatric DRLs to national guidance. The hospital should review the groupings used for paediatric DRLs to allow for meaningful comparison of radiation doses with the national values.

Inspectors were informed by staff about the process in place to justify procedures in advance of the procedure, however, inspectors reviewed a sample of records and spoke with staff and found that records of justification in advance were not available for review for all procedures. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

In addition, inspectors found that information relating to patient exposure did not form part of the report of medical radiological procedures for all modalities as required by Regulation 13(2). The undertaking should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulation.

Inspectors identified that the strict surveillance of medical radiological equipment at the hospital was an area for improvement. The undertaking should ensure that regular performance testing of all equipment is carried out as per local policy. Furthermore, inspectors found that record keeping of the quality assurance (QA)

programme should be improved to ensure all relevant staff have access to up-to-date quality assurance test results. There should also be improved awareness around the status of the QA programme, for example staff should be able to identify if equipment is due QA.

Overall, inspectors were assured that the hospital had systems and processes in place for the safe conduct of medical exposures at SIVUH, however, there are a number of areas for improvement identified in this report that should be addressed by the undertaking.

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures which took place in the hospital was available for review on the hospital's radiology information system. While the hospital was on the national system, other hospitals in the locality were not and hence imaging from those sites were not available for review. The hospital had taken a proactive approach to considering this potential risk and had incorporated measures into routine practice by discussing previous and possible future imaging with patients. In addition, information in relation to the benefits and risks associated with radiation was available on posters in the waiting area of the Radiology Department for individuals undergoing medical exposure.

Inspectors spoke with staff who described how each medical exposure was justified, by a practitioner as per regulations, at the hospital. The process for recording justification in advance was described to inspectors. For example, in fluoroscopy, staff described that vetting was carried out by a radiologist and recorded on the system. Inspectors were informed that justification in other modalities was recorded as part of the triple identification process. An area of good practice was identified by inspectors in relation to justification for DXA procedures. Inspectors were informed that previously up to 70% of referrals were rejected and written feedback was provided to referrers to explain the clinical rationale for the decision where the procedure was deemed not justified. This initiative and communication to referrers was found to reduce the number of inappropriate referrals for DXA procedures. Inspectors recognised this an a positive initiative by the hospital as it demonstrates the considerations made to efficacy, risks and benefits of the medical exposure.

Inspectors reviewed the process of justification in practice and were informed that for some modalities such as general X-ray, justification was recorded as part of the triple identification process, however, these records were disposed of at the end of each day and therefore the hospital was found to not be in compliance with Regulations 8 (8) and 8(15) with the latter stipulating that a record should be available for a period of five years from the date of the medical exposure. Inspectors were informed that compliance with this process was audited regularly. On review of

audits conducted on the compliance with justification, inspectors were not satisfied that audit results or audit frequencies were sufficient to demonstrate compliance with Regulations 8 (8) and 8(15). For example, a single audit of the record of justification was conducted for a one week period during 2021 and this reviewed a sample of 340 records from all clinical areas. While overall compliance with justification was 95%, this level of compliance was not consistently found in all areas audited with one area demonstrating 69% compliance. A re-audit was not evident up to the day of the inspection.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff to determine the processes and procedures in place at SIVUH to ensure that all doses due to medical exposures were kept as low as reasonably achievable while still obtaining the required information. Many examples of good practice were provided to inspectors from practitioners, such as, the involvement of the radiologist in the development of the CT head protocol when it changed from spiral to sequential imaging.

Inspectors were informed how the hospital used DRLs to identify opportunities for optimisation of medical exposures. For example, although, the DRL values from 2021 were below national levels for all common procedures carried out on a recently installed fluoroscopy unit, the staff identified that these could be further optimised resulting in lower DRLs again for 2022, while retaining image quality.

A further example of optimisation was provided in relation to chest X-rays. An audit was carried out which identified that repeat imaging was more frequent on one unit compared to another due to the size of the detector. As a result, chest X-rays were carried out where possible on the unit with the larger detector to reduce the potential of repeat imaging being needed.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors found that DRLs for medical radiological procedures were established, regularly reviewed and used at the hospital. Inspectors were provided with an example where the hospital had conducted a review where the local DRL for a particular CT procedure exceeded the national DRL. The review found that this CT DRL value was acceptable in the context of the hospital's particular patient cohort.

While overall, the hospital were found to have a positive approach to applying DRLs to clinical practice, on discussion with staff, an inconsistency in the grouping of paediatric DRLs to national guidance was identified by inspectors. The hospital should ensure that local DRLs are established in a manner consistent with the specific weight groupings used for the national DRLs and in line with HIQA guidance to allow for a meaningful comparison of dose.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors reviewed written protocols in place for standard medical radiological procedures. Inspectors found that procedures for CT were comprehensive in content and included the date the document was established. However, protocols for other modalities lacked the same consistency in format and content, for example in some cases hand written annotations had been updated to hard copy versions of procedures. Inspectors also identified that the protocols would benefit from more multidisciplinary input. Staff informed inspectors that the department was moving to use a new document management system which would help organise and standardise how protocols were documented. The hospital should progress the implementation of this system to ensure that policies, procedures and guidelines are managed in a controlled manner to reflect version history, approval and updated changes which would provide assurances that all medical radiological procedures are optimised with involvement of appropriate staff.

Referral guidelines were available to referrers through an online resource. Staff articulated a clear knowledge of these guidelines and provided examples of when they were used in clinical practice.

A programme of clinical audit was established and inspectors reviewed a sample of clinical audits conducted at the hospital. An example of audit included a review of referrals for medical exposures from a particular out-patient clinic over a four week period. Inspectors were informed that as a follow up on the findings of this audit a quality improvement plan was in place to try to improve the quality of referrals.

Inspectors reviewed a sample of reports of medical radiological procedures and found that for most modalities the reports did not contain information relating to the patient exposure as required by Regulation 13(2) and therefore the hospital was not compliant with this regulation. Inspectors discussed this finding with management and staff.

Judgment: Not Compliant

Regulation 14: Equipment

Overall, inspectors found that the strict surveillance of medical radiological equipment should be improved by the undertaking at SIVUH. The hospital had a system in place to record equipment faults which enabled trending of equipment issues however, inspectors were informed that the MPE did not have access to this system. The hospital had identified two separate issues relating to software used on medical radiological equipment in CT and DXA. While these issues were rectified, the undertaking should be assured that appropriate acceptance testing is carried out before the first use of equipment for clinical purposes and that performance testing is carried out after any maintenance procedure liable to affect the equipment's performance.

An outline of the quality assurance programme including quality control testing was included in the *"Radiation Safety Procedures".* Inspectors discussed the QA programme in place with staff and were informed that regular quality control testing for fluoroscopy and c-arm units had previously been omitted from the QA programme but was recently added. However, inspectors were informed that regular quality control testing for one of the fluoroscopy units had not yet commenced due to workload constraints and hence performance testing of this equipment on a regular basis was not being carried out in line with the hospital's policy.

An inventory of medical radiological equipment was provided in advance of the inspection. This identified that two pieces of medical radiological equipment, including the CT scanner, were overdue annual QA by the MPE. However, on the day of inspection, the MPE informed inspectors that CT QA had been carried out in November 2021 and was not overdue. However, clinical staff were unaware that this annual QA had been carried out and the record of this QA was not available to review on the system on the day of inspection. Following on from the inspection the report of this QA was supplied to HIQA. Overall, inspectors found that the strict surveillance of equipment, including the implementation and maintenance of a quality assurance programme must be improved by the undertaking to ensure the requirements of this regulation are met.

Further assurance in relation to the strict surveillance of medical radiological equipment and equipment issues was sought by HIQA and provided following on from this inspection.

Judgment: Not Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Due awareness for the protection of pregnant women was in place at the hospital through the use of multilingual public notices in appropriate places, such as in the waiting area. Inspectors were also satisfied that a referrer or practitioner inquired regarding pregnancy status and recorded the answer to the inquiry in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

On the day of inspection, the hospital had an appropriate system in place for recording and analysing events involving, or potentially involving an unintentional or accidental exposure to ionising radiation. The trending of near-miss and actual incidents was displayed through a dashboard which included trending of details such as time of event, severity rating and cause of the event. In addition, inspectors were satisfied that a good culture of reporting was proactively encouraged by management at the hospital.

While the hospital had processes to ensure that significant events were reported to HIQA within the required time frame, based on the trend in reports reviewed by inspectors on the day of the inspection, consideration should be given to the reporting of significant events to HIQA whereby multiple non-notifiable incidents occur of a similar nature and the composite of which may have safety implications.

Inspectors found that the hospital had appropriate measures to ensure that the results of investigations and corrective measures following an incident reported to HIQA were provided in a timely manner, as required. While the reports of the investigations issued to HIQA were limited in content, inspectors were satisfied by the process of investigation and analysis of events as outlined to inspectors, which was found to involve a multidisciplinary team including the risk department overseen by the CEO.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Not Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for South Infirmary Victoria University Hospital OSV-0007405

Inspection ID: MON-0036812

Date of inspection: 05/07/2022

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

This document is divided into two sections:

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

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

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 5: Practitioners	Not Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: A reporting pathway will be implemented between Speech and Language Therapy and Radiology/ENT to ensure compliance with the requirement for appropriate practitioner involvement in clinical evaluation of videoflouroscopic procedures carried out in the Fluoroscopy Unit. This pathway shall be included in the existing SIVUH Videofluoroscopy Policy. Completion Date. 31.10.2022	
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The Terms of Reference of the Radiation Safety Committee have been tabled for correction at the next Radiation Safety Committee meeting to reflect the actual chairperson, Consultant Radiologist. Next RSC meeting 01.09.2022. A medically qualified representative from the Orthopaedic team will be invited to attend the Radiation Safety Committee in order to ensure appropriate representation from all relevant multidisciplinary teams. The SIVUH Operations Manager has also agreed to attend the Radiation Safety Committee. The European Commission (Radiation Protection No 174 – European Guidelines on Medical Physics Expert) indicates that 0.5 WTE of MPE is required for our service based on activity and WTE. A Business Case is in development for increased on-site MPE resource which will be submitted to the Hospital Senior Management Team. A Risk Assessment is being drafted and the risk will also be added to the Hospital Risk Register. Completion date 01.09.22 (See also response to Regulation 20)	

Inconsistencies in policy templates are acknowledged. All existing policies will be reviewed and prioritised. These will be transferred onto the Hospital policy template.
Completion date: 31.12.2022

The process of uploading relevant policies and documents to our Quality Management System (QMS) has begun.

The recent challenges regarding ratification of policies are acknowledged. Clinical Governance Committee meetings are scheduled to resume on 12.09.2022 and will occur quarterly in future. A proposal to increase the frequency of Radiation Safety Committee meetings to quarterly will be tabled for the next RSC meeting.
Currently a report is provided from each RSC Meeting to the subsequent Clinical Governance Committee meeting.
Completion date: 01.09.2022

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
A reporting pathway will be implemented between Speech and Language Therapy and Radiology/ENT to ensure compliance with the requirement for appropriate practitioner involvement in clinical evaluation of videoflouroscopic procedures carried out in the Fluoroscopy Unit. This pathway shall be included in the existing SIVUH Videofluoroscopy Policy.
Completion Date. 31.10.2022

A Business Case is in development for increased on-site MPE resource which will be submitted to the Hospital Senior Management Team. A Risk Assessment is being drafted and the risk will also be added to the Hospital Risk Register. It is envisaged that the MPE will have a greater on-site presence following a review of the current SLA and resource. At such time it is expected that the MPE will have a greater input into the optimisation process. In the interim the RSO will continue to involve the MPE on decisions and changes made in the process of optimisation that may arise following Audit, Update of Equipment or Staff input.
Completion Date. 01.09.2022

Regulation 19: Recognition of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: The SLA will be updated to outline and formalise contingency in place for MPE cover. This is on the agenda for the next Radiation Safety Committee Meeting. 01.09.22	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: The SLA and the Radiation Safety Procedures will be updated to reflect the MPE responsibilities under these regulations more clearly; including involvement in optimisation of protocols and training of practitioners; application and use of DRLs. Completion Date:31.12.2022	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: The European Commission (Radiation Protection No 174 – European Guidelines on Medical Physics Expert) indicates that 0.5 WTE of MPE is required for our service based on activity and WTE. A Business Case is in development for increased on-site MPE resource which will be submitted to the Hospital Senior Management Team. A Risk Assessment is being drafted and the risk will also be added to the Hospital Risk Register. See Regulation 6 above. The current arrangements are being reviewed to ensure greater onsite presence. Completion Date: 01.09.2022	
Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
A trial is taking place in all modalities whereby Radiographers will place the comment JIA (justification in advance) along with their initial in the notes section on the RIS request. This is a permanent record which can be reviewed on inspection.

The triple ID containing the justification tick-box generated by NIMIS will continue to be used by practitioners while this trial is taking place to ensure justification in advance of all radiological examinations.

We undertake to strengthen our Audit programme by auditing the triple ID justification forms quarterly. The most recent audit (17.08.22) will be presented at the upcoming Radiation Safety Committee Meeting on 01.09.2022.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
A new Audit of Paediatric DRLs in a manner consistent with the specific weight groupings used for the national DRLs and in line with HIQA guidance will be conducted. This audit will commence in September 2022 for 3 months in order to collate a sample representative of the paediatric population undergoing each modality in the SIVUH.
Completion date: 31/12/2022

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
A complete review of all medical radiological procedure documents within the Radiology Department will commence and will be led by the RSM. The same format will be used for all standard operating procedures based on the CT model. All protocols will show version history, approval date, authorisation and updated changes. Once compiled, these will be uploaded to the SIVUH Quality Management System.
Completion Date: 31.01.2023

Re Regulation 13(2), following discussion at our Radiation Safety Committee Meeting (01.09.22) we have requested our Chairperson to escalate this issue with the National Professional Body.
Completion Date: 31.01.2023.

Regulation 14: Equipment	Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The SOP on equipment handover submitted on the day will be revised by RSM in PPPG format to clearly outline appropriate acceptance testing practice on equipment, including a handover checklist, following any maintenance or service which may effect equipment output.

Summary QA Log to be submitted to RSC to support oversight and monitoring of maintenance and QA.
Access for MPE to ECRI AIMS is being arranged.
Completion Date: 01.09.2022

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Not Compliant	Orange	31/10/2022
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	31/10/2022
Regulation 5(c)	A person shall not take clinical responsibility for	Not Compliant	Orange	31/10/2022

	an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).			
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	01/09/2022
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its	Substantially Compliant	Yellow	01/09/2022

	behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	01/09/2022
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	31/10/2022
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Orange	01/09/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established,	Substantially Compliant	Yellow	31/12/2022

	regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/01/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/01/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Orange	01/09/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	01/09/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological	Not Compliant	Orange	12/08/2022

	equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	31/12/2022
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Orange	31/12/2022
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the	Substantially Compliant	Yellow	31/12/2022

	medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical	Not Compliant	Orange	31/12/2022

	specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Orange	31/12/2022
Regulation 21(2)(c)	In carrying out its obligation under paragraph (1), an undertaking shall,	Not Compliant	Orange	31/12/2022

	in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.			