



Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	St Marys Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Phoenix Park, Dublin 20
Type of inspection:	Announced
Date of inspection:	09 May 2024
Medical Radiological Installation Service ID:	OSV-0007342
Fieldwork ID:	MON-0040057

About the medical radiological installation:

At St. Mary's Hospital, our X-ray and DXA services cater not only to our hospital's patients but also for residents in the Phoenix Park Community Nursing Unit (PPCNU), Day Hospital and GP referrals for service users over the age of 65. Our newly commissioned X-ray machine, introduced in February 2024, and our new DXA machine, commissioned in April 2023, serve as integral components of our commitment to providing comprehensive care across our campus. Patients, transitioning from our rehabilitation hospital, receive seamless access to our imaging services, aiding their continued recovery and medical management. Additionally, residents from the Phoenix Park Community Nursing Unit benefit from our diagnostic capabilities, ensuring timely assessments and interventions to support their health and well-being. With a focus on patient-centred care, St Mary's Hospital has entered into a Service Level Agreement with the National Orthopaedic Hospital Cappagh, to provide skilled and experienced staff to conduct and report on all aspects of X-Ray and DXA imaging for the Patients of St Mary's Hospital, residents of the PPCNU and DXA scans for GP referrals.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 9 May 2024	10:00hrs to 14:20hrs	Margaret Keaveney	Lead
Thursday 9 May 2024	10:00hrs to 14:20hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

On 9 May 2024, inspectors completed an inspection of the radiological service at St. Mary's Hospital, to monitor the service's compliance with the regulations. Inspectors visited the general radiography room and dual-energy x-ray absorptiometry (DXA) unit room, and spoke with staff and reviewed a suite of documentation developed by the HSE, who is the undertaking for the service. Overall, inspectors were assured that the undertaking's management team were making good efforts to achieve compliance with the regulations. However, further action was required under Regulations 6, 13 and 19 to achieve full compliance. This is further discussed throughout the report.

The radiological service in St. Marys Hospital provides medical exposures of ionising radiation to in-patients in the hospital and to out-patients, including those referred from a designated service for older persons on the hospital grounds. Patients are also referred from general practitioners in the community. The undertaking's management team had engaged the expertise of a Radiation Services Manager (RSM) and radiography staff, from an external radiological service, to carry out medical exposures on the X-ray and DXA units, and to complete associated regulatory responsibilities. Inspectors reviewed documentation which clearly outlined the roles and responsibilities of both parties under this agreement.

The management team had also established a radiation safety committee (RSC), which was scheduled to meet twice yearly and inspectors saw that it had done so in the previous 12 months. Inspectors also reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership. Inspectors noted that the committee had a standing agenda and items such as equipment, incidents and new documentation were discussed. The RSC meetings were chaired by the Hospital Manager, and were also attended by the lead radiologist, medical physics expert (MPE) and RSM. Inspectors were also informed of two radiation protection units (RPU) in place in the service, one for each of the general X-ray and DXA services. Each unit was responsible for operational issues relating to radiation protection and each reported into the RSC. From a review of meeting minutes, inspectors noted that their membership included the lead radiologist, the medical physics expert and the RSM, and that these units effectively and promptly actioned any operational issues in their respective service. Their establishment was identified as an area of good practice in the service.

Although the undertaking's management team had many good systems and measures in place to ensure the radiation protection of service users, action was required to ensure that some of these roles and responsibilities were clearly allocated. For example, on the day of the inspection, inspectors were informed that due to recent changes in the senior management team within the hospital the current designated managers listed for the service were no longer responsible for the day-to-day management of the medical radiological service. Inspectors were also informed that following the inspection, the recently appointed hospital manager

would allocate this role, which would ensure that an appropriate person was in place to facilitate communications between HIQA and the undertaking for operational matters in the radiological service.

During discussions with the management team, inspectors also noted that there was a lack of clarity on the reporting structures to the undertaking, and information obtained during a review of meeting minutes and of an updated organogram did not align with what inspectors were told during the inspection. This is further discussed below under Regulation 6: Undertaking.

A sample of service user records for medical exposures were reviewed by inspectors and showed that appropriate persons, as per the regulations, were involved in referring and justifying medical exposures completed in 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.

From a review of documentation and discussions with staff, inspectors noted that medical physics involvement in the service was proportionate to the radiological risk posed by the service. However, the undertaking's management team must prioritise implementing arrangements to ensure continuity of this involvement. The continued involvement of an MPE in a service assures service users that a safe and quality service is being provided. This is further discussed under Regulation 19 below.

Notwithstanding the issues discussed above, inspectors were assured that service users were receiving safe medical radiological exposures in St. Mary's Hospital.

Regulation 4: Referrers

From a review of a sample of medical exposures records and discussions with staff, inspectors were satisfied that referrals, for medical radiological procedures, were only accepted in the service from persons defined in Regulation 4.

The undertaking's management team had developed a *Radiation Safety Procedures for the Safe use of Ionising Radiation* procedure which outlined that medical practitioners could refer for medical radiological procedures in the service, and that radiographers could make adapted referrals when required.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied, from a review of medical radiological procedure records and from speaking with staff, that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in the service. In St.

Mary's Hospital, only appropriately registered radiologists and radiographers acted as practitioners.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that the undertaking had implemented governance and management arrangements that provided oversight of radiology service locally within St. Mary's Hospital. However, inspectors were not satisfied that there were clear arrangements in place which informed the undertaking of radiation protection matters in St. Mary's Hospital. For example, the organogram outlining the governance and management arrangements was not supported by documentation, such as meeting minutes, to evidence the arrangements in place to report to the undertaking.

Inspectors also noted that action was required to ensure that all roles and responsibilities on radiation protection of service users were clearly allocated and documented in the relevant documentation. For example, from a review of the *Radiation Safety Procedures for the Safe use of Ionising Radiation*;

- it was not clear to inspectors which professional groups had been allocated the role of practitioner in St. Mary's Hospital. Although inspectors were satisfied that appropriate personnel were carrying out this role in the service, a clear allocation of key radiation protection roles is essential in a radiological service.
- the roles for radiation protection responsibilities in the DXA service were not clearly allocated in the *Radiation Safety Procedures for the Safe use of Ionising Radiation*, or in any document provided to inspectors. Although inspectors were satisfied that appropriate personnel completed, for example, the justification process and equipment QA in this service, these roles were not clearly allocated.
- the documented procedure for signing of the pregnancy consent form was not in line with the regulations. Under the regulations, practitioners must be allocated the role of enquiring on and recording the pregnancy status of relevant service users, and in St. Mary's Hospital while this was the actual practice, it was not clearly allocated to practitioners.
- the roles and responsibilities of the full reporting pathways for incidents and near misses were not clearly allocated in documentation reviewed by inspectors. A structured incident reporting mechanism is an integral part of effective incident management system.
- under Regulation 13(2), the undertaking must have arrangements in place to ensure that information relating to patient exposure forms part of the report following of the medical radiological exposure. However, in the

documentation reviewed, responsibility for oversight of this system had not been allocated.

While improvements were required in some governance and management arrangements and in the documented allocation of roles and responsibilities, inspectors were satisfied that the appropriate personnel were carrying out radiation protection measures and that service users in the radiology department received safe exposures of ionising radiation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From a review of documents and discussions with staff, inspectors were satisfied that practitioners, as defined in the regulations, took clinical responsibility for the medical radiological procedures in St. Mary's Hospital.

In addition, practitioners and the MPE were noted to be involved in the optimisation process for all medical exposures to ionising radiation. Inspectors were also satisfied that the justification process for individual medical exposures involved the referrer and practitioner.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The undertaking had engaged a medical physicist to provide medical physics expertise in St. Marys' Hospital. However, from discussions with the undertaking's management team, and a review of a documented agreement between the undertaking and the MPE, inspectors were not satisfied that the undertaking had arrangements in place to ensure the continuity of medical physics expertise. The continued involvement of a medical physicist in a service is a key element in assuring service users that they are receiving a safe and quality radiological service.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and were satisfied that the involvement and contribution of the medical physicist in the service met the requirements of this

regulation. This review included the professional registration certificate of the medical physicist providing expertise in the facility.

Inspectors noted that the MPE had been clearly allocated responsibilities, as specified in Regulation 20(2), across the radiological service. For example, they were involved in acceptance testing and the quality assurance (QA) of medical radiological equipment. Inspectors were informed that they had provided additional monitoring of some new equipment to ensure that it was performing optimally. The MPE was also involved in the development of local diagnostic reference levels (DRLs), attended the local RSC and RPU meetings, and were available to provide advice and dose calculation for radiation incidents.

The medical physicist was assigned the role of radiation protection advisor (RPA) at the facility, which satisfied inspectors that the MPE and the RPA liaised as appropriate.

Judgment: Compliant

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

From a review of documentation and discussions with relevant staff, inspectors were satisfied that the level of MPE involvement in medical radiological practices was commensurate with the radiological risk posed by the facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors noted that the undertaking's management team had implemented a number of radiation protection measures for service users. For example, by the use and refinement of diagnostic reference levels (DRLs) and an appropriate quality assurance programme for equipment.

The sample of referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The justification of medical exposures in advance, by a practitioner, was evident for medical radiological procedures reviewed by the inspector.

Inspectors noted that the multidisciplinary team had established and reviewed local DRLs for medical radiological examinations that were frequently completed in the

service. From discussions with staff the inspector was satisfied that they were used for all medical radiological procedures conducted in the service.

From a review of documentation, inspectors were satisfied that there was an established QA programme for radiological equipment in the service, and that the programme was discussed at local RSC meetings.

Inspectors also reviewed the process in place to determine the pregnancy status of service users, where relevant and was assured that this process was safe and effective. A review of documentation evidenced that there were good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Notwithstanding the action required to comply with Regulation 13, as detailed below, inspectors were satisfied that there were systems and processes in place to ensure the safe delivery of medical radiological exposures to service users in St. Mary's Hospital.

Regulation 8: Justification of medical exposures

Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of posters in the waiting areas of the service, and general X-ray and DXA specific information leaflets were also available to service users.

From a review of a sample of medical records in both the general X-ray and DXA services, inspectors were satisfied that referrals for medical exposures were in writing and stated the reason for the request, and were accompanied by sufficient medical data to enable the practitioner to adequately consider the benefits and risks of the medical exposure. This review also showed that the recording of justification in advance had been completed by practitioners. Although found to be compliant with this regulation at the time of the inspection, a review of the justification in advance process should be carried out to ensure that the undertaking continues to meet the regulatory requirement of retaining records for five years from the date of the exposure, with these records clearly evidencing the practitioner that completed the process.

Practitioner staff demonstrated to inspectors how they obtained previous diagnostic information. As discussed under Regulation 6 above, a review was required to ensure that the roles and responsibilities for the justification process in the DXA device were clearly allocated. However on the day of the inspection, inspectors were satisfied from speaking with staff and a review of medical records that the practices in St. Mary's Hospital, in completing radiological exposures, were compliant with Regulation 8.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

From a review of documentation, inspectors were satisfied that DRLs for frequently completed radiological examinations had been established for both the general X-ray and DXA units, and were compared to national levels. During a tour of the equipment console areas, inspectors noted that local and national DRLs were prominently displayed for easy reference by staff.

Inspectors were informed that there were low numbers for some radiological procedures in the service, which meant that there was insufficient data to establish DRLs for all procedures carried out. However, inspectors saw that as procedure numbers increased to sufficient levels, frequent DRL reviews were completed and DRL data for these procedures were established. For example, local DRLs had been reviewed in May and July 2023, with a DRL for an additional procedure established in July. This system of DRL review and attention to radiation protection for service users was identified as an area of good practice within the facility.

Judgment: Compliant

Regulation 13: Procedures

Inspectors noted that written protocols for each standard radiological procedure had been developed in the service and were available to staff in the console areas of the X-ray and DXA rooms for easy access by staff. Inspectors were also informed that referral guidelines were available to referrers and practitioners.

Although inspectors were informed that the undertaking had implemented a system to ensure that dose information relating to patient exposure was included on procedure reports, during a review of a number of procedure reports on medical exposures, inspectors saw that this information was not included in some of the reports reviewed. Staff who spoke with inspectors were not aware that this information was not available on some of the reports. The undertaking must ensure the implemented system is achieving the expected result, in order to fully comply with the Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that the undertaking had established a quality assurance programme (QA) to ensure that all medical radiological equipment, in use in the service, was kept under strict surveillance. The MPE and radiography team had developed and implemented the QA programme, which included annual testing by the MPE and regular performance testing by radiographers. Inspectors reviewed QA records which verified that the testing programme was effectively implemented with testing timelines adhered to. In addition, inspectors were satisfied that acceptance testing was carried out on equipment prior to the first clinical use.

Inspectors also found evidence that effective systems were in place to ensure that any performance issues with the medical radiological equipment were actioned. For example, inspectors noted that an equipment issue had been discussed by the multi-disciplinary team at a RSC meeting, and reviewed documentation that evidenced that appropriate communications and actions had been implemented to promptly resolve the issue. This multi-disciplinary approach to the monitoring of equipment performance was identified as an area of good practice in the service.

During the inspection, inspectors received an up-to-date inventory of medical radiological equipment.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed that notices were displayed in the service user waiting area to raise awareness of the special protection required during pregnancy, in advance of medical exposure to ionising radiation. From a review of a sample of medical records, inspectors saw practitioners had inquired on and recorded in writing the pregnancy status of patients.

Overall, inspectors were assured that appropriate measures were in place to ensure the protection of patients that were pregnant while attending the radiology service in St. Mary's Hospital. However, as discussed under Regulation 6 Undertaking, action was required to ensure that the *Radiation Safety Procedures for the Safe use of Ionising Radiation* procedure clearly outlines the personnel responsible for enquiring on patients pregnancy status, to ensure that it aligns with the requirements of the regulations.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From discussions with staff, inspectors were informed of an appropriate system in place for the recording and review of any incidents and near misses involving accidental or unintended exposures to ionising radiation in the service. Staff who spoke with inspectors described how they recorded any such incidents and near misses, and who they then informed. The *Radiation Safety Procedures for the Safe use of Ionising Radiation* procedure outlined the incident management process in place and included information on the requirement to notify HIQA of certain reportable incidents. However, as discussed under Regulation 6 Undertaking, some action was required to ensure that the documented incident management system was updated to provide clear guidance to all staff on the roles and responsibilities in relation to this system.

From a review of meeting minutes and discussions with the management team, inspectors noted that incidents were a standing agenda item for the local RPU and the RSC meetings. All such incidents were also then discussed at a local Quality and Patient Safety (QPS) meeting, which was attended by the Hospital Manager and QPS adviser amongst others.

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	Not 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 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for St Marys Hospital OSV-0007342

Inspection ID: MON-0040057

Date of inspection: 09/05/2024

Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <p>The <i>Radiation Safety Procedures for the Safe use of Ionising Radiation</i> will be reviewed and amended to include the following:</p> <ul style="list-style-type: none"> • Allocation of key radiation protection roles • Roles for radiation protection responsibilities in the DXA services • Procedure for signing of pregnancy consent form • role of responsibilities for reporting pathways for incidents and near misses • responsibility of oversight of medical radiological exposure • Review of Local Rules is underway and planned completion date for this action is on or before 1st August 2024 	
Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:</p> <p>An amendment has been made to the current SLA to include provisions for continuity of medical physics expertise (MPE). In the event of an absence of the current MPE/RPA in the service then a second named MPE has been appointed with immediate effect to provide cover for this period.</p>	
Regulation 13: Procedures	Substantially Compliant

<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>A memo has been sent to all consultants by the Picture Archive and Communications (PACs) manager to ensure radiation dose information relating to patients exposure is included on all procedure reports prior to signing. Communication was sent on 13th June 2024 by PAC's Manager from National Orthopaedic Hospital, Cappagh.</p> <p>An audit of procedure reports will be conducted by PAC's Manager to ensure compliance with Regulation 13.</p> <p>Implementation and completion date on or before: 1st August 2024</p>	

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such	Substantially Compliant	Yellow	01/08/2024

	form and manner as may be prescribed by the Authority from time to time.			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	01/08/2024
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.	Not Compliant	Orange	Complete 14/06/2024