



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	St. James's Private Clinic Radiology Department
Undertaking Name:	St. James's Private Clinic Radiology Group
Address of Ionising Radiation Installation:	Hospital 2 top floor, st. James's Hospital, Dublin 8
Type of inspection:	Announced
Date of inspection:	13 September 2023
Medical Radiological Installation Service ID:	OSV-0006372
Fieldwork ID:	MON-0039456

## About the medical radiological installation:

St. James's Private Clinic, Radiology, is a diagnostic imaging department, which provides a comprehensive range of imaging services including Computed Tomography (CT), Mammography, Dual-energy x-ray absorptiometry (DXA), and Ultrasound.

The department consists of a multidisciplinary team of radiologists, radiographers, an administrative team and medical physicists.

All radiological services are on an out-patient basis, referred predominantly by private clinic consultants, St James Hospital referrers, or externally by General Practitioners (GPs).

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

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

<sup>4</sup> 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 13 September 2023	10:00hrs to 14:30hrs	Lee O'Hora	Lead

## Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation and visited the mammography, DXA and CT departments and spoke with staff and management. The inspector found effective governance, leadership and management arrangements in place with a clear allocation of responsibility for the protection of service users undergoing medical exposures. Staff at St. James's Private Clinic Radiology Department used a Radiation Safety Committee (RSC) within the governance structure to ensure that radiation safety related issues could be considered and escalated to the undertaking appropriately.

The inspector reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, the inspector was 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.

Following review of documents and records, and speaking with staff, the inspector was 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. Similarly, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

### Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that St. James's Private Clinic Radiology Department only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

### Regulation 5: Practitioners

After speaking with staff, visiting the clinical area and reviewing a sample of referrals for medical radiological procedures the inspector was assured that St. James's Private Clinic Radiology Department had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual

medical exposures.

Judgment: Compliant

### Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by St. James's Private Clinic Radiology Group operating at St. James's Private Clinic Radiology Department.

Staff at St. James's Private Clinic Radiology Department used a RSC within the governance structure to ensure that radiation safety related issues could be considered and escalated to the undertaking appropriately. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection. The inspector noted that the observed commitment of staff tasked with key radiation safety roles was complimented by a clear allocation of responsibility by the undertaking and both aspects of the service combined to ensure the protection of service users from medical exposures to ionising radiation at St. James's Private Clinic Radiology Department.

Judgment: Compliant

### Regulation 10: Responsibilities

Following a review of the radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner.

The inspector was assured that the optimisation process involved the practitioner and the MPE. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer, as required by the regulations.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the facility were described to the inspector by staff and management and the details

were available in St. James's Private Clinic Radiology Department radiation safety documents as well as a service level agreement (SLA) reviewed as part of this inspection. All evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. From reviewing the documentation and speaking with staff at the hospital, the inspector was satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at St. James's Private Clinic Radiology Department.

Judgment: Compliant

## Safe Delivery of Medical Exposures

The Inspector reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this facility.

Following review of a sample of referrals for CT, mammography and DXA the inspector was satisfied that St. James's Private Clinic Radiology Department had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Good practice was evident in the justification process which routinely incorporated multiple previous imaging reviews and

procedure matching which helped to mitigate the risks associated with duplicate referrals for imaging. This process was supported by the undertaking's system for recording and analysing accidental and unintended exposures and significant events and near misses. The inspector noted that duplicate imaging referrals were recorded as near miss events due to the thorough processes discussed under Regulation 8 and these did not result in reportable incidents.

The inspector was satisfied that DRLs were established, used and reviewed. Records of acceptance and performance testing for all radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained a QA programme.

Overall, the inspector was assured that St. James's Private Clinic Radiology Department had appropriate systems in place to support the safe delivery of medical exposures.

### Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded.

In line with Regulation 8, all referrals reviewed by the inspector on the day of inspection were available 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. Staff spoken with on the day consistently informed the inspector that the justification process was also used to review previous imaging and facilitate procedure matching. Records reviewed also highlighted that the justification process was repeated the day before the patient was scheduled to attend St. James's Private Clinic Radiology Department. This added step was considered good practice as it actively reduced the possibility of unnecessary repeat imaging due to duplicate requests.

The inspector visited the clinical area and observed multiple posters, both general and modality specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pre-procedure patient questionnaires also included patient information on risks and benefits of medical exposures.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels



Following a review of DRLs, the inspector was satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility.

All local facility DRLs had been compared to national DRLs, and where national DRLs were not available local facility DRLs were compared with UK DRLs. The document *MPE review of patient dose and DRLs* detailed the multidisciplinary approach to the investigation and agreed corrective actions for a CT procedure that was above the UK DRL. This was seen a positive use of information gained through DRL review to optimise patient dose even when national comparisons were not available.

The inspector visited the clinical area and observed multiple examples of local facility DRLs displayed.

Judgment: Compliant

### Regulation 14: Equipment

From the evidence available, the inspector was assured that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a quality assurance programme including appropriate acceptance and regular performance testing. Evidence was also available to show that any issues identified as part of the equipment QA programme had been followed up in a timely manner.

The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspector that St. James's Private Clinic Radiology Department had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner, where appropriate, and the answer was recorded.

Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

## Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at the RSC, thus the undertaking had oversight of events involving or potentially involving accidental or unintended medical exposures in this facility. Good practice in relation to Regulation 8 also mitigated the risk associated with duplicate requests for imaging, which were noted in the undertakings record keeping system as near miss events.

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
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant