



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	St Camillus Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Shelbourne Road, Limerick
Type of inspection:	Announced
Date of inspection:	10 April 2024
Medical Radiological Installation Service ID:	OSV-0007340
Fieldwork ID:	MON-0037598

About the medical radiological installation:

The Department of Radiology, St Camillus Community Hospital is an outpatient diagnostic facility providing dual-energy X-ray absorptiometry (DXA) and general radiography. The X-Ray service is available two and a half days per week. There are two iDXA (lunar iDXA) machines and these run Monday to Friday each week. Radiation protection and medical physics services are provided by staff from the Department of Medical Physics and Bioengineering at St James's Hospital.

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
Wednesday 10 April 2024	10:07hrs to 15:38hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

An inspection was carried out at St Camillus Hospital on 10 April 2024 to assess compliance with the regulations. The inspector spoke with staff and management, reviewed documentation and visited both the general radiography and dual-energy X-ray absorptiometry (DXA) services as part of this inspection.

The evidence gathered during this inspection demonstrated to the inspector that there was a clear allocation of responsibilities for the radiation protection of service users attending this facility. The undertaking had ensured that all medical exposures to ionising radiation took place under the clinical responsibility of a practitioner and had processes in place to ensure that referrals for medical radiological procedures were only accepted from individuals entitled to refer as per the regulations. In addition, the inspector was satisfied that a medical physics expert (MPE) was appropriately involved in a range of responsibilities in line with regulatory requirements.

Overall, the inspector found that the undertaking at St Camillus Hospital was compliant with Regulations 4, 5, 6, 8, 10, 14, 17, 19, 20 and 21 with some action required to comply with Regulations 11 and 16. Staff at the hospital demonstrated a commitment to the radiation protection of service users attending for X-ray and DXA scans at this facility.

Regulation 4: Referrers

The inspector was satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that medical exposures in this facility only took place under the clinical responsibility of a practitioner as recognised under this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Governance arrangements for the radiation protection of service users were reviewed as part of this inspection. The inspector found that the governance and management structure in place was clearly defined. A radiation safety committee (RSC) with multidisciplinary representation was evident in minutes viewed. The RSC met twice a year and was the forum for ensuring the radiation protection of service users and compliance with the regulations. The designated manager reported up to the general manager of St Camillus Hospital who was ultimately responsible for the radiation protection of all persons attending for X-ray at its facility. The structures viewed in documentation provided, and confirmed in discussions with management, demonstrated that there was an effective communication system to ensure that relevant information was communicated to the undertaking at the Health Service Executive (HSE) as required.

The undertaking for this facility had ensured that the allocation of responsibilities for the protection of service users undergoing medical exposure to ionising radiation was in place as required under this regulation. Staff who spoke with the inspector were clear on their individual roles and responsibilities regarding medical radiological practices. Staff training records regarding radiation protection viewed by the inspector confirmed that all staff involved in providing medical radiological procedures attended regular training and were up-to-date with training requirements.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. However, while meeting the requirements of Regulation 10(1), the inspector noted an area of improvement was required in the hospital policy *Making and Accepting Referrals* which should be reviewed to align with day-to-day practices, as described by staff to the inspector.

The inspector was satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. There was also evidence to show that practitioners and the MPE were involved in the optimisation process as per the requirements of this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed formal arrangements in place that provided assurance regarding the continuity of medical physics expertise at St Camillus Hospital and therefore verified the undertaking's compliance with this regulation.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificates of MPEs at St Camillus Hospital and was satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Following discussion with staff, the MPE and review of documentation, the inspector was satisfied that the requirements set out under Regulation 20(2) regarding MPE roles and responsibilities were met. For example, an MPE attended the facility's RSC meetings, gave advice on medical radiological equipment, contributed to the definition of the quality assurance (QA) programme and carried out annual QA testing. This included acceptance testing which was evident in records viewed for new equipment commissioned for use in 2021 and 2022. The evidence gathered also confirmed MPE involvement in optimisation including the establishment, application and use of diagnostic reference levels (DRLs).

The inspector noted that MPEs also acted as radiation protection advisers for the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussions with staff including an MPE, the inspector found that there was appropriate involvement of an MPE in all aspects of medical exposure to ionising radiation conducted at the hospital, therefore, demonstrating compliance with this regulation.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector viewed the systems and processes in place to assess the safe delivery of medical exposures at St Camillus Hospital and found compliance with the majority of regulations overall, with improvements required to comply with Regulations 11(7) and 16.

From a sample of medical radiological procedure records viewed, the inspector found that referrals were in writing, stated the reason for the request and were accompanied by medical data to inform the process of justification by a practitioner. Justification of medical exposures in advance by a practitioner was also evident in these records, thereby demonstrating compliance with Regulation 8.

The inspector was satisfied that regulatory requirements were met for Regulation 13 with written protocols for standard procedures evident in general radiography and DXA services. In addition and as per the requirements of Regulation 13(2), information regarding patient exposures was also included as part of the reports viewed. The inspector found that medical radiological equipment was kept under strict surveillance as per Regulation 14(1). This meant that equipment was subjected to regular performance testing and maintenance to ensure it was safe for clinical use.

The inspector reviewed documentation relating to the process for the management of accidental and unintended exposures and significant events and found there were appropriate oversight and systems in place to support staff in the management of radiation incidents or potential incidents. From documentation viewed, the inspector noted from that no incidents or near misses were identified or reported in the last year. While meeting the requirements of Regulation 17, the inspector identified that there was scope to improve reporting levels given the overall activity levels in this facility.

The inspector was satisfied that diagnostic reference levels (DRLs) had been established by staff, regularly reviewed and used, having regard to national DRLs, as required by Regulation 11(5). A review of facility DRLs identified that a number of common procedures in the DXA service had consistently exceeded national DRLs. Regulation 11(7) requires that the undertaking retains a record of reviews and corrective actions carried out in this scenario. While staff informed the inspector that action had been taken in response to this issue, a record of this review and corrective actions was not evident at the time of the inspection.

Following review of the processes implemented to meet the regulatory requirements set out under Regulation 16, the inspector was satisfied that there was a process in place to determine the pregnancy status of service users, where relevant. However, the inspector identified that some improvement was required in the DXA service to ensure that pregnancy enquiries for all relevant service users as per Regulation 16(1) are made by the appropriate personnel.

While noting that some improvements in compliance were required following this inspection, the inspector was satisfied that the radiation protection of service users was a priority and a focus for staff working in this facility.

Regulation 8: Justification of medical exposures

A sample of medical radiological procedure records were viewed in the general X-ray service and the DXA scanning unit. The records viewed showed that a written referral was available for each examination performed that stated the reason for the request and was accompanied by sufficient clinical data to inform the justification process. Justification in advance of each medical radiological procedure was recorded on the referral by the radiographer in general X-ray or on the image management and communication system by the consultant with responsibility for the DXA service.

Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users and displayed in the format of posters throughout the facility.

The evidence viewed demonstrated compliance with the requirements of this regulation.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Staff at St Camillus Hospital had a document titled *Guidelines for DRLs of Medical Exposures Standard Operating Procedure* which had been approved for use in May 2022 and set out staff responsibilities regarding the establishment, review and use of DRLs. This document also outlined the process to be followed by staff in circumstances where DRLs consistently exceeded national DRLs. This included an immediate investigation of equipment and practices to ensure that medical exposures to ionising radiation were optimised.

The inspector found from documentation reviewed and speaking with staff that facility DRLs were established and compared with national DRLs. Records viewed showed that the facility had two DXA scanners in use, both from the same manufacturer, which were installed and commissioned in 2021 and 2022 respectively. The inspector was informed that the technical specification of these scanners differed from the previous scanners and were selected to suit the scanning requirements of bariatric service users attending for DXA scans at St Camillus Hospital. However, the scanning technology employed by these systems were associated with higher doses which resulted in facility DRLs that consistently exceeded current national DRLs in three out of the four common procedures

provided in this setting. The inspector was informed by staff that action was taken to seek further clarification from the manufacturer regarding these doses and this issue was also discussed with the practitioner with responsibility for the service and at the RSC. However, as per the requirements of Regulation 11(7), a formal record of this review and summary of corrective actions was not evident at the time of the inspection. The undertaking should continue to work to reduce and optimise the doses of those procedures that remain outside the national DRLs.

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspector saw evidence to demonstrate that written protocols were in place for standard medical radiological procedures in both general X-ray and DXA scanning services which met the requirements of Regulation 13(1). An area of improvement was identified by the inspector regarding the process for approval of protocols to be applied at the hospital which needed to be strengthened.

The inspector reviewed a sample of medical radiological records for DXA and general X-ray services and found that information relating to the patient exposure was evident in each of the reports of the procedures viewed as required under Regulation 13(2).

Referral guidelines for medical imaging were available to staff in each setting as per Regulation 13(3). The inspector was satisfied that the undertaking had a clinical audit programme in place with regular audit undertaken in the DXA and general radiology services. In addition, an audit schedule for 2024 was viewed and staff informed the inspector that work was in progress to enhance the hospital's clinical audit programme to ensure it aligned with the national procedures for clinical audit established by HIQA.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided to the inspector and verified during the inspection. Documentation including records of acceptance testing and quality assurance by an MPE, in addition to records of regular performance testing carried out by radiography staff and service engineers provided evidence that medical radiological equipment was kept under strict surveillance at St Camillus Hospital as required under this regulation.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector reviewed the procedure that detailed the process to be applied for enquiring about the pregnancy status of women of childbearing age which was available in the document *Radiation Safety Procedures*. The inspector noted that this procedure was applied in general X-ray and DXA services and placed the responsibility to enquire about the pregnancy status on the referrer and on the practitioner who accepts the referral.

A sample of referrals were reviewed and the process for making the pregnancy status enquiry was described by staff to the inspector in both settings visited. In the majority of referrals viewed, pregnancy was ruled out by the referrer or practitioner, however, in one record viewed in the DXA service, the pregnancy enquiry was not evident. The inspector found that the process for enquiring and recording the pregnancy status of patients should be reviewed and strengthened to comply with this regulation.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector reviewed the processes in place for the management of events involving or potentially involving accidental or unintended medical exposures and was satisfied that an appropriate system was implemented at St Camillus hospital. A summary report for radiation incidents and near misses was provided and showed that there was zero incidents reported between March 2023 and March 2024. While meeting the requirements of this regulation, the inspector noted that given the activity levels in the DXA service, there was scope to improve the identification and reporting of potential incidents in the future.

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	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for St Camillus Hospital OSV-0007340

Inspection ID: MON-0037598

Date of inspection: 10/04/2024

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 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <p>The St. Camillus's DRL report addressed the methodology for determining Local Facility DRLs, and the discrepancy with the National DRL due to the advanced technology and improved image quality. The report will be supplemented to record the techniques and technical parameters used for the procedures, confirm compliance with local clinical protocols, and to record that communication with the manufacturer confirmed the DXA scanner is operating within specification. Approval of the Local Facility DRL was recorded in the minutes of the Radiation Safety Committee, where it was agreed no actions were required. The MPE is satisfied that no further options are available to optimise DXA scans.</p>	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <p>The local Pregnancy Policy will be revised and in line with National Pregnancy Policy will remove DXA as an examination for which pregnancy is queried for radiological safety reasons.</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 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	30/06/2024
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	30/06/2024

Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	30/06/2024
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