



**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:	Tallaght University Hospital
Undertaking Name:	Tallaght University Hospital
Address of Ionising Radiation Installation:	Tallaght, Dublin 24
Type of inspection:	Announced
Date of inspection:	28 June 2023
Medical Radiological Installation Service ID:	OSV-0007409
Fieldwork ID:	MON-0037849

## About the medical radiological installation:

Tallaght University Hospital is a teaching hospital affiliated to Trinity College Dublin. Located in south-west Dublin, the hospital is a provider of local, regional, supra-regional and national medical and surgical speciality departments catering for a direct catchment area of 110,000 and broader catchment area of 697,000. Tallaght University Hospital has an adult Emergency Department and is a National Urology Centre, a Regional Dialysis Centre and a Regional Orthopaedic Trauma Centre. The clinical referral base includes General Surgery, Colorectal Surgery, Hepatobiliary and Pancreatic Surgery, Vascular Surgery, Urology, Orthopaedics, Gynaecology, ENT, Gastroenterology, Hepatology, Neurology, Endocrinology, Rheumatology, Medical Oncology and Haematology, Radiation Oncology, Cardiology, Respiratory Medicine and Emergency Department.

Diagnostic facilities include two magnetic resonance imaging (MRI) scanners, three computed tomography (CT) scanners, two single-photon emission computed tomography (SPECT) CT gamma cameras, three ultrasound (US) rooms, a fluoroscopy suite, and an interventional radiology (IR) suite. The IR suite provides urologic, gynaecologic, vascular and oncologic interventions under ultrasound, CT and fluoroscopic guidance. Other subspecialties include musculoskeletal ultrasound and interventions, cardiac CT and MRI, neuroradiology, gastrointestinal and genitourinary including women's imaging and prostate imaging with fused MRI/US transrectal biopsy and CT colonography. The radiology department staff includes consultant radiologists, radiographers, radiology specialist registrars (SPRs), nursing staff, radiography department assistants (RDAs), health care assistants (HCAs) and clerical administrative staff. The Medical Physics Department are also on-site within the Radiology Department.

## 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 28 June 2023	09:00hrs to 14:50hrs	Kirsten O'Brien	Lead
Wednesday 28 June 2023	09:00hrs to 14:50hrs	Lee O'Hora	Support

## Governance and management arrangements for medical exposures

An inspection of Tallaght University Hospital was carried out on the 28 June 2023 by inspectors to assess compliance against the regulations. As part of this inspection, inspectors visited the radiology department including the computed tomography (CT) and nuclear medicine areas.

On the day of inspection, local governance and management arrangements were found to be in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital. However, while these governance and management arrangements were communicated to inspectors on the day of inspection by staff and management, documentation reviewed as part of the inspection did not fully reflect what was described. To ensure clarity these overarching responsibilities for the radiation protection of service users should be clearly documented and align with the arrangements in place.

Inspectors found that medical exposures were only carried out when referred by a person entitled to refer as per the regulations. Documentation reviewed described the different categories of referrers from which referrals for medical radiological procedures were accepted. Inspectors spoke with staff and reviewed a sample of referrals and other records and were satisfied from the evidence found that only those entitled to act as practitioners took clinical responsibility for individual medical exposures. However, documentation reviewed did not clearly specify who could take clinical responsibility for medical exposures to ionising radiation at Tallaght University Hospital. In particular, who could act as a practitioner in the hospital for the different aspects of clinical responsibility was not documented.

Improvements in the arrangements to ensure the continuity of medical physics expertise was found by inspectors since the last inspection. Medical physics experts (MPEs) were found to be appropriately involved in line with the radiological risk for the medical radiological procedures conducted at the hospital. Inspectors noted that the hospital had recently employed and had begun training medical physicists to facilitate MPE registration, once completed. This was seen as a positive measure to ensure the continuity of MPE involvement at the hospital in the future.

Overall inspectors were satisfied that governance and management arrangements were in place to ensure the safe delivery of medical radiological procedures at Tallaght University Hospital. However, the hospital could benefit from strengthening these arrangements by reviewing and updating documentation to ensure the clear allocation of responsibility for the radiation protection of service users.

## Regulation 4: Referrers

Inspectors reviewed a sample of referrals and spoke with staff and found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at Tallaght University Hospital.

Judgment: Compliant

### Regulation 5: Practitioners

On the day of inspection only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

### Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at Tallaght University Hospital were reviewed by inspectors. Documentation, including local policies, procedures, guidelines and records and an organisational chart, was reviewed in advance of the inspection. Inspectors also spoke with staff and management at the hospital over the course of the day to confirm the allocation of responsibilities for the radiation protection of service users at Tallaght University Hospital.

On the day of inspection, an overarching allocation of responsibility through the hospital's governance and management structure was found to be in place and was communicated to inspectors. However, the radiation protection structure described had additional oversight mechanisms in place that were not included on the organogram (diagram of the organisation's structure) or in the other documents provided to inspectors.

Inspectors found that the Clinical Director of Radiology was the designated manager and the person responsible for governance and management of the radiation protection of service users undergoing medical radiological procedures at the hospital. The designated manager was the chair of the RSC which was the main forum of oversight for radiation protection at the hospital and met twice a year. A report from the Radiation Safety Committee (RSC) was presented to the Quality Safety Risk Management (QSRM) committee annually by the MPE. Representatives from the QSRM, including the chair of the QSRM, were members of the RSC. The QSRM committee reported up into a sub-committee of the Hospital Board. A Radiation Incident Group had also been recently established which reported into the RSC.

Additional oversight mechanisms were also found to be in place on the day of

inspection. These included the Deputy Chief Executive Officer (CEO) Radiology Directorate Meeting which met monthly. This monthly meeting provided oversight for the hospital's day-to-day operations involving medical exposure to ionising radiation and reported to the CEO and Executive Management Team (EMT). An internal Radiology Directorate meeting was also held monthly which included radiography, nursing and clerical management and the Clinical Director of Radiology. The Medical Physics Department had also relocated to the Radiology Directorate since the last inspection and now had a reporting structure through the Clinical Director of Radiology. The Radiography Services Manager (RSM) also reported through the Clinical Director of Radiology. In turn the Clinical Director of Radiology had monthly meetings with the CEO.

Inspectors also spoke with staff about their day-to-day roles and responsibilities relating to the conduct of medical exposures to ionising radiation. Management at the hospital informed inspectors that those recognised as practitioners who were allocated aspects of clinical responsibility for individual patient exposures included radiologists, radiographers, cardiologists and gastroenterologists. However, this allocation was not clearly documented in the policies and procedures reviewed by inspectors. In particular, who was entitled to act as a practitioner for medical exposures at Tallaght University Hospital was not clearly indicated in any of the documents reviewed. It is important that policies, procedures and guidelines clearly indicate the allocation of responsibility for radiation protection of service users at Tallaght University Hospital. Similarly, this documentation should be made specific to practices at Tallaght University Hospital and should be updated to clearly explain the allocation of the roles and responsibilities of a practitioner for the different aspects of clinical responsibility. Inspectors did note, however, that the scope of the different categories of referrers (internal and external), and what each category could refer for, was included in documentation reviewed.

Overall, while inspectors found evidence that a governance and management structure were in place to oversee the delivery of medical radiological procedures at the hospital, the documentation of these arrangements should be reviewed and updated to ensure clarity of the reporting structures and responsibility for the radiation protection of service users. Similarly, the allocation of day-to-day responsibilities of practitioners should also be reviewed to ensure that these are clearly allocated and understood by all staff.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

From speaking with staff and management, and reviewing documents and other records, the inspectors were satisfied that only those entitled to act as practitioners took clinical responsibility for medical radiological procedures at Tallaght University Hospital. Practitioners and MPEs were also found to be involved in the optimisation process for medical exposure to ionising radiation. However, while documentation

and records reviewed indicated that the referrer was involved in the justification process, inspectors found that a record of justification by a practitioner was not present for three referrals reviewed on the day of inspection. While staff spoken with informed inspectors that radiographers review and justify these referrals before they are carried out, in order to achieve full compliance with this regulation, management should review the processes and systems in place to assure themselves that a person entitled to act as a practitioner is involved in the individual justification of all medical exposures.

Additionally, the practical aspects of medical radiological procedures were only carried out by appropriate individuals as defined in the regulations. As an additional assurance staff and management at Tallaght University Hospital informed inspectors that they had also retained the presence of radiographers and or radiologists for all medical radiological procedures carried out at the hospital. In the absence of training requirements being prescribed for some of the personnel involved in medical exposure to ionising radiation, as per Regulation 22, this was viewed as good practice to ensure the radiation protection of service users.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that sufficient measures were in place on the day of inspection to ensure the continuity of medical physics expertise at Tallaght University Hospital. Inspectors were informed about recent changes which had been put in place to support compliance with this regulation. These included moving the medical physics team to within the Radiology Directorate and the recruitment of new physics staff who were training to become MPEs.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users. For example, MPEs were found to take responsibility for dosimetry and contributed to quality assurance and acceptance testing at the hospital. Additionally, inspectors found evidence that MPEs contributed to optimisation, including the establishment of DRLs and the evaluation of doses delivered to service users at Tallaght University Hospital.

Judgment: Compliant



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

On the day of inspection, mechanisms were in place to facilitate the involvement of MPEs in medical radiological procedures in line with the level of radiological risk at Tallaght University Hospital.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Tallaght University Hospital. Leaflets and posters containing information about the benefits and risks associated with different medical exposures were also observed in waiting rooms.

All referrals reviewed were in writing, stated the reason for the request and were accompanied by medical data as required. However, while staff informed inspectors that all medical exposures were justified in advance, written records of justification in advance of medical radiological procedures were not available for all medical radiological procedures reviewed on the day of inspection. Inspectors also found some ambiguity between documentation and practice regarding the allocation of responsibility of a practitioner for justifying CT referrals which had resulted in the absence of a record of justification in advance by a practitioner for some procedures.

Inspectors found that radiographers at the hospital inquired about, and recorded in writing, the pregnancy or breastfeeding status of individuals prior to the conduct of medical exposures, where appropriate. Diagnostic reference levels (DRLs) had been established and were reviewed for medical radiological procedures at the hospital. Inspectors also found that the hospital had implemented a quality assurance programme for medical radiological equipment and were assured that all medical radiological equipment was kept under strict surveillance.

Inspectors found evidence that a mechanism to record events involving, or potentially involving, accidental and unintended exposures to ionising radiation was in place. Since the last inspection inspectors noted that arrangements to ensure that HIQA was notified of the occurrence of a significant event within the appropriate time frames had been implemented.

Overall, notwithstanding the areas identified on the day of inspection which needed to be addressed for full compliance, inspectors were satisfied that Tallaght University Hospital had systems in place for the safe delivery of medical exposures.

## Regulation 8: Justification of medical exposures

All records of referrals for medical exposures reviewed by inspectors 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. Inspectors observed specific posters for each area, for example CT, and leaflets in each waiting area which provided information about the benefits and risks of medical radiological procedures. In some areas, inspectors observed that pictures of the equipment in the room were also included on the posters to provide a visual aid for patients about the procedure that was being carried out and this was identified as an example of good practice.

Documentation reviewed by inspectors in advance of the inspection indicated that radiologists or cardiologists were allocated responsibility for justifying all CT procedures in advance. On the day of inspection, inspectors spoke with practitioners who also explained how medical exposures are justified in advance of each medical exposure. However, inspectors found that a record of justification by a practitioner was not available for all medical radiological procedures reviewed over the course of the inspection. In particular, in the CT department, three referrals for imaging from one cohort of patients were reviewed and did not have a record of justification in advance by a person entitled to act as a practitioner. Inspectors were informed that this cohort of referrals were justified by radiographers before the CT scan was carried out. However, this justification was not recorded and did not align with the documented process as outlined in the hospital's policies.

In order to achieve compliance with this regulation, management at the hospital should have appropriate systems in place to ensure that a record of justification in advance by a practitioner is available for all individual medical exposures and the allocation of clinical responsibility for justification should be clearly documented to ensure clarity for staff.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

DRLs for radiodiagnostic examinations were found to have been established and reviewed, where appropriate, at Tallaght University Hospital. Inspectors also spoke with staff around the process for further investigation and corrective actions where a local facility DRL was found to exceed a national DRL and were satisfied that measures were in place to support the conduct of this process.

Judgment: Compliant

## Regulation 14: Equipment

Inspectors were satisfied that appropriate quality assurance programmes, which included an assessment of dose, were in place to ensure that medical radiological equipment at Tallaght University Hospital was kept under strict surveillance. An up-to-date inventory was provided to inspectors, and documentation reviewed on the day of inspection demonstrated that regular quality control and acceptance testing before first clinical use was performed.

Inspectors noted that a prospective medical radiological equipment replacement programme for medical radiological equipment was in place where equipment was identified for replacement for a three year period. Staff also informed inspectors that an enhanced preventative maintenance schedule had been implemented for one piece of equipment which was past its nominal replacement date and this was seen as an example of good practice to ensure compliance with this regulation.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in public places such as changing rooms and waiting areas. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy or breastfeeding status where relevant in line with the regulations. Inspectors reviewed a sample of records for medical exposures and found that an inquiry regarding the pregnancy and breastfeeding status of the patient had taken place, where required, and was recorded in writing.

Judgment: Compliant

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

Inspectors spoke with staff and management, and reviewed documentation and other records and were assured that arrangements were in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. Similarly, inspectors found that improvements had been implemented at the hospital since the last inspection and were now satisfied that the hospital had adequate arrangements in place to ensure that HIQA was notified of the occurrence of a significant event within the required time frame.

Staff who spoke with inspectors identified that the analysis of non-significant events involving, or potentially involving, accidental or unintended medical exposures, offered an opportunity for learning. Staff also provided an example of how trending and review following a potential (near-miss) radiation incident had assisted in the identification and implementation of appropriate measures to minimise the probability of occurrence of a similar incident at the hospital. Inspectors noted however, that as an area for improvement, given the relatively low number of potential accidental or unintended exposures recorded, efforts to promote reporting of potential accidental or unintended exposures should be considered.

A Radiation Incident Group had also been established to investigate and oversee the management of radiation incidents at Tallaght University Hospital. Inspectors were informed that the hospital's Risk Manager had provided resources and attended this group as required. This multidisciplinary approach and support for radiation incident management was identified as a positive measure to ensure on-going compliance with the requirements of this regulation.

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	Substantially Compliant
Regulation 10: Responsibilities	Substantially 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	Substantially 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

# Compliance Plan for Tallaght University Hospital OSV-0007409

Inspection ID: MON-0037849

Date of inspection: 28/06/2023

## Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

## Section 1

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

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The RSM2 at Tallaght University Hospital (TUH) will update the radiology Organogram to reflect the reporting structures already in place such as the Radiation Incident Group (RIG), DCEO Directorate Meeting, Radiology Directorate Meeting, reporting structure to Quality Safety and Risk Management (QSRM) Directorate &amp; Clinical Director meetings with the CEO. Action to be complete by 6th September 2023.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: All CT referrals will be justified (vetted) prior to scheduling by a Consultant Radiologist or Radiology Specialist Registrar. This change has been implemented for all CT referrals since 1st August 2023. We have a plan in place for the Radiology SPR to justify the referrals already on NIMIS. This will be completed prior to the patient's individual appointment date. Action owner, Radiology Clinical Director</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p>	

The RSM3 will update PPPGs to specify those recognised as Practitioners and their responsibilities. We will complete this when the existing PPPGs are due for update & include it in all new PPPGs going forward.



## Section 2:

### Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	06/09/2023
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	01/08/2023

	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.	Not Compliant	Orange	01/08/2023
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	01/08/2023