



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	South Tipperary University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Clonmel, Tipperary
Type of inspection:	Announced
Date of inspection:	13 April 2023
Medical Radiological Installation Service ID:	OSV-0007374
Fieldwork ID:	MON-0039406

## About the medical radiological installation:

South Tipperary University Hospital (TippUH), Clonmel, Co. Tipperary, is a Model 3 Acute Hospital. The hospital is part of the South/South West Hospital Group and is governed by the Executive Management Team. The organisation's clinical and corporate functions is the delivery of safe, efficient, effective, high-quality patient care. TippUH has bi-directional patient flow with the Model 4 hospitals in the region, University Hospital Waterford, and Cork University Hospital and with other specialist centres in Dublin. It provides Shared Care Programmes for those attending Paediatrics and Maternity Services outside the region. Mental Health services are linked with St. Luke's Hospital Kilkenny (IEHG) and University Hospital Limerick (Ennis, Co. Clare). TippUH is also a teaching hospital with academic partnership with University College Cork (UCC), University of Limerick (UL), University College Dublin, (UCD), and Waterford Institute of Technology (WIT). The hospital has 206 inpatient beds, 14 day beds and provides acute hospital services to the geographically wide catchment area of Tipperary, West Waterford, and varying areas of North Cork. The catchment population for the hospital is up to 134,000 people. The Radiology Department provides diagnostic services across a spectrum of acute, sub-acute and outpatient services. The department is dedicated to excellence in clinical care and comprises staff with expertise and experience across a range of specialities.

The Radiology Department comprises of two radiology departments, one in TippUH and a smaller supporting radiology department in Our Lady's Hospital Campus (OLC) in Cashel. The Radiology Department at TippUH has three general X-ray rooms; two X-ray rooms have been upgraded to a fully digital system while the other remaining system is being upgraded in 2023. The Department has a digital fluoroscopy unit; three digital mobile units; three ultrasound scanners and a CT scanner. In 2022 a new MRI Scanner was installed and became operational in September 2022. The department operates from 08:00 to 17:00 hours Monday to Friday and provides a 24/7 Radiographer on-call service. There are two Radiographers on duty at night in the hospital, providing urgent access to X-ray and CT 24/7. TippUH uses NIMIS (National Integrated Medical Information System), which provides electronic radiology systems for 35 Irish hospitals. NIMIS ensures that radiological services are

'filmless' and enables secure and rapid movement of patient image data throughout the health service.

## 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
Thursday 13 April 2023	09:35hrs to 14:50hrs	Noelle Neville	Lead
Thursday 13 April 2023	09:35hrs to 14:50hrs	Margaret Keaveney	Support

## Governance and management arrangements for medical exposures

An inspection was carried out at South Tipperary University Hospital on 13 April 2023 by inspectors to assess the facility's compliance with the regulations. As part of this inspection, inspectors visited clinical areas, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking at South Tipperary University Hospital demonstrated compliance with Regulations 4, 5, 6, 8, 10, 11, 14, 16, 17, 19, 20 and 21 and substantial compliance with Regulation 13.

The undertaking at South Tipperary University Hospital had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures. In addition, inspectors noted involvement in, and oversight of, radiation protection by the hospital's medical physics expert (MPE) across a range of responsibilities.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at South Tipperary University Hospital and clear and effective management structures were in place to ensure the radiation protection of service users.

### Regulation 4: Referrers

The *Radiation Safety Procedures* at South Tipperary University Hospital, the most recent document version of which was issued in January 2023, clearly outlined who can refer for medical radiological procedures at the facility. Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

### Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at South Tipperary University Hospital.

Judgment: Compliant

### Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms and spoke with staff and management in relation to governance arrangements in place at South Tipperary University Hospital.

The Health Service Executive (HSE) was the undertaking for South Tipperary University Hospital and the hospital had a radiation safety committee (RSC). Inspectors reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership including the general manager who was also the designated manager, the MPE, a radiologist, radiographic service manager and quality and risk managers. The committee was incorporated into local governance structures, reporting to the Quality, Risk and Patient Safety Committee which in turn reported to the Executive Management Team (EMT). The EMT reported to the general manager of the hospital who in turn reported to the South/South West Hospital Group. A radiation protection unit (RPU) was also in place at the hospital, inspectors were informed that this committee managed day-to-day operational issues relating to radiation protection and its membership included the MPE, radiographic service manager and radiation protection officer.

Overall, inspectors were satisfied that the undertaking at South Tipperary University Hospital had clear and effective governance and management structures in place to ensure the radiation protection of service users.

Judgment: Compliant

### Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at South Tipperary University Hospital by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from discussions with staff and a review of documentation that the undertaking at South Tipperary University Hospital had arrangements in place to ensure access to and continuity of MPE services as required by Regulation 19.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at South Tipperary University Hospital and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors noted that the MPE was involved across a range of responsibilities outlined in Regulation 20(2). The MPE was responsible for dosimetry and gave advice on medical radiological equipment. Records reviewed by inspectors demonstrated that the MPE had contributed to quality assurance and acceptance testing of medical radiological equipment and was involved in optimisation including review and sign-off of facility DRLs. The MPE also provided advice and dose calculations for radiation incidents and attended RSC and RPU meetings.

In addition, the MPE had been assigned the role of radiation protection advisor (RPA) at the hospital, therefore satisfying the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with the MPE and staff, inspectors were satisfied that the level of MPE involvement at South Tipperary University Hospital was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

## Safe Delivery of Medical Exposures



Inspectors visited clinical areas at South Tipperary University Hospital, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the facility.

Since the previous inspection, inspectors found that improvements had been made in relation to recording of justification in advance for each medical exposure conducted at the hospital. Evidence of justification in advance was now retained in the hospital's radiology information system, therefore meeting the requirements of Regulations 8(8) and 8(15). However, the undertaking had not made progress in relation to meeting the requirements of Regulation 13(2) since the previous inspection. Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors found that while interim measures had been provided by the HSE through the National Integrated Medical Imaging System (NIMIS) to facilitate compliance with this regulation, these interim measures had not been implemented by practitioners at the hospital. The HSE, as undertaking for the hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Despite the issue relating to Regulation 13(2), overall inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

### Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of information leaflets and posters in all waiting areas of the facility.

The *Radiation Safety Procedures* at South Tipperary University Hospital outlined the justification process and who was responsible for carrying out this process at the hospital. Since the previous inspection, inspectors found that improvements had been made in relation to recording of justification in advance for each medical exposure conducted at the hospital. Evidence of justification in advance was now retained in the hospital's radiology information system, therefore meeting the requirements of Regulations 8(8) and 8(15).

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

The undertaking at South Tipperary University Hospital had a document titled *Radiology Dose Audit*, the latest version of which was issued in May 2022. This document set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using local DRLs. Inspectors observed that DRLs had been established, regularly reviewed and used at South Tipperary University Hospital and were compared to national DRLs. DRL charts were displayed in each clinical area and staff spoken with demonstrated an awareness of how to use DRLs when carrying out medical exposures to ionising radiation.

Judgment: Compliant

## Regulation 13: Procedures

Inspectors noted that written protocols were available for each standard radiological procedure provided at South Tipperary University Hospital as required by Regulation 13(1). The hospital had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3). In addition, the hospital had completed a range of clinical audit including audit of the justification process, the patient identification process and adherence to the pregnancy policy. Inspectors noted that the hospital viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service users.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors found that while interim measures had been provided by the HSE through the National Integrated Medical Imaging System (NIMIS) to facilitate compliance with this regulation, these interim measures had not been implemented by practitioners at the hospital. Some records indicated where the dose could be found if required and others reviewed did not include any reference to the patient dose, therefore not meeting the requirements of Regulation 13(2). The HSE, as undertaking for the hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Judgment: Substantially Compliant

## Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at South

Tipperary University Hospital as required by Regulation 14(1). The hospital had two policies, *Procedures for QA and Acceptance Testing of X-ray Equipment* and *Quality Assurance Checks*, the latest versions of which were issued in December 2022. These policies outlined staff responsibilities in relation to quality assurance and the quality assurance programmes in place at the hospital. Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). Inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

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

The *Radiation Safety Procedures* at South Tipperary University Hospital included a *Policy on Protection of Patients of Reproductive Capacity*. This policy outlined specific staff responsibilities, for example, the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age.

Inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

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

Inspectors were satisfied from discussions with staff and management and a review of documents, that the undertaking at South Tipperary University Hospital had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The incident management process at the hospital was outlined in the *Radiation Safety Procedures* and also included information on the requirement to notify HIQA of certain reportable incidents. Inspectors noted that two incidents had been reported

to HIQA since the commencement of the regulations in 2019.

While the undertaking at South Tipperary University Hospital demonstrated compliance with this regulation, inspectors determined that there was potential scope for improvement in relation to the identification and reporting of potential incidents, analysis and learning in the context of the relatively high number of procedures taking place at the hospital each year and the low levels of incidents and near misses being reported.

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 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 South Tipperary University Hospital OSV-0007374

Inspection ID: MON-0039406

Date of inspection: 13/04/2023

## 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 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:            Letter to be sent from the General Manager of Tipperary University Hospital to HSE National Radiation Protection Office asking for a computer based technical solution which will provide the actual patient radiation dose for particular procedure using automated information transfer be expedited.</p> <p>This issue has been escalated to the Tipperary University Hospital Quality Patient Safety Committee and to the South /South West Hospital Group Quality Patient Safety Directorate during performance review to look at all possible solutions</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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	30/12/2023