



## 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 General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Clonmel, Tipperary
Type of inspection:	Announced
Date of inspection:	29 January 2020
Medical Radiological Installation Service ID:	OSV-0007374
Fieldwork ID:	MON-0028243

## About the medical radiological installation:

The Radiology Department in South Tipperary General Hospital (STGH) provides diagnostic services across a spectrum of acute, sub-acute and outpatient services. The department comprises staff with expertise and experience across a range of specialties. The department has academic links with UCC and UCD and supports placement for undergraduate students and Post Graduate Masters. The Radiology Department in South Tipperary SSWHG comprises of two Radiology Departments; one in STGH and a smaller supporting Radiology Department in Our Lady's Hospital Campus (OLC) in Cashel.

The Radiology Department at STGH has three general X-ray rooms. One X-ray room was upgraded in 2016 to a digital system, the second (whilst retaining the original X-ray equipment for image acquisition) has just recently been upgraded with a Digital radiography retrofit and the third is a conventional X-ray system, approximately 14 years old. The department has a fluoroscopy unit; three mobile X-ray units and a computed tomography (CT) scanner. MRI scans are provided by a private operator in a mobile MRI unit adjacent to the hospital. The department operates from 08:45 to 17:00 hours Monday to Friday and provides a 24/7 radiographer on-call service. Out of hours service for general X-ray is provided by is one radiographer on site in the hospital and a second radiographer is on-call from home, to provide CT cover. As a model 3 hospital with 2.5 whole time equivalent radiologists, the majority of out of hours radiologist on-call service from Friday evening to Monday morning is outsourced. The outsourced service provides for justification and reporting of CT examinations and limited Ultrasound examinations.

The Radiology Department at Our Lady's Hospital Campus in Cashel has a DXA scanner, an ultrasound machine and a DR X-ray system. This Radiology Department is operational two days per week when staff are available.

## 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 29 January 2020	10:00hrs to 16:00hrs	Noelle Neville	Lead
Wednesday 29 January 2020	10:00hrs to 16:00hrs	Kay Sugrue	Support

## Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership, governance and management arrangements in place at the hospital with systems and processes detailing a clear allocation of responsibility for the protection of service users. The General Manager was a member of the hospital's Radiation Safety Committee. This 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 reported to the South/ South West Hospital Group.

Inspectors found that the commitment of staff to both patient and radiation safety was strongly evident within the Radiology Department. This was despite the staffing challenges outlined to inspectors and in the context of a relatively busy department with over 72,000 procedures carried out each year.

From the records reviewed and discussions with management and staff, inspectors were 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. Inspectors were also assured that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and medical physics expert (MPE) were involved in the optimisation process.

An area of potential improvement was required in relation to the alignment of the hospital's radiation safety procedures to the practices taking place at the hospital, specifically in relation to Regulation 4 and Regulation 5. Inspectors found that the procedures should be updated to ensure that they are reflective of day-to-day practice and ensure clarity regarding roles and responsibilities of staff within the hospital.

MPE involvement in medical radiological practices was evident, with the level of involvement in line with the services provided at the hospital. However, staff and management stated that on-site MPE presence would be of benefit to the hospital, particularly in relation to optimisation, equipment and training, given the high activity level of the Radiology Department including over 7,000 computed tomography (CT) procedures carried out each year. Inspectors were also informed that there were contingency arrangements in place for the continuity of MPE expertise should the need arise.

Overall, inspectors were assured of the governance and management arrangements in place at the hospital to oversee patient protection.

## Regulation 4: Referrers

The hospital's radiation safety procedures reviewed by inspectors stated that medical radiological procedures may only be carried out on the basis of a referral from a referrer. On the day of inspection, referrals for medical radiological procedures were accepted from registered medical practitioners and inspectors were also informed that radiographers were entitled to refer for supplementary views within medical exposures, where necessary. Referrals were also accepted from recognised advanced nurse practitioners. Inspectors spoke with staff who demonstrated a clear understanding of the referral process. The hospital received referrals in electronic and hard copy format from internal and external sources. A sample of referrals viewed by inspectors were in line with the regulations and the referrer was consistently identifiable.

While the hospital was compliant with this regulation, inspectors found that the hospital's radiation safety procedures should be reviewed and updated to definitively identify those that can act as a referrer within the hospital.

Judgment: Compliant

## Regulation 5: Practitioners

Documentation viewed by inspectors stated that medical exposures may only take place under the clinical responsibility of a practitioner. Inspectors reviewed a sample of records in relation to medical exposures on the day of inspection and found that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures as per the regulations.

While the hospital was compliant with this regulation, inspectors found that the hospital's radiation safety procedures should explicitly define who can act as a practitioner within the hospital.

Judgment: Compliant

## Regulation 6: Undertaking

The hospital had a clear allocation of responsibilities for the radiation protection of service users undergoing medical exposure to ionising radiation. The lines of governance and clinical oversight were communicated to inspectors by management and other staff during the inspection. In addition, documentation reviewed, including a hospital organogram, outlined the reporting structures in place within the

hospital for radiation safety.

The General Manager was a member of the hospital's Radiation Safety Committee. This 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 reported to the South/South West Hospital Group.

Judgment: Compliant

### Regulation 10: Responsibilities

Systems and processes were in place in the hospital to ensure that all medical exposures took place under the clinical responsibility of a practitioner. Inspectors noted that the practitioner and MPE were involved in the optimisation process and only those recognised as practitioners conducted medical exposures at the hospital.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

A contractual arrangement was in place to provide MPE services to the hospital by an off-site MPE. The MPE stated that contingency arrangements were in place to access MPE cover from another hospital should the need arise. In addition, the MPE was supported by a physicist to carry out quality assurance of equipment at the hospital.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Documentation reviewed by inspectors and discussions with management and staff indicated that the MPE had contributed to aspects of this regulation relevant to the medical radiological practice including the optimisation process, diagnostic reference levels (DRLs), quality assurance of medical radiological equipment and training of staff in relevant aspects of radiation protection. The hospital's radiation safety procedures outlined that the MPE also carried out the separate role of radiation protection adviser within the hospital.

Judgment: Compliant

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

MPE involvement in medical radiological practices was evident, with the level of involvement in line with the services provided at the hospital. However, inspectors were informed through discussions with staff and management that on-site MPE presence would be of benefit to the hospital, particularly in relation to optimisation, equipment and training, given the high activity level of the Radiology Department including over 7,000 computed tomography (CT) procedures carried out each year. Although, this was seen as an area for improvement by hospital staff and inspectors, inspectors were satisfied from documentation reviewed and discussions with management and staff that the MPE was available for consultation and advice on matters relating to radiation protection concerning medical exposure.

Judgment: Compliant

### Safe Delivery of Medical Exposures

Inspectors found that the hospital had assurances in place to ensure that effective and safe medical exposures were provided to service users in compliance with the regulations. This included evidence of the use of DRLs, written protocols for each type of procedure carried out and posters relating to pregnancy and the risks associated with radiation exposure in the Radiology Department. An up-to-date inventory and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place.

Areas of good practice were identified by inspectors including the conduct of clinical audits at the hospital including computed tomography pulmonary angiogram (CTPA) requests, last menstrual period (LMP) policy, abdominal requests from the Accident and Emergency Department and computed tomography (CT) helical brain audit lens exposure. Staff outlined that due to limitations of staff availability, audits were focused on small but high impact areas, with the aim of making meaningful improvements to practice.

Inspectors identified some areas requiring improvement in relation to Regulation 8 and Regulation 13 which were accepted and acknowledged by management and staff. Inspectors reviewed a sample of records and spoke with staff and found that justification in advance was not documented for all procedures carried out at the hospital. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

In addition, inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. In respect of Regulation 13(2), the hospital should ensure that information relating to patient exposure, forms part of the report of the medical radiological procedure.

Overall, inspectors were satisfied that the areas noted to require improvement did not represent a safety concern to service users.

## Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures which took place in the hospital was available for review on the hospital's radiology information system.

Information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure on posters and information leaflets in the waiting area of the Radiology Department.

The hospital's radiation safety procedures stated that medical exposures should not be carried out unless clinically justified and also outlined shared responsibility amongst key personnel for adherence to the justification procedures in place. Inspectors found that while justification was conducted by appropriate individuals as defined in Regulation 5, documentation should be updated to reflect day-to-day practice at the hospital.

Inspectors spoke with staff responsible for the justification of medical exposures, who described how each medical exposure was justified. Inspectors reviewed a sample of records and spoke with staff and found that while justification was conducted by appropriate individuals as defined by Regulation 5, the record of justification was not documented for all procedures carried out at the hospital. As a result, the hospital was not in full compliance with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that all medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

Judgment: Substantially Compliant

## Regulation 11: Diagnostic reference levels

The hospital's radiation safety procedures provided an outline of the process for the establishment and review of DRLs. Inspectors were informed that DRLs for radiodiagnostic examinations were established, regularly reviewed and used with reference to national DRLs. DRLs relevant to the medical exposures carried out were displayed in the Radiology Department.

Inspectors were informed that dose audits were conducted on a regular basis, compared to DRLs used and the hospital and the majority were found to be consistently below national DRLs. This provided additional assurance to the hospital in relation to the safe delivery of medical exposures.

Judgment: Compliant

## Regulation 13: Procedures

Written protocols were established for each type of standard medical radiological procedure. These protocols were available in both electronic and hard copy and staff demonstrated an awareness of and ability to access these to inspectors. Referral guidelines for medical imaging taking into account the radiation doses, were available in electronic and hard copy in the Radiology Department and staff demonstrated an awareness of their availability.

Inspectors were informed that a number of clinical audits were conducted at the hospital and viewed a sample of these including an audit of computed tomography pulmonary angiogram (CTPA) requests, last menstrual period (LMP) policy, abdominal requests from the Accident and Emergency Department and computed tomography (CT) helical brain audit lens exposure. Staff outlined that due to limitations of staff availability, audits were focused on small but high impact areas with the aim of making meaningful improvements to practice.

Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. As a result, the hospital was not fully compliant with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

Judgment: Substantially Compliant

## Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted the equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by inspectors showed that appropriate quality assurance (QA) programmes, including regular performance testing had been implemented and maintained for each piece of medical radiological equipment on the inventory.

Inspectors viewed records demonstrating that a number of pieces of equipment at the hospital had exceeded their nominal replacement age. However, while these pieces of equipment had passed their nominal replacement dates, inspectors were informed that they were approved for clinical use and had passed all necessary QA testing. Inspectors were also informed that a system was in place for reporting and recording equipment faults and processes were in place to take equipment out of service where it was deemed necessary for patient safety.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors found from the evidence reviewed that the hospital was meeting the requirements of this regulation. The hospital had a policy on the protection of patients of reproductive capacity. This policy outlined the process for determining pregnancy status and the process to be followed if pregnancy cannot be ruled out. Staff demonstrated a good knowledge and understanding of the hospital's pregnancy policy. Inspectors viewed a sample of written records documenting pregnancy inquiries made by staff.

The hospital took measures to increase the awareness of people to whom this regulation applies. Inspectors observed posters in a variety of languages alerting patients to inform staff of their pregnancy status in the waiting area and corridors of the Radiology Department.

Judgment: Compliant

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

The hospital had taken reasonable measures to minimise the risk of accidental or unintended exposures to people using the service. This was demonstrated through the hospital's procedures, surveillance of equipment and quality assurance and audit programmes. The hospital's Radiation Safety Committee standing agenda included a

review of incident and accident reports. While the hospital did not have cause to notify the Authority of the occurrence of any incident, management and staff demonstrated a clear knowledge of the process to be followed should the need arise.

Inspectors were satisfied that the hospital had an appropriate system for the record keeping and analysis of incidents and staff demonstrated a good knowledge and understanding of the incident reporting process within the hospital. However, due to the lack of incidents or potential incidents reported at the hospital in relation to radiation safety, it was not possible to carry out trending. In addition, staff described situations to inspectors that could be considered as potential incidents; however, these were not recorded using the hospitals incident reporting system. As a result, inspectors identified incident and potential incident reporting as an area of improvement and learning for the hospital in the context of the large number of procedures taking place each year.

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	Substantially 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 General Hospital OSV-0007374

Inspection ID: MON-0028243

Date of inspection: 29/01/2020

## 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 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> <p>Justification is the process of weighing up the expected benefits of an exposure against the detriment of the associated radiation dose.</p> <p>Regulation 8(8) states that “an undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved”</p> <p>STGH will provide documented evidence to ensure compliance with justification of medical exposure which will include;</p> <ul style="list-style-type: none"> <li>• Checking patient I.D = name, DOB and address.</li> <li>• Clinical history - what is to be gained by carrying out the exposure, how will the outcome affect the patient management?</li> <li>• Characteristics of the individual involved - checking previous imaging, medical history, age, and body habitus.</li> <li>• Checking pregnancy status.</li> <li>• What other alternative imaging modalities are available that could answer the diagnostic question, Ultrasound, MRI?</li> </ul> <p>This will be evidenced on reviewing the patient’s record on NIMIS by March 1st 2020. This evidence will be held on a scanned document linked to patient’s record whilst awaiting response from Change Healthcare seeking electronic area for justification compliance.</p> <p>Time: March 1st 2020</p> <p>Following existing review process non justified X-ray examinations are documented through the cancelling order process on RIS. Comment is included by the Radiographer to state why the examination is not justified and that the referring doctor is informed.</p> <p>Time: In –situ</p>	

A cancellations log list is printed and monitored each day during office hours.

Time: In –situ.

Regulation 8(15) states that an undertaking shall retain records evidencing compliance with this regulation for a period of 5 years from the date of the medical exposure and shall provide such records to the authority on request.

The above records shall be maintained for a minimal of 5 years.

Time: In situ

Regulation 13: Procedures	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures: Regulation 13(2) states the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

STGH are consulting with digital x-ray manufacturers, working towards radiation dose availability on radiology report. Presently all radiation doses can be retrospectively reviewed on NIMIS on request- National project to assist with compliance for regulation 13

Time: April 1st 2021

Currently in situ the DRX Evolution rooms display the dose, this is transmitted to NIMIS with the patient images. This gives a dose value per projection. Difficulty for total calculation for clients that require multiple x-rays.

CT and fluoroscopy the total dose is transmitted to NIMIS with the patient images.

Time: insitu.

STGH use communication tools to include Posters and leaflets explaining radiation doses and related risks, frequently asked questions about radiation and radiation safety which are available in the waiting areas. E.g. MERU information on patient radiation dose posters.

Time: in situ

STGH justify all requests, keeping the ionising radiation dose as low as possible, audits and review diagnostic reference levels safe delivery of medical exposures.

Time: –in situ

## 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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	01/03/2020
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.	Substantially Compliant	Yellow	01/03/2020
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms	Substantially Compliant	Yellow	01/04/2021

	part of the report of the medical radiological procedure.			
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