



**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 Michael's Hospital
Undertaking Name:	St Michael's Hospital
Address of Ionising Radiation Installation:	Lower Georges' Street, Dun Laoghaire, Co. Dublin
Type of inspection:	Announced
Date of inspection:	12 April 2023
Medical Radiological Installation Service ID:	OSV-0007406
Fieldwork ID:	MON-0031220

## About the medical radiological installation:

St Michael's is an acute general hospital providing a range of specialised clinical services to the people of South Dublin and Wicklow. St Michael's Hospital is part of St Vincent's Healthcare Group (SVHG) with St Vincent's Private Hospital, under the governance of the Board of Directors. Each hospital has a separate management team and a Chief Executive Officer (CEO) who reports to the SVHG Director of Operations. St Michael's Hospital is an academic teaching hospital and shares resources and expertise with St Vincent's University Hospital (SVUH), Elm Park, Dublin. St Michael's Hospital is also a member of the Ireland East Hospital Group (IEHG). The department of radiology at St Michael's Hospital provides an ultrasound and radiography service to inpatients and outpatients attending the hospital, as well as to patients attending the emergency department. General, dental and dual-energy X-ray absorptiometry (DXA) services are provided within the radiology department, while mobile X-rays and theatre fluoroscopy are performed outside the radiology department. The radiology department is staffed by a radiology services manager, clinical specialists, senior and staff grade radiographers, a radiology assistant and a radiology aide. Consultant Radiologists (based in SVUH) rotate to St. Michael's Hospital. The department has 2 fixed systems, 1 OPG system, 2 mobile DR systems, theatre c-arm system and 2 ultrasound machines. The majority of radiography requests are for chest radiographs. Urology and orthopaedic procedures are carried out in theatre using a mobile c-arm. Cross-sectional imaging is provided at SVUH.

## 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 12 April 2023	09:30hrs to 15:00hrs	Lee O'Hora	Lead
Wednesday 12 April 2023	09:30hrs to 15:00hrs	Emma O'Brien	Support

## Governance and management arrangements for medical exposures

An inspection of St Michael's Hospital was carried out on the 12 April 2023 to assess compliance with the regulations. As part of this inspection inspectors reviewed documentation and visited the general radiography department which included general radiography (X-ray) and dual-energy X-ray absorptiometry (DXA) rooms and spoke with staff and management. A review of theatre fluoro-scopic procedures was also conducted during this inspection.

On this inspection, inspectors found effective governance and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures. Documentation viewed by inspectors in relation to governance arrangements demonstrated the reporting relationship from St Michael's Hospital to both the St Vincent's Healthcare Group (SVHG) and Ireland East Hospital Group (IEHG). Staff spoken with on the day of inspection clearly articulated that while the Chief Executive Officer (CEO) reported directly to the SVHG Director of Operations St Michael's Hospital operated as an individual legal entity within the SVHG and therefore, St Michael's Hospital was the undertaking with overall responsibility for the radiation protection of service users.

The CEO was both the undertaking representative and designated manager and therefore the person responsible for the radiation protection of service users at the hospital. The CEO was a member of the Radiation Safety Committee (RSC) which was the main forum for providing oversight of radiation protection at the hospital. The RSC and the Patient Safety Committee cross reported to each other and both reported directly to St Michael's Executive Council which reported upwards to the CEO.

Following a review of documents and records, and speaking with staff, inspectors were assured that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Inspectors were satisfied from evidence viewed that a referrer and practitioner were involved in the justification process within the radiology department. However, further assurance was required in relation to the justification process for medical exposures carried out in the theatre fluoroscopy service.

From the records viewed and discussions with staff, inspectors were satisfied that staff in St Michael's Hospital had ensured contingency arrangements for the continuity of Medical Physics Expert (MPE) expertise in the facility. Inspectors saw strong evidence of MPE involvement in all areas of MPE responsibilities as per the regulations and were therefore satisfied that the level of MPE involvement was proportionate to the level of radiological risk posed by the service.

Overall, inspectors found that there was a good level of compliance with regulations

at St Michael's Hospital and were satisfied that there was a clear and effective allocation of responsibility for the protection of service users attending for medical radiological procedure.

#### Regulation 4: Referrers

A sample of referrals were viewed by inspectors who also spoke with staff at the hospital. Inspectors were satisfied that only referrals for medical radiological procedures from individuals entitled to refer as per Regulation 4 were carried out at St Michael's Hospital.

In line with the regulations, radiographers and advanced nurse practitioners were also considered referrers in this hospital. The role and scope of practice for a nurse and a radiographer to act as referrers within the hospital was delineated in the document *Diagnostic Imaging Department Radiation Safety Procedures* which was reviewed by inspectors. Inspectors spoke with staff who demonstrated a clear understanding of the referral process which was consistent with hospital policies viewed.

Judgment: Compliant

#### Regulation 5: Practitioners

Following a review of the radiation safety procedure documentation, a sample of referrals for medical radiological procedures and from speaking with staff and management, inspectors were satisfied that St Michael's Hospital had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures. Professions considered as practitioners were limited to radiologists and radiographers at this hospital. Inspectors noted that this information was clearly and consistently documented, understood and articulated by all staff spoken with on the day.

Judgment: Compliant

#### Regulation 6: Undertaking

Inspectors reviewed documentation and spoke to a number of staff and found that governance arrangements at the hospital were understood and effective. While St Michael's Hospital was part of the SVHG and the IEHG, with the CEO reporting to the SVHG Director of Operations, it was clearly articulated to inspectors by all staff spoken with that St Michael's Hospital operated as a separate legal entity within

these groups and had overall responsibility for the radiation protection of service users.

The hospital had a RSC which was responsible for radiation safety and protection of service users undergoing medical exposures involving ionising radiation at the hospital. The RSC had multidisciplinary membership, including Consultant Radiologists, the Radiation Protection Advisor/Medical Physics Expert, the Radiation Protection Officer, Radiology Services Manager, Risk Manager and the Surgical Services Development Manager. The CEO was both the undertaking representative and designated manager of the radiological services and was a member of this committee which provided assurance of oversight of the radiation protection of service users at St Michael's Hospital.

Inspectors reviewed minutes of the previous three RSC meetings in addition to speaking with staff and management and found evidence that this forum met the established terms of reference. Items discussed at the RSC meetings included risk assessments, incidents and near misses, staff training and education, diagnostic reference levels (DRLs), clinical audit, quality assurance (QA) and equipment. The hospital also had a Patient Safety Committee established which cross reported with the RSC and both committees reported directly to St Michael's Executive Council. Membership of the Executive Council included members of the senior management team from St Michael's Hospital and the St Vincent's Healthcare Group. The Executive Council reported directly to the CEO.

A clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation was outlined in documentation reviewed by inspectors. The roles and responsibilities of the referrer, practitioner and MPE were clearly defined in the document *Diagnostic Imaging Department Radiation Safety Procedures*. Inspectors also spoke to numerous staff in the service who were aware of their own and collective responsibilities in ensuring the safe delivery of medical exposures to patients.

Judgment: Compliant

## Regulation 10: Responsibilities

Following a review of documentation and discussions with staff inspectors were not fully assured that the justification process for all medical exposures took place under the clinical responsibility of a practitioner as discussed under Regulation 8. While this non compliance related specifically to the justification of a small number of medical radiological exposures carried out in theatre, it still requires action by the undertaking to ensure regulatory compliance for all medical exposures.

However, staff clearly articulated to inspectors that a radiographer was present for all medical exposures including fluoroscopy procedures in theatre and this provided assurance of the involvement of a practitioner in the optimisation process.

Additionally, there was evidence provided to show that an MPE was also involved in the optimisation process for all radiological procedures.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

On the day of inspection inspectors were informed that MPE services were supplied to St Michael's Hospital by St Vincent's University Hospital's medical physics department. The mechanisms in place to provide continuity of MPE expertise at the hospital were described to inspectors by staff and management spoken with on the day. Staff who spoke with inspectors reported that they had adequate access to medical physics expertise and a service level agreement (SLA), reviewed on site by inspectors, formalised this arrangement.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

St Michael's Hospital had a SLA in place on the day of inspection which ensured that an MPE was available to act or give specialist advice on matters relating to radiation physics as required by the regulations. The SLA outlined the responsibilities and duties of an MPE. MPE professional registration certificates were reviewed by inspectors on the day of inspection and found to be up to date and met regulatory requirements.

Inspectors reviewed documentation and records and spoke with staff and found that an MPE took responsibility for dosimetry and gave advice on medical radiological equipment. An MPE was also found to contribute to optimisation, including the application and use of DRLs, the definition and performance of QA, acceptance testing and the analysis of events involving, or potentially involving, accidental or unintended medical exposures.

An MPE provided training in the area of radiation protection to staff at the hospital and had assisted in the development of an online training programme for staff. This bespoke training tool was seen as an example of good practice in the provision of relevant and efficient radiation protection training to staff.

Judgment: Compliant

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



From speaking with the relevant staff members and following radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the radiological risk associated with the services provided at St Michael's Hospital.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at St Michael's Hospital. Evidence of good practice was seen by inspectors in the strict surveillance of medical radiological equipment. Inspectors found that there was an appropriate QA programme in place and regular performance testing was undertaken as per Regulation 14. Inspectors were assured from documentation reviewed that equipment beyond its nominal date for replacement was formally approved for clinical use based on regular assessment and consultation with the MPE.

DRLs were established, used and reviewed. Where doses were identified as above national figures inspectors were satisfied that St Michael's Hospital had systems in place to ensure such occurrences were appropriately investigated.

Inspectors found that there was a system in place for the reporting and analysis of accidental and unintended exposures and significant events ensuring that any radiation incidents and near misses were discussed at the relevant forums within the radiology governance structure. Similarly, there were appropriate measures in place to ensure that an enquiry as to the pregnancy status of service users was undertaken as relevant to Regulation 16. St Michael's Hospital demonstrated an effective pathway for patients undergoing fluroscopy procedures in theatre to ensure that pregnancy enquiry was carried out and documented by the appropriate individual in advance of the procedure.

Inspectors were satisfied that written protocols were available for all adult radiological procedures however there were no written paediatric protocols available for review. This gap in documentation must be addressed by the undertaking to come into full compliance with Regulation 13(1).

Inspectors were satisfied that for all general X-ray and DXA procedures referrals were in writing, accompanied by sufficient medical information and justified in advance by a practitioner. There was also evidence of the record of justification for these procedures. However, inspectors identified that referrals for theatre fluroscopy procedures did not meet the criteria laid out in Regulation 8(10) and also there was no record of justification for these procedures. Action is therefore required by the undertaking to conduct a review of the referral and justification processes for all

radiological procedures to ensure compliance with Regulation 8.

Overall, inspectors were assured that St Michael's Hospital had effective systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

### Regulation 8: Justification of medical exposures

Inspectors viewed records relating to medical radiological procedures conducted at the hospital and spoke with staff and management in relation to the process of justification. The justification process detailed in the document *Radiology Justification Procedures & Guidelines* outlined how justification was recorded for each modality. For example, for justification of procedures carried out in general X-ray, the radiographers will state "Justified" followed by their initials in the radiographers note on the radiology information system (RIS). Additionally, for each patient attending for procedure in the radiology department at St Michael's a checklist is completed in advance of the procedure by the practitioner. This checklist prompts the practitioner to check that the referral is from an individual entitled to act as a referrer, that the referral states the reason for the request and includes sufficient clinical information, that previous diagnostic images have been obtained and viewed if applicable, the triple ID check is completed and that the service user has received information about the risks and benefits of the procedure. On the day of the inspection staff informed the inspectors that each radiographer working in St Michael's has their own stamp which includes their name and professional registration number and the checklist is stamped and signed by the radiographer once it has been completed. For all records reviewed for procedures within the radiology department the record of justification was evident to inspectors on the radiology information system and on the checklists.

However, a sample of theatre fluoroscopy procedure records viewed by inspectors did not include any evidence that the individual medical exposures in theatre were justified in advance or that the referrals contained sufficient medical data to satisfy the practitioner that the procedure is justified. The sample of theatre fluoroscopy procedure records viewed by inspectors did not state the reason for the procedure or contain sufficient medical data to enable the practitioner to carry out an assessment of justification. There was also no record of justification on the theatre records viewed. Inspectors concluded that the process for referring and justifying medical radiological procedures in theatre fluoroscopy services required action by the undertaking to meet the requirements of Regulations 8.

Judgment: Not Compliant

### Regulation 11: Diagnostic reference levels

A DRL policy underpinned the process for the establishment, use and review of facility DRLs at St Michael's Hospital which was viewed by the inspectors. Inspectors observed DRL values displayed in the control areas of general X-ray and DXA scanner in the radiology department. Staff spoken with on the day of inspection explained how local facility DRLs were used and reviewed and compared with national DRLs. This process facilitated the identification of any medical radiological procedure found to exceed the national DRL to ensure that all medical exposures were adequately optimised. The inspector found an example of this process being used on the day of inspection, which included the investigation and review of a DXA procedure in line with the requirements of the regulations.

Judgment: Compliant

### Regulation 13: Procedures

On the day of inspection inspectors assessed compliance of Regulations 13(1) and 13(3). Inspectors found that written protocols were established and available for general X-ray, DXA and theatre fluoro procedures for adults. However, no written protocols were available for paediatric procedures. While the number of paediatric procedures carried out at St Michael's Hospital is low this gap in documentation should be addressed by the undertaking to ensure compliance with Regulation 13(1).

Referral guidelines were identified in the *Diagnostic Imaging Department Radiation Safety Procedures* document and were available to staff on the hospital's shared policy drive. Inspectors were also informed by staff that all new medical practitioners are informed of these referral guidelines on induction.

Judgment: Substantially Compliant

### Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in advance of the inspection. There was evidence viewed in documentation and from discussion with staff to demonstrate that the undertaking had adequate arrangements in place to ensure that all medical radiological equipment in use in the service was kept under strict surveillance regarding radiation protection.

Inspectors were satisfied that an appropriate QA programme for the equipment had been established, implemented and maintained. This programme included annual MPE testing, monthly and fortnightly testing by the RPO and daily testing by

radiographers. Inspectors also found evidence that effective systems were in place to ensure that any performance issues with the medical radiological equipment were addressed and actioned immediately.

Inspectors were also satisfied that there was a formal process in place for monitoring any equipment that was past the nominal date for replacement through regular assessment and consultation with the MPE.

Overall, the evidence gathered satisfied inspectors that the processes and arrangements in place ensured that medical radiological equipment was kept under strict surveillance which provided assurance that equipment was safe for clinical use, thereby meeting the requirements of 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 in the radiology department.

Documentation reviewed satisfied inspectors that St Michael's Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Inspectors were informed that for theatre fluoroscopy procedures service users attended the radiology department in advance of the procedure to have the relevant pregnancy documentation completed by a radiographer. This was seen as an example of good practice to ensure the appropriate enquiry regarding pregnancy status was carried out by a practitioner before the patient underwent general anaesthetic in the theatre department.

Judgment: Compliant

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

Inspectors were satisfied that St Michael's Hospital had implemented an appropriate system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures. Similarly, inspectors were also satisfied that the hospital had a good reporting culture and that arrangements were in place to ensure that HIQA is notified of the occurrence of a significant event within the time frame as required.

Minutes of the RSC were reviewed by inspectors and detailed that radiation incidents

were a standing agenda item. Staff spoken with were satisfied that they received regular feedback on incident and near miss trends and inspectors were informed that there was a process in place to ensure that all staff reviewed decisions and actions from incident investigations.

Inspectors reviewed the annual incident report for 2022 and the quarterly report for Q1 2023. These reports demonstrated the trending of incident and near miss data across different incident categories and also highlighted any notifiable incidents. The identification of near misses offers the potential to identify a hazard or risk and implement corrective action to help prevent a more serious incident from occurring.

At the time of this inspection a system to enable electronic entry of incidents was being implemented in the radiology department to replace the paper based process and staff training to support this new system was ongoing.

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	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	Not 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 St Michael's Hospital OSV-0007406

Inspection ID: MON-0031220

Date of inspection: 12/04/2023

## 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 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: This finding relates to patients undergoing imaging to assist surgeons during surgical procedures (133 procedures per year, 0.53% of 24907 exams involving ionising radiation 2022). Imaging is only carried out if required during the procedures. Radiation Safety Procedures outlines the delegation of responsibilities for all aspects of medical exposures. For referral of the procedure the responsibility lies with the surgeon, all surgeons submitting these requests in advance of the procedures were notified from 20/04/2023 that they must include the name of the specific procedure planned and brief details of the patient's clinical information on the request. An email stating the same was sent to all surgeons 23/05/2023. For checking justification of theatre exposures the responsibility lies with the radiographer. The theatre pre-exposure evidence of documentation check sheet has been revised to ensure this justification check is captured in writing. It includes a statement that the justification of the imaging has been reviewed and checked. This will be signed by the radiographer. Radiographers implemented the pre-exposure evidence of documentation check sheet on 17/05/2023. An audit will be carried by 31/12/2023 to ensure compliance.</p>	
Regulation 8: Justification of medical exposures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: As above, all surgeons submitting these requests in advance of the procedures have been notified from 20/04/23 that they must include the name of the specific procedure planned and brief details of the patient's clinical information on the request. For checking justification of theatre exposures the responsibility lies with the radiographer.</p>	



The theatre pre-exposure evidence of documentation check sheet has been revised to ensure this justification check is captured in writing. It includes a statement that the justification of the imaging has been reviewed and checked, this will be signed by the radiographer, this was implemented on 17/05/2023 and all surgeons and radiographers have been notified (follow up email sent 23/05/23). An audit will be carried out to ensure compliance by 31/12/2023.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:  
Written protocols for paediatric procedures will be drafted in consultation with colleagues in Paediatric hospitals, protocols will include national DRLs for the age groups accepted by St Michael's Hospital > 14 years. The new draft will be circulated in advance of the Radiation Safety Committee on Tuesday 3rd October 2023 and approved at the meeting.

## 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.	Not Compliant	Orange	17/05/2023
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Orange	17/05/2023
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Orange	17/05/2023

Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	17/05/2023
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Not Compliant	Orange	17/05/2023
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	17/05/2023
Regulation 10(1)	An undertaking shall ensure that all medical	Not Compliant	Orange	23/05/2023

	exposures take place under the clinical responsibility of a practitioner.			
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Not Compliant	Orange	23/05/2023
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	03/10/2023