



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Kilcreene Regional Orthopaedic Hospital, Kilkenny
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Kilcreene, Kilkenny
Type of inspection:	Announced
Date of inspection:	31 August 2021
Medical Radiological Installation Service ID:	OSV-0007359
Fieldwork ID:	MON-0032672

## About the medical radiological installation:

Kilcreene Regional Orthopaedic Hospital, Kilkenny, is a statutory specialist hospital owned and managed by the Health Service Executive (HSE) and is a part of the South/South West Hospital Group. Since 29 January 2021, delivery of radiology services at Kilcreene Regional Orthopaedic Hospital, Kilkenny has been transferred under the governance and management of University Hospital Waterford. Kilcreene Regional Orthopaedic Hospital, Kilkenny is an elective orthopaedic hospital and it provides an elective orthopaedic service for the entire South East Region. Elective orthopaedic services are provided at the hospital by consultant orthopaedic surgeons, all based at University Hospital Waterford. The hospital has a bed capacity of 31 beds (20 in-patient beds, five day-case beds and six day-case spaces) and two operating theatres. Due to Covid-19 restrictions in University Hospital Waterford, radiology services at Kilcreene Regional Orthopaedic Hospital, Kilkenny have been expanded to include a trauma review clinic and a paediatric hip clinic and some surgical trauma work. There is also an on-site anaesthetic review clinic at the hospital. The main radiology services delivered at Kilcreene Regional Orthopaedic Hospital, Kilkenny includes general radiography for preoperative and postoperative imaging, trauma review and paediatric hip clinic imaging and theatre fluoroscopy.

## 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
Tuesday 31 August 2021	09:30hrs to 12:30hrs	Kirsten O'Brien	Lead
Tuesday 31 August 2021	09:30hrs to 12:30hrs	Noelle Neville	Support

## Governance and management arrangements for medical exposures

An inspection of Kilcreene Regional Orthopaedic Hospital, Kilkenny (Kilcreene Hospital) was carried out on the 31 August 2021 to review measures put in place to come into compliance with the regulations following a previous inspection of the hospital on the 18 November 2020.

Inspectors found that since the transfer of governance for medical radiological procedures at Kilcreene Hospital from St. Luke's Hospital, Kilkenny to University Hospital Waterford (UHW) on the 29 January 2021 measures to ensure accountability and oversight had been established regarding the clear allocation of responsibility for the radiation protection of service users. A dedicated radiation safety committee (RSC) had been established for Kilcreene Hospital and inspectors reviewed the terms of reference and minutes of meetings of this committee. Membership of the RSC included the clinical director of radiology and radiography management, risk management, the designated manager and local management and representatives from Kilcreene Hospital. Risk management for the radiology service had also been fully integrated with UHW in addition to the establishment of clear line management and oversight structures for the service.

All medical radiological procedures at the hospital took place under the clinical responsibility of a practitioner. A named medical physics expert (MPE) had been identified within the governance structures for medical exposures at Kilcreene Hospital to act and provide advice on matters relating to medical physics. Similarly, the practitioner and the MPE were involved in the optimisation process for all medical exposures. Inspectors also found that measures had been put in place to ensure that the referrer and the practitioner were involved in the justification process for individual medical radiological procedures.

Overall, inspectors were satisfied that Kilcreene Hospital had implemented the measures outlined in the compliance plan submitted to HIQA following the previous inspection at the hospital. It was clear that mechanisms and processes had put in place to come into compliance with the regulations through the provision of clear governance and management arrangements for medical exposures at the hospital.

## Regulation 6: Undertaking

Since the previous inspection of this hospital, governance and management structures for radiology services have been transferred from St. Luke's Hospital Kilkenny to UHW on the 29 January 2021. On inspection, inspectors spoke with staff and management and reviewed documentation and found that there was a reconfigured allocation of responsibility for the radiation protection of service users at the hospital. All medical exposures were carried out by staff from UHW and a

clear line management structure was now in place. A named MPE had responsibility for providing medical physics expertise, advice and consultation at the hospital.

A RSC has been established at the hospital and inspectors reviewed the terms of reference and previous minutes for this committee. Membership of the RSC includes local management at Kilcreene Hospital, and other appropriate persons involved in the provision of the radiology services at the hospital, such as the clinical director of radiology who is also the chair of the RSC, risk management representatives, an MPE and the radiography services manager. The designated manager for medical exposure to ionising radiation at Kilcreene Hospital was the general manager of the hospital who had oversight of the medical exposures through line management reporting structures and membership of the RSC.

On the day of inspection, the risk management structures had been fully integrated for medical exposures at Kilcreene Hospital and inspectors were satisfied that a clear line of reporting for accidental or unintended exposures, and potential accidental and unintended exposures was in place. Additionally, inspectors noted that legacy issues identified on the previous inspection regarding the Health Service Executive (HSE) National Integrated Medical Imaging System (NIMIS) Picture Archiving and Communication System (PACS) at Kilcreene Hospital had been addressed with the alignment of this system to UHW. This ensures that there is now consistent oversight of all systems related to the conduct of medical exposures at the hospital.

Judgment: Compliant

## Regulation 10: Responsibilities

Inspectors reviewed documentation and other records and found that all medical exposures took place under the clinical responsibility of a practitioner. Similarly, the practitioner and the MPE were found to be involved in the optimisation process for all medical exposures. An annual report which reviewed current optimisation measures was provided to inspectors in advance of the inspection and included a clear description of the involvement of these individuals in the optimisation process at the hospital. From a review of policies and other documentation and from speaking with staff, inspectors were satisfied that the justification process of individual medical exposures involved the practitioner and the referrer.

The practical aspects of medical radiological procedures were only carried out by individuals entitled to act as practitioners at the hospital. As an additional assurance, Kilcreene Hospital had retained the presence of a radiographer for medical radiological procedures conducted in theatre using fluoroscopy. In the absence of new training requirements being established and implemented by the Medical Council, as per Regulation 22, this was viewed as a positive radiation protection mechanism for service users at the hospital.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from communication with staff and a review of relevant policies and other records, that the Kilcreene Hospital had adequate processes in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff at the hospital and were satisfied that appropriate arrangements were in place to ensure that the involvement and contribution of an MPE was in line with the requirements of Regulation 20. A named MPE had overall responsibility for providing medical physics expertise at the hospital, and took responsibility for dosimetry and gave advice on medical radiological equipment.

Records reviewed by inspectors also demonstrated that the MPE contributed to quality assurance and was involved in the optimisation of medical exposures at the hospital. Additionally, the MPE was found to contribute to training of staff in the area of radiation protection at Kilcreene Hospital.

Judgment: Compliant

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

On the day of inspection, an MPE was found to be appropriately involved in all aspects of medical exposure to ionising radiation at the hospital, in line with the level of radiological risk.

Judgment: Compliant

## Safe Delivery of Medical Exposures

On the day of inspection, staff and management demonstrated a comprehensive

approach to optimisation of medical radiological procedures at the hospital. Inspectors spoke with staff and reviewed an optimisation report and this provided a comprehensive overview of measures in place to ensure that medical radiological procedures conducted at the hospital were kept as low as reasonably achievable. However, while diagnostic reference levels (DRLs) had been established for general radiography exposures at the hospital, inspectors noted that DRLs for fluoroscopic procedures conducted in theatre should also be established. Inspectors were satisfied however that the hospital had an appropriate programme of assessment of dose in place for all medical exposures carried out at Kilcreene Hospital.

All referrals reviewed on the day of inspection were in writing and stated the reason for requesting the medical radiological procedure. Inspectors also reviewed how justification in advance by a practitioner was recorded. Written protocols for every type of standard medical radiological procedure had been established at the hospital together with a programme of clinical audit. However, inspectors found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2).

Since the last inspection of Kilcreene Hospital, a comprehensive quality assurance programme for medical radiological equipment had been established. This programme now included regular routine performance testing of equipment and records of all quality assurance testing were available to inspectors for review. Inspectors also found that a clear allocation of responsibility for reporting accidental and unintended or potential accidental and unintended exposures was now in place at Kilcreene Hospital. Trending and analysis of potential incidents was available to inspectors for review and an incident reporting flow-chart was available to staff in the clinical area.

Overall, inspectors were assured that appropriate systems to ensure the safe delivery of medical exposures at this hospital were in place at Kilcreene Hospital.

## Regulation 8: Justification of medical exposures

Inspectors reviewed documentation and records relating to referrals and found that all referrals were in writing and stated the reason for requesting the medical radiological procedure. On the day of inspection, staff at the hospital described the process for justification of individual medical exposures in advance. A sample of the records of justification for medical radiological procedures by a practitioner were also reviewed.

Information relating to the benefits and risks associated with medical exposures to ionising radiation was available to service users in the waiting area in the form of leaflets and a poster. Staff also described to inspectors the process for obtaining previous diagnostic information and records using the HSE NIMIS PACS system.



Judgment: Compliant

### Regulation 9: Optimisation

From documentation and records reviewed and communication with staff and management at Kilcreene Hospital, inspectors were satisfied that doses due to medical exposures were kept as low as reasonable achievable consistent with obtaining the required information. An optimisation report was reviewed by inspectors who identified this comprehensive overview and evaluation of the optimisation processes at the hospital an area of good practice.

Inspectors also noted that since the previous inspection, a number of measures relating to the selection of equipment for Kilcreene Hospital, a quality assurance programme, optimisation of the practical aspects of medical exposures and evaluation of patient doses had been implemented. Staff at the hospital who spoke with inspectors also provided a number of examples of where practitioners and the MPE had been involved in the optimisation of medical exposures, including an instance where exposure factors used for taking an X-ray were reviewed to ensure the consistent production of adequate diagnostic information.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs were found to have been established, regularly reviewed and used for general radiography procedures at Kilcreene Hospital. However, inspectors noted that for some common medical exposures involving fluoroscopy for the purposes of guiding medical procedures DRLs had not been established. However, inspectors did note that while DRLs for these procedures were not established, records of the dose for fluoroscopic medical exposures were available and regularly reviewed. Additionally, inspectors observed a poster for staff in the X-ray room to raise awareness of the importance of DRLs in the optimisation of medical exposures.

Overall, while inspectors were satisfied that appropriate reviews of radiation doses are carried out to ensure that adequate optimisation for the radiation protection of patients, Kilcreene Hospital should ensure that DRLs are established for common medical exposures conducted for the purpose of guiding medical procedures at the hospital.

Judgment: Substantially Compliant

## Regulation 13: Procedures

Written protocols had been established for every type of standard medical radiological procedure carried out at Kilcreene Hospital. This included site specific orthopaedic projections due to the specialised nature of orthopaedic procedures conducted at the hospital. Inspectors spoke with staff and reviewed documentation and were satisfied that referral guidelines for medical imaging were also available to referrers at Kilcreene Hospital.

A programme of clinical audit had commenced since the last inspection at the hospital and inspectors reviewed records of clinical audits performed to date. The inclusion of a clinical audit sub group in the RSC terms of reference was noted as a positive measure and an opportunity to further develop a culture of clinical audit in the hospital going forward.

However, on the day of inspection information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2). The HSE, as the undertaking for Kilcreene Hospital, should ensure that appropriate measures are put in place to come into compliance with this requirement of the regulations.

Judgment: Substantially Compliant

## Regulation 14: Equipment

On the day of inspection, all medical radiological equipment at Kilcreene Hospital was found to be kept under strict surveillance regarding radiation protection. From reviewing the documentation and speaking with staff, inspectors were satisfied that an appropriate quality assurance programme had been implemented and maintained. A programme of assessment of radiation dose had also been implemented at the hospital. Inspectors also reviewed records of performance testing and were satisfied that testing was carried out on a regular basis and a mechanism to report any equipment faults or issues arising from testing was in place.

Inspectors were provided with an up-to-date inventory of the medical radiological equipment at the hospital. Similarly, from communication with management, inspectors were satisfied that an equipment replacement plan was in place where equipment exceeded its nominal replacement dates.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors spoke with staff and reviewed documentation regarding the measures in place relating to the special protection of patients during pregnancy. Records were reviewed verifying that a practitioner inquired as to the pregnancy status of patients where appropriate. In situations where pregnancy could not be ruled out due to obvious reasons, the referrer and the practitioner were found to rejustify the appropriateness of the medical exposure.

Inspectors also observed posters in the waiting area of the X-ray department used to increase service user awareness of the importance of informing staff at the hospital of their pregnancy status in advance of medical exposures.

Judgment: Compliant

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

From a review of records, documentation and speaking with staff and management, inspectors found that an appropriate system had been implemented for record keeping and analysis of events involving or potentially involving accidental or unintended exposures to ionising radiation. A flow-chart was available to staff which outlined the process for reporting any incidents or potential incidents at the hospital.

Inspectors also reviewed trending of potential incidents, and the minutes of RSC meetings, which occurred since the governance of the radiology services at Kilcreene Hospital had been realigned and were satisfied that a strong culture of reporting was in place.

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 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 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially 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 Kilcreene Regional Orthopaedic Hospital, Kilkenny OSV-0007359

Inspection ID: MON-0032672

Date of inspection: 31/08/2021

## Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

## Section 1

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

### Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: DRLs for common medical exposures involving fluoroscopy for the purposes of guiding medical procedures in KROH have been established and are now clearly on display in KROH (copy of the information poster attached).	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Information relating to patient exposure forming part of the report of medical radiological procedures as required by Regulation 13(2) – this will be implemented immediately when the technical changes permitting this functionality are released on the national NIMIS system by the HSE NIMIS Programme in collaboration with the National Radiation Protection Committee – [NRPC] (as advised by the NRPC to HGCEOs on 23.02.21)	



## Section 2:

### Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	01/09/2021
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	01/03/2022