



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:	18 November 2020
Medical Radiological Installation Service ID:	OSV-0007359
Fieldwork ID:	MON-0030674

About the medical radiological installation:

Kilcreene Regional Orthopaedic Hospital, Kilkenny provides orthopaedic radiography to include fixed computed radiography, mobile digital radiography and digital 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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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:

¹ 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.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ 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 18 November 2020	10:30hrs to 14:30hrs	Kirsten O'Brien	Lead
Wednesday 18 November 2020	10:30hrs to 14:30hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Kilcreene Regional Orthopaedic Hospital, Kilkenny or Kilcreene Hospital, as it is referred to in this report, is a statutory hospital managed by the Health Service Executive (HSE) and is part of the South/South West Hospital Group. Historically, Kilcreene Hospital had been previously managed by St. Luke's Hospital, Kilkenny (St. Luke's Hospital) which is part of the Ireland East Hospital Group. Inspectors were informed that the radiology service at Kilcreene Hospital was resourced and provided by St. Luke's Hospital, rather than University Hospital Waterford. As a result of these legacy arrangements at Kilcreene Hospital, there was a lack of clarity in arrangements relating to governance and oversight of the radiology service with neither University Hospital Waterford or St. Luke's Hospital, correctly assuming the required oversight role.

On the day of inspection, inspectors found that clear governance and management arrangements for the oversight and allocation of responsibility for medical exposures at Kilcreene Hospital were not evident. The on-site conduct of medical radiological procedures was provided by agency staff, directly contracted by Kilcreene Hospital, with informal oversight and support provided by University Hospital Waterford. The general manager of University Hospital Waterford and Kilcreene Hospital informed inspectors that this interim staffing arrangement, currently in place at Kilcreene Hospital, was as a result of a withdrawal of staffing by St. Luke's Hospital in early 2020. However, inspectors noted that a number of off-site services, such as local support for the HSE National Integrated Medical Image System (NIMIS) Picture Archiving and Communication System (PACS), were still provided by St. Luke's Hospital. Kilcreene Hospital had also been part of St. Luke's Hospital's Radiation Safety Committee (RSC), but inspectors were informed that this was no longer the case. However, as responsibility for the conduct of medical exposures at Kilcreene Hospital had yet to be formally handed over to University Hospital Waterford, Kilcreene Hospital was not included as part of University Hospital Waterford's RSC as of the day of inspection.

Despite the current lack of governance and management of radiology services at the hospital, an appropriately registered practitioner took clinical responsibility for all medical exposures conducted at Kilcreene Hospital. Additionally, a practitioner and a referrer were involved in the justification process for individual medical exposures. Although the practitioner was found to be involved in some aspects of the optimisation process, the undertaking must take steps to ensure that both practitioners and medical physics experts are fully involved in the optimisation process for all medical exposures carried out at the hospital.

Management at Kilcreene Hospital accepted and acknowledged that there was a lack of formal governance and oversight regarding the conduct of medical exposures at the hospital and had made efforts to begin the process of addressing the legacy arrangements which resulted in this lack of clarity. Arrangements for the clear allocation of responsibility for the protection of service users from medical exposure

to ionising radiation, must be implemented by the HSE, as the undertaking for Kilcreene Hospital, as a matter of urgency.

Regulation 4: Referrers

All referrals reviewed by inspectors were from referrers as defined in the regulations.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Formalised lines of governance and oversight of the radiology service, including the clear allocation of responsibility for the radiation protection of patients and other service users undergoing medical radiological procedures, were not in place at Kilcreene Hospital on the day of inspection. The undertaking, the HSE, had delegated the role of designated manager at Kilcreene Hospital to the general manager of the hospital. Inspectors were informed by the general manager, that they did not have oversight of radiology services at the hospital due to legacy arrangements, and the responsibility for provision of the medical radiological services was provided and resourced by St. Luke's Hospital.

However, on the day of inspection, the majority of on-site radiology resources were found to be provided by agency staff, directly contracted by Kilcreene Hospital. Inspectors found that informal on-site operational oversight and support was provided by a senior radiographer from University Hospital Waterford one day a week. Management informed inspectors that despite this informal staffing arrangement, in place at the request of management at Kilcreene Hospital to ensure service continuity for patients; no clear or formalised governance or reporting structure existed. Subsequently, inspectors noted that aspects of the radiology service, such as the provision of HSE NIMIS PACS and reports of individual medical radiological procedures, in addition to organising equipment maintenance by vendors, were still provided by St. Luke's Hospital.

Management at Kilcreene Hospital acknowledged the current deficit in a clear definition of responsibility for radiation protection at the hospital and informed inspectors that efforts are currently being made to rectify this.

Judgment: Not Compliant

Regulation 10: Responsibilities

Although inspectors found that a practitioner took clinical responsibility for all medical exposures, and the referrer and practitioner were involved in the justification process of procedures performed at Kilcreene Hospital, there was an absence of policies describing this allocation of responsibility by the undertaking including a clear definition of how the practitioner and referrer are involved in medical radiological procedures at the hospital.

On the day of inspection, while the practitioner was involved in some parts of the optimisation process, such as the practical aspects of medical radiological procedures, inspectors did not find evidence that the undertaking had ensured that practitioners were involved in all aspects of the optimisation process for all medical exposures. For example, practitioner involvement in quality assurance and the assessment and evaluation of patient dose, such as through the establishment, use and review of diagnostic reference levels (DRLs), was not evident. Similarly, inspectors found that the medical physics expert was not involved in the optimisation process for all medical exposures as required by the regulations.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, medical physics expertise was in place at Kilcreene Hospital which was provided by University Hospital Waterford. However, inspectors were informed that the necessary agreements to ensure the continuity of medical physics expertise at the hospital was largely dependent on legacy arrangements, with no formal arrangements in place. A formalised agreement to ensure the continuity of medical physics expertise at Kilcreene Hospital should be put in place.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors found that while a medical physics expert was available to give specialist advice as necessary, the undertaking had not ensured that they were available to act, as appropriate, on matters relating to medical physics for implementing key requirements of the regulations, for example, taking responsibility for dosimetry.

Records reviewed demonstrated that a medical physics expert performed acceptance testing and annual quality assurance testing of medical radiological equipment. However, a medical physics expert did not contribute to the optimisation of the radiation protection of patients including the application of DRLs, or the training of practitioners and other staff in relevant aspects of radiation protection at Kilcreene Hospital.

Judgment: Not Compliant

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

Inspectors found that a medical physics expert was available for some consultation and advice at Kilcreene Hospital. However, inspectors were informed that the level of involvement of medical physics expertise was not appropriate, commensurate with the radiological risk at the hospital. The level of involvement and access to appropriate consultation and advice to medical physics expertise must be reviewed and improved to address the non-compliances found under Regulation 20. For example, while a medical physics expert had performed annual quality assurance and acceptance testing on medical radiological equipment, responsibility for dosimetry had not been taken. Additionally, there was a lack of oversight by a medical physics expert of doses at Kilcreene Hospital, or contribution to the establishment, use or review of DRLs.

Judgment: Not Compliant

Safe Delivery of Medical Exposures

On the day of inspection an appropriately registered radiographer justified all medical exposures in advance. Records of referrals reviewed by inspectors were in writing and from a referrer, entitled to refer as per the regulations. However, inspectors found that DRLs had not been established at Kilcreene Hospital for medical radiological procedures. Similarly, there was an absence of clinical audits relating to medical radiological procedures conducted at the hospital.

Inspectors found that the arrangements to ensure strict surveillance of medical radiological equipment regarding radiation protection were not in place. Management at Kilcreene Hospital informed inspectors that St. Luke's Hospital

retained responsibility for the maintenance and oversight of the medical radiological equipment. Conversely, minutes from St Luke's Hospital's RSC, indicated that maintenance, replacement and repair of medical radiological equipment was not funded by St. Luke's Hospital. Inspectors were informed by management that funding for the maintenance, replacement and repair of medical radiological equipment at the hospital was provided by Kilcreene Hospital itself.

Additionally, there was no clear reporting pathway for events involving, or potentially involving, accidental or unintended medical exposures at the hospital. Patient related incidents were currently reported to the director of nursing at Kilcreene Hospital and to the risk manager and the radiology services manager at University Hospital Waterford. However, inspectors were informed by the general manager of Kilcreene Hospital that the management of such events, or potential events, involving medical exposures did not fall within the current remit of University Hospital Waterford.

While multiple non-compliances were found on the day of inspection, inspectors were satisfied following discussions with senior management, and the professionals involved in providing the service that there was no immediate risk to patient safety. However, the HSE, as the undertaking, must take immediate steps to ensure compliance with the regulations.

Regulation 8: Justification of medical exposures

On the day of inspection, a sample of records of medical radiological procedures were reviewed. All referrals were in writing and stated the reason for requesting the particular procedure. Inspectors were informed that a radiographer, registered with CORU, Ireland's multi-profession health regulator, took clinical responsibility for justifying all individual medical exposures in advance. Inspectors were informed that the presence of a radiographer's signature was the record of justification in advance. However, a formal process for documenting and recording justification in advance at Kilcreene Hospital was not evident.

Additionally, while inspectors were informed that leaflets were available to provide information about the risks and benefits of medical radiological procedures, these were not routinely available to patients in the waiting area and were subsequently restocked during the inspection. Consequently, the undertaking must have a mechanism in place to ensure that the referrer or the practitioner provides information about the benefits and risks associated with the radiation dose to patients prior to a medical exposure taking place.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors found that DRLs had not been established for radiodiagnostic examinations at Kilcreene Hospital. The absence of DRLs at the hospital had been self-identified as not compliant in a self-assessment questionnaire in late 2019 and plans to establish DRLs were not in place at the time of inspection.

Judgment: Not Compliant

Regulation 13: Procedures

While some written policies and protocols were available on the day, these were not site, or equipment specific, and their scope did not extend to Kilcreene Hospital. Additionally, information relating to patient exposure did not form part of the report of medical radiological procedures carried out at the hospital.

Inspectors were informed that clinical audits relating to medical exposure to ionising radiation were not carried out at the hospital.

Judgment: Not Compliant

Regulation 14: Equipment

Records of the medical physics expert's recent annual quality assurance and acceptance testing were provided to inspectors in advance of the inspection. However, records of regular performance testing were not available. Additionally, inspectors were informed that the equipment required to carry out regular performance testing on medical radiological equipment at Kilcreene Hospital had not been available for a period of time up to the day of inspection and therefore regular performance testing had not been performed.

Inspectors also found that an appropriate programme of assessment of dose had not been implemented at the hospital. Overall, inspectors found that the allocation of responsibility to ensure strict surveillance of medical radiological equipment regarding radiation protection was unclear and as a result the undertaking had not ensured that all medical radiological equipment in use at Kilcreene Hospital was kept under strict surveillance.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

A clear allocation of responsibility for the management, recording or analysis of events involving, or potentially involving, accidental or unintended medical exposures was not evident on the day of inspection. Inspectors were informed that while there was an informal mechanism in place for reporting incidents, and potential incidents, this process was not formally documented due to the current interim staffing arrangements in place at Kilcreene Hospital.

Accidental or unintended medical exposures were reported to the director of nursing at Kilcreene Hospital and to the radiology services manager and risk manager at University Hospital Waterford. However, inspectors were informed that the management of such events, or potential events involving medical exposures was not the responsibility, or within the current remit, of University Hospital Waterford as a result of the current legacy arrangements in place.

Kilcreene Hospital had no reported or recorded events, or potential events, involving accidental or unintended medical exposures. Inspectors found that as a result of a lack of clarity regarding the reporting pathway, there was a lack of awareness about reporting potential incidents and a potential incident described to inspectors had not been formally recorded. While HSE National Incident Management System (NIMS) notification forms were available to staff, additional information to facilitate reporting at Kilcreene Hospital was not available. Clarity regarding the reporting process is required, and subsequent steps must be taken to raise awareness of what constitutes an incident, or potential incident, involving medical exposures to ensure that the hospital is compliant with the requirements of this regulation.

Judgment: Not 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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant

Compliance Plan for Kilcreene Regional Orthopaedic Hospital, Kilkenny OSV-0007359

Inspection ID: MON-0030674

Date of inspection: 18/11/2020

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 6: Undertaking	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The process of transfer of governance is progressing and will be completed by the end of January 2021.</p> <p>It is proposed to establish a separate Radiation Safety Committee (RSC) for Kilcreene Regional Orthopaedic Hospital (KROH) under the governance of UHW; the inaugural meeting for which is scheduled for Tuesday 19th January 2021.</p> <p>UHW are also in the processing of drafting Radiation Safety Procedures which will provide for a clear allocation of responsibilities as required, and will be signed off prior to the Radiation Safety Committee meeting by the Designated Manager for KROH (also the General Manager, KROH).</p>	
Regulation 10: Responsibilities	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: UHW are currently advancing, in conjunction with NIMIS National Team and the relevant vendor, the transfer of KROH NIMIS system alignment from St. Luke's Hospital, Kilkenny to UHW NIMIS facility.</p> <p>Practitioners in KROH (& relevant practitioners in UHW) will assume responsibility for authorisation of medical exposures and will be involved in all aspects of the optimisation process for all medical exposures. They will also be represented on the KROH Radiation Safety Committee and will engage on assessment and evaluation of patient dose, DRLs, and other optimisation measures.</p> <p>The UHW MPE will become the MPE for KROH and as such will also be involved in the optimisation process as required.</p>	

Regulation 19: Recognition of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:</p> <p>Further to the transfer of governance to UHW, the role of the Medical Physics Expert in UHW will be expanded to include Kilcreene Hospital. There are currently 3 physicists in the Medical Physics Department in UHW who are all qualified MPEs, and continuity of medical physics support is ensured through mutual cover arrangements.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:</p> <p>Further to the transfer of governance to UHW, the role of the Medical Physics Expert in UHW will be expanded to include KROH. Furthermore, the management of KROH radiography services will come under the remit if the RSM2 in UHW and the RPO in UHW will also assume responsibility for KROH.</p> <p>Also as noted above, an RSC will be established for KROH under the governance of UHW. As such, the level of interaction between the MPE and the radiography services in KROH will mirror those currently established in UHW which will ensure the required level of input from the MPE.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:</p> <p>As for regulation 20 above.</p>	

Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>All radiography procedures and practices currently in place in UHW will be mirrored in KROH under the UHW radiography department management team. This will include a formal process for documenting and recording justification in advance in KROH and appropriate provision of patient information.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <p>The initial process of establishing LDRLs for KROH has been completed and the relevant data has been submitted for the HIQA National DRL Survey.</p> <p>A more comprehensive analysis will be carried out in 2021. The audit data will be analysed with respect to the HIQA published NDRLs, with a view to the implementation of further optimisation measures as necessary.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>Further to the transfer of governance, the Radiography Department in KROH will come under the remit of the UHW radiography department. All UHW written procedures with regard to all operational and compliance matters will be mirrored in KROH (tailored to be site specific for KROH as necessary). These will include policies on Clinical Audit, and any UHW initiatives to address the inclusion of patient exposure data on radiology reports.</p>	

Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: Records of the regular performance testing have been requested from SLK. Similarly Medical Physics performance testing records have been requested and will be held in UHW. A framework for a comprehensive QA programme for all 3 items of medical radiological equipment in KROH has been devised by the UHW RPO and the requisite QA testing tools will be purchased. These tools will be permanently allocated to KROH. The EPA has been informed of the impending licence change by the RPA in UHW. When this transfer is complete, all KROH medical radiological equipment will be kept under strict surveillance by the RSMs, RPO, MPE and Biomedical Engineering in UHW.</p>	
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: Further to the transfer of governance, there will be a clear pathway for the management of accidental or unintended medical exposures, mirroring procedures and practices currently in place in UHW.</p>	

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Red	29/01/2021
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	29/01/2021

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Substantially Compliant	Yellow	29/01/2021
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	29/01/2021
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	29/01/2021
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation	Not Compliant	Orange	29/01/2021

	process for all medical exposures involves the practitioner,			
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Red	29/01/2021
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	29/01/2021
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Substantially Compliant	Yellow	29/01/2021
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.	Not Compliant	Red	29/01/2021
Regulation 13(1)	An undertaking shall ensure that written protocols	Not Compliant	Orange	29/01/2021

	for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.			
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	29/01/2021
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	29/01/2021
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	29/01/2021
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Red	29/01/2021
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance	Not Compliant	Red	29/01/2021

	testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.	Not Compliant	Orange	29/01/2021
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Not Compliant	Red	29/01/2021
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of	Substantially Compliant	Yellow	29/01/2021

	persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Not Compliant	Orange	29/01/2021
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Red	29/01/2021
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical	Not Compliant	Red	29/01/2021

	<p>radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none"> (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection 			
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	of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Not Compliant	Red	29/01/2021
Regulation 21(2)(c)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical	Substantially Compliant	Yellow	29/01/2021

	exposure.			
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