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:	MRH Mullingar
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Longford Road, Robinstown (Levinge), Mullingar, Westmeath
Type of inspection:	Announced
Date of inspection:	08 March 2022
Medical Radiological Installation Service ID:	OSV-0007363
Fieldwork ID:	MON-0034868

About the medical radiological installation:

Midlands Regional Hospital (MRH) Mullingar is a model 3 acute teaching hospital managed by the Health Service Executive (HSE). The hospital is a member of the Ireland East Hospital Group and is managed by the Hospital Manager, who reports to the Chief Executive Officer of the hospital group. The hospital provides acute, general hospital services to the population of a geographical area encompassing Westmeath, Longford, Leitrim, Offaly and Kildare.

Summary of hospital activities and service delivery:

- Department of Medicine treating medical patients via the Medical Assessment Unit
- 196 In-patient beds including Intensive Care Unit & Stroke Unit - Rehabilitation Unit
- Emergency Department which includes the regional stroke service and FAST response team
- Day Surgery including General, Gastro-Intestinal and Gynaecology services
- Maternity Services
- Paediatrics
- Radiology

The Radiology department at MRH Mullingar provides a 24/7 diagnostic imaging service across several modalities including general radiography (X-ray), fluoroscopy, computed tomography (CT) , dual-energy x-ray absorptiometry (DXA) and ultrasound. CT and general X-ray services are available 24/7 with over 85,000 patient examinations performed annually. The Radiology Department, incorporates satellite services in Longford and Athlone, which provide general diagnostic radiography services to GP's in the locality. All imaging is reported by on-site radiologists, with the exception of some out-of-hours CT imaging, which is delegated to an external remote radiology service.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] 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
Tuesday 8 March 2022	09:30hrs to 16:00hrs	Kirsten O'Brien	Lead
Tuesday 8 March 2022	09:30hrs to 16:00hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

An inspection of Midlands Regional Hospital (MRH) Mullingar was carried out on the 8 March 2022 by inspectors to assess compliance against the regulations. As part of this inspection, inspectors visited the radiology department at MRH Mullingar including the dual-energy x-ray absorptiometry (DXA), general radiography (X-ray) and computed tomography (CT) areas.

On the day of inspection, local governance and management arrangements in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital were reviewed by inspectors. The hospital manager was the designated manager and the person responsible for the radiation protection of service users at the hospital. The hospital manager was also the chair of the hospital's radiation safety committee (RSC) which was found to be the main forum for providing oversight to senior management regarding the radiation protection of service users at the hospital. Terms of reference and minutes for the RSC were also reviewed by inspectors in addition to speaking with staff and management. The RSC met three times a year and its membership included representation from individuals involved in the conduct of medical exposures at the hospital, as well as other relevant departments, such as the Clinical Quality and Patient Safety Department. The RSC also had a reporting relationship to the Health and Safety Committee, however inspectors were informed radiation safety had been recently added as a standing item according to the diagram of radiation protection governance provided to inspectors in advance of the inspection. However, the inclusion of radiation safety as an agenda item was not reflected in the most recent minutes which were reviewed on the day of inspection. To ensure that a clear allocation of oversight and responsibility for the radiation protection of service users at the hospital is in place, the hospital should ensure that reporting relationships are implemented in line with documented governance and management arrangements for MRH Mullingar.

Inspectors were satisfied that all medical radiological procedures took place under the clinical responsibility of a practitioner, as defined in the regulations.There was evidence that referrers and practitioners were involved in the justification of individual medical radiological procedures. Furthermore, radiographers, radiologists and a medical physics expert (MPE) were found to be involved in optimising medical exposures. However, the allocation of radiographers' scope of clinical responsibility for medical exposures was not clearly documented by the hospital in their local polices and procedures. MRH Mullingar must ensure that documentation is consistent and accurately reflects day-to-day practice and the allocation of responsibilities for the radiation protection of services users. This will help ensure the radiation protection of patients and other service users. The practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations. As an additional assurance MRH Mullingar had also retained the presence of radiographers for all medical radiological procedures carried out at the hospital. This is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation in the

absence of new training requirements being implemented by professional bodies listed under Regulation 22.

Inspectors reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users at MRH Mullingar. A service level agreement was in place within the Ireland East Hospital Group which ensured appropriate access to an MPE at the hospital and included the provision of an MPE on-site each week. This provided an assurance that the MRH Mullingar had access to an MPE to act and provide specialist advice in line with the radiological risk at the hospital. An area noted for improvement on the day of inspection related to the undertaking's responsibility to ensure the contribution of an MPE in the preparation of technical specifications for all medical radiological equipment and installation design at the hospital.

Notwithstanding the areas for improvement identified over the course of the inspection, inspectors found that MRH Mullingar demonstrated a commitment to ensuring the radiation protection of service users undergoing medical radiological procedures at the hospital.

Regulation 4: Referrers

Inspectors reviewed a sample of referrals and spoke with staff and found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at the MRH Mullingar.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed and inspectors found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at MRH Mullingar were reviewed by inspectors. Inspectors spoke with staff and management at the hospital and found that the hospital manager was the designated manager and the person responsible

for governance and management of the radiation protection of service users undergoing medial radiological procedures at the hospital. Documentation, including local policies, procedures, guidelines and records and an organisational chart, was also reviewed in advance of the inspection.

The RSC had been established as the main forum of oversight for radiation protection at the hospital. The hospital manager, as designated manager, was the chair of the RSC which provided an assurance to inspectors regarding oversight of radiation protection at the hospital. Inspectors also noted that management at the hospital had taken appropriate measures where attendance of representatives of different disciplines was identified as an issue. This included replacing members as necessary to ensure all appropriate stakeholders involved in medical exposure to ionising radiation were appropriately represented at the RSC. From a review of documentation and speaking with staff and management relating to governance and oversight arrangements for radiation protection at the hospital, inspectors were informed that a reporting relationship between the RSC and the Health and Safety Committee had been established. From a review of recent minutes, inspectors noted that radiation safety had not been a standing item. To ensure that a clear allocation of oversight and responsibility for the radiation protection of service users at the hospital is in place, the hospital should ensure that reporting relationships are consistent with documented governance and management arrangements at the hospital.

While the hospital had measures in place to ensure that only individuals, as defined in the regulations, could take clinical responsibility for medical radiological procedures, inspectors found that documentation reviewed did not clearly specify who could take clinical responsibility for medical exposure to ionising radiation. In particular, the role of radiographers as referrers and practitioners was found to be incompletely documented. For example, while the process for performing adapted referrals and inquiring about the pregnancy status of service users were clearly communicated to inspectors by staff, inspectors found that these day-to-day practices were not consistently documented in policies and procedures at the hospital. It is important that policies, procedures and guidelines clearly indicate the allocation of responsibility for radiation protection at MRH Mullingar. Similarly, this documentation should be specific to practices at MRH Mullingar and should be updated to clearly explain the allocation of the role of a practitioner for the different aspects of clinical responsibility as required by the regulations.

Overall while inspectors were satisfied that governance and management arrangements are in place to ensure the safe delivery of medical radiological procedures at MRH Mullingar the hospital could benefit from strengthening these arrangements by consolidating and streamlining documentation to ensure the clear allocation of responsibility for the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Additionally, the practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations. As an additional assurance MRH Mullingar had also retained the presence of radiographers and or radiologists for all medical radiological procedures carried out at the hospital. In the absence of new training requirements being implemented, as per Regulation 22, this is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation

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 MRH Mullingar had adequate processes in place to ensure the continuity of medical physics expertise at the hospital. Inspectors found that a service level agreement was in place within the Ireland East Hospital Group which ensured appropriate access to an MPE at the hospital and included the provision of the on-site presence of an MPE each week.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff about MPE involvement and contribution to the radiation protection of service users at MRH Mullingar. On the day of inspection, an MPE was found to take responsibility for dosimetry and contributed to quality assurance and acceptance testing at the hospital. An MPE was also involved in optimising medical exposures at the hospital, in the analysis of events involving, or potentially involving, accidental or unintended medical exposures and was also involved in providing training in the area of radiation protection. In particular, a periodic newsletter which focused on topics relating to the radiation protection of service users was available to staff and was noted as a positive example of ongoing training and education at MRH Mullingar.

However, from speaking with staff on the day of inspection, inspectors were not

assured that the HSE, as the undertaking for MRH Mullingar, had ensured that measures were in place to ensure the appropriate contribution of an MPE in the preparation of technical specifications for all medical radiological equipment and installation design at the hospital.

Overall, notwithstanding the area for improvement identified above, inspectors were assured that arrangements were in place, in conjunction with the hospital group, to ensure MPE involvement to act or give specialist advice as appropriate on matters relating to medical physics at MRH Mullingar.

Judgment: Substantially Compliant

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

On the day of inspection, mechanisms were in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at MRH Mullingar.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at MRH Mullingar. Written protocols were available for standard medical radiological procedures. Leaflets and posters containing information about the benefits and risks associated with medical exposure to ionising radiation were also observed in waiting rooms. A programme of clinical audit was established and inspectors reviewed a sample of clinical audits conducted at the hospital. Referral guidelines for medical imaging were also available for referrers on hospital computers.

All referrals reviewed were in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff informed inspectors that radiographers or radiologists justified all medical exposures in advance and written records of justification in advance of medical radiological procedures were available for review on the day of inspection.

Inspectors found that radiographers at the hospital inquired about the pregnancy status of individuals prior to the conduct of medical exposures, where appropriate. These inquiries were recorded in writing and radiography staff could clearly describe this process to inspectors. However, day-to-day practice was not fully aligned with the allocation of clinical responsibility for this inquiry as documented in the hospital's

Policy for protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures.

While diagnostic reference levels (DRLs) were reviewed annually for some medical radiological procedures at the hospital, inspectors found that some DRLs at the hospital were not reviewed regularly in line with national guidance documentation. Similarly, while the majority of DRLs were in line with the national DRLs, some were found to exceed the national DRLs. A risk assessment had been conducted by MPEs at the hospital under the requirements of different legislation which did provide an assurance to inspectors that corrective actions to ensure the optimisation of medical radiological procedures had been taken. However, a formalised process to ensure that an appropriate review of medical radiological procedures found to consistently exceed national DRLs is carried out should be put in place at the hospital to ensure compliance with the regulations. This was discussed with staff and management on the day of inspection and noted as an area for improvement at MRH Mullingar.

Inspectors found that the hospital had a quality assurance programme, including performance testing, in place for medical radiological equipment. A quality assurance group had been established to provide additional oversight regarding the continued implementation of the quality assurance programme at MRH Mullingar and this was noted as an area of good practice in ensuring that medical radiological equipment at the hospital is kept under strict surveillance.

On the day of inspection arrangements were found to be in place regarding recording events involving, or potentially involving, actual accidental and unintended exposures to ionising radiation. Inspectors were also satisfied that the hospital had arrangements in place to ensure that HIQA was notified of the occurrence of significant events. However, inspectors spoke with staff and management, and reviewed documentation and other records, and identified that the analysis of non-reportable events involving, or potentially involving, accidental or unintended medical exposures, as an area for improvement at the hospital. Proactive trending of events involving, and potentially involving accidental and unintended exposures offers an opportunity for learning and would assist management in identifying and taking appropriate measures to minimise the probability and magnitude of actual incidents.

Subject to addressing areas for improvement noted in this section, inspectors were satisfied that MRH Mullingar had good systems in place to help ensure safe delivery of medical exposure to ionising radiation.

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The hospital accepted referrals from internal and external referrers, as defined in the regulations. Information about the benefits and risks associated with the radiation dose from

medical exposures in radiology was available to patients in the form of leaflets and in posters in waiting areas at the hospital.

On the day of inspection, inspectors spoke with practitioners who explained how medical exposures are justified in advance of the medical exposure. The record of justification of medical radiological procedures in advance by a practitioner was available for all medical radiological procedures reviewed over the course of the inspection. Results of a recent clinical audit of the referral process demonstrated improvements in adherence to local policies and procedures and provided assurances that MRH Mullingar had mechanisms in place to ensure that all referrals were appropriately justified by a person entitled to act as a practitioner in the regulations

Judgment: Compliant

Regulation 11: Diagnostic reference levels

MRH Mullingar had established DRLs for radiodiagnostic examinations and for interventional radiology procedures, where appropriate. Inspectors observed DRLs clearly displayed in all control rooms in poster format. While DRLs were reviewed annually for some areas at the hospital, inspectors found that not all DRLs were regularly reviewed in line with national policy. This was highlighted to staff and management as an area of improvement at the hospital.

Similarly, while the majority of DRLs were in line with the national DRLs, some were found to exceed the national DRLs. Where DRLs had been found to consistently exceed the national DRLs, a risk assessment for the particular item of medical radiological equipment had been conducted by MPEs at the hospital under the requirements of different legislation. This risk assessment provided an assurance to inspectors that corrective actions to ensure the optimisation protection and safety of patients had been taken at the hospital, however an appropriate multidisciplinary review by management and staff at the hospital to ensure the optimisation of medical radiological procedures and resultant corrective actions was not formally documented. While inspectors were satisfied that staff at the hospital demonstrated a commitment to optimisation by ensuring the implementation of the corrective actions outlined in the risk assessment, a formalised mechanism for the conduct of such reviews would provide an assurance to the HSE and management at MRH Mullingar regarding the implementation of corrective actions to ensure the radiation protection and safety of patients at the hospital.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, inspectors found that written protocols were established for standard medical radiological procedures and these protocols were available in each area where medical exposures were conducted. A programme of clinical audit was established and inspectors reviewed a sample of clinical audits conducted at the hospital. Referral guidelines for medical imaging were also available for referrers on hospital computers. The availability of these referral guidelines had been brought to the attention of referrers at the hospital by the Radiology Clinical Lead who also encouraged their use when referring patients for medical radiological procedures. This was noted as a proactive and positive finding.

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). The HSE, as the undertaking for MRH Mullingar, 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

Inspectors were satisfied that appropriate quality assurance programmes, which included an assessment of dose, were in place to ensure that medical radiological equipment at the MRH Mullingar was kept under strict surveillance. An up-to-date inventory was provided to inspectors, and documentation reviewed on the day of inspection demonstrated that regular quality control, including equipment service by equipment vendors and acceptance testing before first clinical use, was performed.

On the day of inspection, some medical radiological equipment at the hospital was identified as being past their nominal replacement dates. Inspectors reviewed records of risk assessments and the formal documentation that such equipment met the criteria for acceptability of equipment for clinical use. Inspectors did note that a prospective equipment replacement programme for medical radiological equipment was in place. However, the HSE, as the undertaking, should ensure that opportunities for the further optimisation of medical exposures in line with the technological advancements in medical radiological equipment are availed of where appropriate.

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. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status where relevant in line with the regulations. Inspectors reviewed a sample of referrals and found that an inquiry regarding the pregnancy status of the patient had taken place where required, and was recorded in writing.

However upon review of the hospital's policies and procedures, inspectors found the hospital's *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* did not recognise radiographers as practitioners. Although compliant with this regulation, the lack of consistency between the day-to-day practice and the hospital's documentation of delegation of clinical responsibility in the local radiology policy should be reviewed to ensure that the roles and responsibilities of staff carrying out the inquiry into pregnancy status are clearly allocated and understood by staff at the hospital.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were assured that arrangements were in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. Similarly, inspectors were also satisfied that the hospital had arrangements in place to ensure that HIQA is notified of the occurrence of a significant event and had taken reasonable measures to minimise the probability of re-occurrence of significant events at the hospital.

However, inspectors spoke with staff and management, and reviewed documentation and other records, and identified that the analysis of non-significant events involving, or potentially involving, accidental or unintended medical exposures, as an area for improvement at the hospital. Proactive trending of events involving, and potentially involving accidental and unintended exposures offers an opportunity for learning and would assist management in identifying and taking appropriate measures to minimise the probability and magnitude of actual incidents.

Judgment: Substantially 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	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	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	Substantially Compliant

Compliance Plan for MRH Mullingar OSV-0007363

Inspection ID: MON-0034868

Date of inspection: 08/03/2022

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	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: • Radiation Safety is now a standing item on the agenda of the Health & Safety Committee Meeting. The Radiation Safety Committee will be represented on the Health & Safety Committee by the Quality and Patient Safety Manager who sits on both committees. • The Radiation Protection Unit will bring to the attention any urgent matters related to Radiation Safety to the Quality and Patient Safety Manager for discussion at Health and Safety Committee Meetings. • Radiation Safety is also a standing agenda item on the Radiology Governance committee which meet monthly and the Quality and Patient Safety Manager also attends these meetings as well as members of the Radiation Protection Unit. • The organograms detailing the hospitals Governance Structure for Radiation Safety have been updated to show the HSE as the Undertaking under SI 256. • All Radiology policies and procedures will be reviewed and amended to clearly specify clinical responsibility for Medical Exposure, in particular roles and responsibilities of radiographers where they may act as referrers and/or practitioners.	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: • The Designated Manager has written to the HSE National Radiation Protection Office to seek reassurances that there is contribution by an MPE in preparation of technical specifications for all medical radiological equipment. Tendering for medical radiological equipment is done centrally by the HBS Procurement Office.	

• Any new medical radiological equipment assigned to the hospital undergoes a review by a multidisciplinary team including the MPE to ensure it meets the needs of the service.
• There is a significant contribution of the RPA/MPE to installation design at the hospital in the form of shielding recommendations for new installations and review of same in the format of Radiation Risk assessments.
• The RHM MPE will be involved in the annual preparation of the list of medical radiological equipment in conjunction with the RHM clinical engineering department as part of HSE National Equipment Replacement Programme.
• The Designated Manager has written to the HSE National Radiation Protection Office to highlight the need for the guidance document "Prioritising Medical Device Equipment Replacement" to include the role of the MPE.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
• The Local DRL policy will be reviewed and updated with inclusion of a review frequency for DRLs.
• A system will be put in place to review, discuss and take action on any DRLs that deviate significantly from the National DRLs.
• DRLs are currently a standing agenda item on the RSC meetings. The Radiation Safety working group (formally known as QC Committee) will report annually to the RSC on the results of any DRL reviews which they carry out.
• The 2021 General Radiography DRLs are currently being collated and will be discussed at the next Radiation Safety Committee in June 2022

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
• A memo from the HSE National Radiation Protection Office was recently circulated regarding adjustments made to the NIMIS system that have been introduced to ensure compliance with the above.
"An auto-text workflow has now been introduced into the Voice Recognition system which will enable the reporter to record the appropriate dose range on the medical report, based on international values, which is most applicable to the imaging procedure performed. The information will transfer to the medical report and provide the reader with an indication of the general exposure risk to the patient during the procedure."
• The HSE has requested that all hospitals implement this change. This change will be

discussed at the next Radiology Clinical Governance meeting.	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: • Radiation Incidents is a standing agenda item on Radiation Safety Committee Meetings. For future meetings this will include analysis and trending of non-significant events involving accidental or unintended medical exposures. This will be provided by the risk manager based on incident report forms logged on the National Incident Management System (NIMS) • Staff will continue to receive regular updates on the importance of reporting all near miss incidents to help minimise the probability and magnitude of significant events through educational sessions and staff meetings.	

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.	Substantially Compliant	Yellow	30/06/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	30/06/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Substantially Compliant	Yellow	30/06/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	30/06/2022
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for	Substantially Compliant	Yellow	30/06/2022

	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,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (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	Substantially Compliant	Yellow	30/06/2022

	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 of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			