



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Mater Misericordiae University Hospital
Undertaking Name:	Mater Misericordiae University Hospital
Address of Ionising Radiation Installation:	Eccles Street, Dublin 7
Type of inspection:	Announced
Date of inspection:	13 February 2020
Medical Radiological Installation Service ID:	OSV-0007396
Fieldwork ID:	MON-0028240

About the medical radiological installation:

The Mater Misericordiae University Hospital is part of the Ireland East Hospital Group and provides emergency, elective and urgent care for services including cancer, cardiovascular disease, spinal trauma and stroke. The hospital also provides tertiary care to hospitals within and beyond the hospital group. The hospital's radiology department provides imaging services to patients within the hospital, as well as to general practitioners (GPs) in the hospital's catchment area. Medical radiological imaging services are provided during core hours, Monday to Friday, 08:00hrs to 17:00hrs, and unscheduled care is also provided 24 hours, seven days a week (24/7). The Mater Misericordiae University Hospital conducts approximately 155,600 medical radiological procedures annually across a variety of modalities, both within and external to the radiology department, including:

- General and dental radiography
- Dual-energy X-ray Absorptiometry (DXA)
- Computed tomography (CT)
- Interventional radiology and cardiology
- Fluoroscopy
- Nuclear medicine and
- Mammography.

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
Thursday 13 February 2020	09:00hrs to 16:30hrs	Kirsten O'Brien	Lead
Thursday 13 February 2020	09:00hrs to 16:30hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

On the day of inspection, documentation outlining the allocation of responsibility to individuals for the radiation protection of service users at the hospital was reviewed by inspectors. The chief executive officer (CEO) was the designated person responsible for ensuring the radiation protection of patients and other service users undergoing medical exposure to ionising radiation at the hospital. The CEO directly reported to the Board of Directors of the Mater Misericordiae University Hospital and was a member of the Hospital Executive.

The Radiation Safety Committee was incorporated into the governance structures of the Mater Misericordiae University Hospital, which is seen as a positive measure to ensure appropriate oversight of the hospital for medical exposure to ionising radiation. The Radiation Safety Committee reported upwards to the Hospital Executive and the Quality and Patient Safety Steering Group, as well as communicating with the Radiology Directorate and the Health and Safety Committee. However, while many areas which conducted medical exposures were adequately represented on the Radiation Safety Committee, some departments and directorates did not have suitable clinical representation, in particular interventional cardiology. Inspectors noted that appropriate representation from all clinical directorates was not addressed in the updated Radiation Safety Committee terms of reference for 2020. Governance and oversight arrangements for medical exposures should be reviewed and strengthened to ensure the appropriate inclusion of all areas external to the radiology directorate.

The Mater Misericordiae University Hospital had implemented arrangements to ensure the continuity of medical physics expertise. The roles and responsibilities of medical physics experts (MPEs) were documented and inspectors were satisfied that MPEs were appropriately involved in medical radiological practices. However, radiographers' scope of clinical responsibility for medical exposures was found to be inconsistent with the formal allocation of responsibilities by the hospital. The Mater Misericordiae University Hospital must ensure that day-to-day practice is reflective and consistent with their allocation of responsibilities for the radiation protection of services users. The hospital must ensure that such delegations are clearly communicated and understood by staff so that they are aware of their regulatory requirements when taking clinical responsibility for medical radiological procedures. This will help ensure the radiation protection of patients and other service users. Local policies should align with the hospital's overarching documentation on practitioner allocation for medical exposures. The hospital should also ensure that when local policies in radiology are being updated that the correct version is appropriately documented, in line with the hospital's document management process.

Overall, while inspectors found that governance and management structures were in place at the Mater Misericordiae University Hospital, inspectors found that clear allocation of responsibility for the radiation protection of service users was not

always consistent with day-to-day practice at the hospital.

Regulation 4: Referrers

Inspectors found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at the Mater Misericordiae University Hospital. Staff were familiar with, and could articulate, the process for ensuring that only medical radiological procedures referred from referrers were performed.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that clinical responsibility for individual medical exposures was only undertaken by persons who are defined in the regulations as a practitioner.

Judgment: Compliant

Regulation 6: Undertaking

On the day of inspection, inspectors reviewed documentation such as the delegation of responsibilities by the undertaking, an organogram depicting radiation protection governance, and local policies, procedures and guidelines. Inspectors also spoke with staff and management at the hospital to establish the reporting and oversight arrangements which existed for medical exposure to ionising radiation.

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 day-to-day practices did not align with the hospital's allocation of who could take clinical responsibility for medical exposure to ionising radiation. In particular, the role of radiographers as practitioners was found to be inconsistently documented. A document detailing the delegation of clinical responsibility outlined that radiographers were not recognised as practitioners at the hospital, which differed from the hospital's other local radiation protection policies, procedures and guidelines. It is important that policies, procedures and guidelines clearly and consistently indicate the allocation of practitioner responsibility at the Mater Misericordiae University Hospital.

From documentation reviewed and communication with staff and management, the Radiation Safety Committee was identified as the main forum for providing

governance and oversight to ensure the radiation protection of patients and other service users at the hospital. While many areas which conducted medical exposures were adequately represented on the Radiation Safety Committee, some departments and directorates did not have suitable clinical representation, in particular interventional cardiology.

Considering that areas external to the main radiology department, for example interventional cardiology, can potentially result in high radiation exposure to patients, it is important that the hospital reviews the measures in place to ensure that it has good oversight of the radiation protection of services users in all areas where medical exposure to ionising radiation is used.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Over the course of the inspection, the staff at the Mater Misericordiae University Hospital demonstrated a strong commitment to optimising medical radiological procedures. The involvement and participation of core groups of staff in optimisation was identified by inspectors as an area of good practice. Practitioners, MPEs, and those conducting the practical aspects were involved in the optimisation process for all medical exposures at the hospital. Similarly, referrers and practitioners were found to be involved in the referral and justification process. Inspectors noted that radiographers were the only group of staff to which the practical aspects of medical radiological procedures had been delegated. There were a small number of instances documented locally where equipment was operated by untrained and unrecognised individuals. However, the reporting of, and consequent actions arising as a result of these incidents, was seen as positive. The Mater Misericordiae University Hospital should continue to ensure that only appropriate persons, as per the regulations, carry out the practical aspects of medical radiological procedures.

Inspectors were satisfied that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. However, day-to-day practice and policies were not consistent with the delegation of responsibility as radiographers were not recognised as practitioners locally. There was a lack of consistency and clarity regarding the roles and responsibilities of radiographers in respect of justification of individual medical exposures. This should be reviewed to ensure that day-to-day practices and local policy reflect each individual's scope of practice locally.

Judgment: Substantially 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 Mater Misericordiae University 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

The Mater Misericordiae University Hospital had arrangements to ensure that the involvement and contribution of MPEs was in line with the requirements of Regulation 20. Documentation reviewed by inspectors demonstrated that MPEs had not only contributed to quality assurance and acceptance testing, but had also implemented key performance indicators (KPIs) to ensure that regular performance testing was completed as required. Staff who spoke with inspectors indicated that MPEs were also appropriately involved in optimising medical exposures at the hospital and were actively involved in providing training in the area of radiation protection.

Judgment: Compliant

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

The Mater Misericordiae University Hospital had mechanisms in place to ensure that MPEs were appropriately involved in medical radiological procedures. For example, a dedicated MPE was found to be appropriately involved in therapeutical nuclear medicine practices at the hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection, only radiographers and radiologists and, where appropriate, specialist consultant medical practitioners such as cardiologists, were found to justify medical radiological procedures. Additionally, the Mater Misericordiae University Hospital had retained radiographers to carry out the practical aspects of medical radiological procedures in areas outside the radiology department. In the absence of new training requirements from the relevant professional regulators, as

specified in Regulation 22, this is viewed as good practice in ensuring the radiation protection of people undergoing medical exposure to ionising radiation in these areas.

Inspectors noted that MPEs at the hospital had implemented effective and proactive measures to oversee and ensure that medical radiological equipment was kept under strict surveillance regarding radiation protection. A multidisciplinary Quality Assurance and Risk Assessment Group had been set up which held fortnightly meetings to assess KPIs of quality assurance programmes and performance testing. This is a positive approach in providing assurances to the hospital of its compliance with Regulation 14.

The hospital demonstrated a strong cross-discipline culture of working to improve the optimisation of medical radiological procedures. Inspectors did note that a consolidated multidisciplinary approach to carrying out clinical audit of medical exposure to ionising radiation would provide better assurances of a comprehensive approach to audit. Clinical audit is a key tool in providing assurances to the hospital that all medical exposures are carried out safely and in compliance with the regulations. Clinical audit was acknowledged as an area for improvement by management during the inspection.

While diagnostic reference levels (DRLs) were reviewed annually for the majority of areas at the hospital, inspectors found that DRLs for areas usually associated with a lower radiation dose, such as general radiography and theatre were reviewed every three years. A more regular review of all DRLs in line with national policy was seen as an area for improvement.

The hospital was found to have a good incident reporting culture which was facilitated by the availability of a hospital-wide electronic incident reporting system. While incidents and potential incidents, involving medical exposures were recorded, inspectors found that analysis of radiation incidents, or potential radiation incidents, had not been performed.

While the Mater Misericordiae University Hospital must take action to become compliant with some regulations, inspectors were satisfied that there was no significant risks to the safety, health and welfare of service users on the day.

Regulation 8: Justification of medical exposures

Inspectors found evidence that the review of previous diagnostic information or medical records was well embedded in practice to help ensure that unnecessary exposures were avoided. Posters containing information relating to the benefits and risks associated with medical exposures were placed in the main waiting rooms. Information leaflets were also sent out with appointment letters to patients for particular medical radiological modalities, for example, nuclear medicine.

Records of medical radiological procedures were reviewed on the day of inspection

in respect of the hospital's vetting policy. While staff informed inspectors that all medical exposures were justified by a practitioner, as defined in the regulations, this justification in advance was not consistently recorded for all medical radiological procedures performed at the hospital. Furthermore, while all referrals reviewed were in writing, one of the referrals reviewed was not sufficiently legible. Management at Mater University Hospital should review the quality of hard copy referrals scanned onto the electronic system so as to ensure the requirements of Regulation 8(10) are met.

Finally, the Mater Misericordiae University Hospital did not recognise radiographers locally as practitioners; however, radiographers were found to have taken clinical responsibility for justifying individual examinations. Departmental policies and procedures were not in line with the hospital's overarching allocation of clinical responsibility and there was lack of clarity in documentation reviewed and observed clinical practice by inspectors. Documentation outlining roles and responsibilities regarding different elements of clinical responsibility should be reviewed and measures implemented to ensure consistency and clarity.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The Mater Misericordiae University Hospital had established DRLs for radiodiagnostic examinations and for interventional radiology procedures, where appropriate. Where local DRLs were reviewed, these were found to be below available national DRLs. DRLs were clearly displayed in all control rooms in poster format and a DRL policy was in place. While DRLs were reviewed annually for the majority of areas at the hospital, inspectors found that DRLs for areas usually associated with a lower radiation dose, such as general radiography and theatre were reviewed every three years. A more regular review of all DRLs in line with national policy was seen as an area for improvement.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical radiological procedures. These were available in soft copy on the shared drive and in hard copy in some control rooms. The Mater Misericordiae University Hospital had adopted referral guidelines which were available to referrers. Referrers were also informed about the availability of these at induction and on an information board for referrers in the radiology department.

On the day of inspection, information relating to patient exposure did not form part of any reports of medical radiological procedures reviewed by inspectors. Staff spoken with also confirmed that this information was not included, and management acknowledged this as an area which needs to be addressed when highlighted to them on the day.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that appropriate quality assurance programmes were in place to ensure that medical radiological equipment at the Mater Misericordiae University Hospital was kept under strict surveillance. An up-to-date inventory was provided to inspectors, and documentation reviewed on the day demonstrated that regular quality control, including equipment service by equipment vendors and acceptance testing before first clinical use, was performed.

An online system to report equipment faults was in place which provided good oversight for management and MPEs. Similarly, inspectors found evidence that an electronic system to verify the administered activity in nuclear medicine was also in place.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices in public places were observed in changing rooms and waiting areas to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Upon review of day-to-day practice, radiographers were found to take responsibility for carrying out the inquiry of the patient's pregnancy and breastfeeding status where relevant. Although this is aligned with the requirements of the regulations, inspectors found that overarching hospital policy did not recognise radiographers as practitioners. The lack of clarity between the hospital's delegation of clinical responsibility and the role of the radiographer in local radiology policies, procedures and guidelines and day-to-day practice should be reviewed to ensure that staff carrying out the inquiry into pregnancy status determination carry out their roles and responsibilities as required by the regulations.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied that the Mater Misericordiae University Hospital took reasonable measures to minimise the probability and magnitude of accidental and unintended exposures to service users. The hospital had an established electronic incident reporting system to report incidents, which automatically notified relevant management. A positive reporting culture was found to be in place at the hospital, and near misses and incidents were available for review on the day of inspection. The electronic reporting system had a mechanism to analyse incidents and potential incidents, and there was evidence that some instances had been identified and escalated to the Radiation Safety Committee. For example, reoccurring incidents from the orthopaedic department. However, inspectors found that formal analysis of radiation incidents and potential radiation incidents was not routinely or regularly performed although mechanisms were in place to analyse such incidents. This was acknowledged by management as an area for improvement.

Additionally, while the hospital reported significant events to HIOA, the majority of significant events and the reports of the results of the investigation and corrective measures of these significant events, were not submitted within the prescribed time frame. Management assured inspectors that this had been identified as an area for improvement and measures had already been implemented to ensure that all incidents were reported to HIOA within the required timeline going forward. Inspectors reviewed a specifically developed incident reporting flowchart for radiation incidents and noted that it did not outline the entire reporting process, individual responsibilities or timelines for the submission of notifications to HIOA. This may have contributed to the failure to submit the significant notifications to HIOA within the prescribed time frame and should be addressed as a matter of urgency by local management to meet the requirements of the regulations.

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	Substantially Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially 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	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant

Compliance Plan for Mater Misericordiae University Hospital OSV-0007396

Inspection ID: MON-0028240

Date of inspection: 13/02/2020

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	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: A large body of work had been completed prior to the inspection, with inconsistencies in policies identified and corrected to facilitate transition to radiographer as practitioner. Policies, such as "Justification of Medical Exposures" and "Protection of the Unborn Child from Ionising Radiation", were drafted and awaiting sign off following release of the National Scope of Practice issued by the IIRRT on the 20th February 2020. These policies have since been approved, although implementation of radiographer as practitioner has been delayed due to the intervening health crisis. The Radiographic Services Manager 2 has responsibility for implementation.</p> <p>A phased introduction of the Radiographer as practitioner is to be implemented. Phase 1 included the identification of specific elements of clinical responsibility and allocation of practitioner per element for general fixed radiography and mobile radiography. The Radiographic Services Manager 2 is responsible for implementation. Audit of the implementation will be undertaken.</p> <p>Phase 2 is the allocation of individual elements of clinical responsibility in areas such as fluoroscopy where multiple practitioners may be present for an examination. Allocation of practitioner may consider shared responsibility for some elements. The RSC is responsible for implementation.</p> <p>Further phases include planning the training required for allocation of full practitioner responsibilities to non-radiology practitioners in areas of low risk but is dependent on a national training syllabus, and will take into consideration any guidance issued by the HSE National Radiation Protection Committee.</p>	

Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: A phased introduction of the Radiographer as practitioner is being implemented. Phase 1 is the identification of specific elements of clinical responsibility and allocation of practitioner per element for general fixed radiography and mobile radiography. The Radiographic Services Manager 2 has responsibility for implementation. Audit of the implementation will be undertaken.</p> <p>Phase 2 is the allocation of individual elements of clinical responsibility in areas such as fluoroscopy where multiple practitioners may be present for an examination. Allocation of practitioner may consider shared responsibility for some elements. The RSC will be responsible for implementation.</p> <p>Further phases include planning the training required for allocation of full practitioner responsibilities to non-radiology practitioners in areas of low risk but is dependent on a national training syllabus, and will take into consideration any guidance issued by the HSE National Radiation Protection Committee.</p> <p>Medical Practitioner's, with core radiation protection training, as approved by the Medical Council under previous regulations are not permitted use of equipment without the presence of a radiographer at MMUH, except in emergencies. Further training on the new regulations was delivered by the Radiation Protection Adviser on 5th November 2019 stressing the continued presence of the radiographer. The Radiation Safety Officer addressed the issue with individual medical practitioners immediately following two occurrences of screening without the radiographer, one of which was an emergency STEMI case. This has prevented a recurrence of equipment operated without the presence of a radiographer. Any change to MMUH policy will be dependent on national guidelines as to the extra competency and skills training in radiation protection required by the regulations.</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: MMUH is satisfied that all examinations are justified in advance but recognising the limitations of the current digital systems (local RIS and NIMIS) for recording justification in advance of an examination MMUH had been developing an eVetting module for the local RIS.</p> <p>This is now in Pilot Phase, and will be first trialled in general radiography and CT for rigorous testing and audit. Once development in these areas is fully complete the eVetting module will be extended to other modalities.</p>	

A phased introduction of the Radiographer as practitioner is to be implemented. Phase 1 is the identification of specific elements of clinical responsibility and allocation of practitioner per element for general fixed radiography and mobile radiography. Audit of the implementation will be undertaken.

Phase 2 will consider allocation of individual elements of clinical responsibility in areas such as fluoroscopy where multiple practitioners may be present for an examination. Allocation of practitioner may consider shared responsibility for some elements.

Further phases will consider the training required for allocation of practitioner responsibilities to non-radiology practitioners in areas of low risk but is dependent on a national training syllabus, and will take into consideration any guidance issued by the HSE National Radiation Protection Committee.

Regulation 11: Diagnostic reference levels	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
 Following the issue of HIQA guidance on the 20th February 2020 MMUH completed changes to the DRL Policy. All DRLs have been updated in the past year, and will be updated annually by the RSO and Medical Physics using the methodologies outlined in the HIQA guidance. 2020 DRLs are available for all modalities.

Regulation 13: Procedures	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:
 This action is dependent on integration between the radiological equipment and NIMIS. MMUH previously highlighted this issue to the national NIMIS team. On the 8th February 2020 the national NIMIS Team Project Manager informed MMUH that the upgrade to NIMIS 2.0 does not include integration of patient dose information into the radiology report.
 MMUH have further written to the Chair of the HSE National Radiation Protection Committee and the National NIMIS Project Leader requesting an update on transition to compliance, and await their response.

Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <p>A large body of work had been completed prior to the inspection, with inconsistencies in policies identified and corrected to facilitate transition to radiographer as practitioner. The "Protection of the Unborn Child from Ionising Radiation" policy had been drafted and awaiting sign off following release of the National Scope of Practice issued by the IIRRT on the 20th February 2020. This policy has since been approved, although full implementation of radiographer as practitioner has been delayed due to the intervening health crisis</p> <p>A phased introduction of the Radiographer as practitioner is being implemented. Phase 1 includes the identification of specific elements of clinical responsibility and allocation of practitioner per element for general fixed radiography and mobile radiography. The Radiographic Services Manager 2 has responsibility for implementation. Audit of the implementation will be undertaken.</p> <p>Phase 2 includes the allocation of individual elements of clinical responsibility in areas such as fluoroscopy where multiple practitioners may be present for an examination. Allocation of practitioner may consider shared responsibility for some elements. The RSC will be responsible for implementation.</p> <p>Further phases includes planning the training required for allocation of full practitioner responsibilities to non-radiology practitioners in areas of low risk but is dependent on a national training syllabus, and will take into consideration any guidance issued by the HSE National Radiation Protection Committee.</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:</p> <p>Incidents are a standing item on the RSC agenda. The RSC Terms of Reference include "monitor and share the learning of both patient and staff related incidents". Since the inspection MMUH have implemented a more formal analysis of incidents reported on the National Incident Management System to be prepared and presented to the Radiation</p>	

Safety Committee on a quarterly basis, modelled on the format of analysis undertaken by the HSE National Radiation Protection Committee. The Risk Manager is responsible for preparing the analysis of radiation incidents which is brought to the attention of the Radiation Safety Committee for discussion.

In addition, work had been done prior to inspection to ensure improvements in the administrative reporting to meet the required timeframes. Of those significant incidents reported no patient harm had been identified, and all incidents were acted upon locally to ensure no significant risk to the safety, health and welfare of patients using the radiology service. The administrative delays were within a few days of the timeline.

The Incident Management flowchart pathway has been further updated to include individual responsibilities for the entire reporting process and the strict timelines for reporting to HIQA. The Risk Manager is responsible for management of external reporting.

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	31/12/2020
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	31/12/2020

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Substantially Compliant	Yellow	31/12/2020
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	30/06/2020
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	31/12/2020
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic	Substantially Compliant	Yellow	25/05/2020

	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.			
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	31/12/2021
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	31/12/2020
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry	Substantially Compliant	Yellow	31/12/2020

	under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.			
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,	Substantially Compliant	Yellow	30/06/2020
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and	Not Compliant	Orange	30/06/2020
Regulation 17(1)(f)	An undertaking shall ensure that the results of the investigation into any significant event notified under subparagraph (e)	Not Compliant	Orange	30/06/2020

	and the corrective measures to avoid such events, are reported to the Authority within the time period specified for such events by the Authority in guidelines issued by it for that purpose.			
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