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:	Mercy University Hospital
Undertaking Name:	Mercy University Hospital
Address of Ionising Radiation Installation:	Glenville Place, Cork
Type of inspection:	Announced
Date of inspection:	23 August 2022
Medical Radiological Installation Service ID:	OSV-0007403
Fieldwork ID:	MON-0035869

About the medical radiological installation:

The Mercy University Hospital Radiology Department provides an extensive range of radiological services comprising of both diagnostic imaging and interventional procedures. In 2021, the department performed approximately 60,000 examinations, providing imaging services for inpatients, outpatient, emergency referrals, as well as offering imaging services to general practitioners within the South/South West Hospital Group region. Emergency imaging provision is available 24/7/365 via on-call consultant radiologists and radiographer cover. Imaging services currently provided include:

• Plain-film imaging, including mobile radiography

• Mobile fluoroscopic imaging support for theatre, pain and endoscopy procedures

• CT scanning – a comprehensive range of CT examinations are provided, as well as CT-guided interventions

• Nuclear medicine - full range of technetium-based nuclear medicine examinations are provided for paediatric and adults patients. Scans includes static, dynamic, planar and SPECT studies. Sestamibi and Octreotide scans are also available.

• A wide range of interventional radiological procedures are available for vascular, urological, gastro-intestinal, hepatobiliary, oncology and thoracic referrals. Procedures include angioplasties, embolisations, drainages and stent insertions, biopsies, and gastrostomy/gastrojejunostomy insertions. Mercy University Hospital is also the national centre for diagnostic and interventional referrals for patients with hereditary haemorrhagic telangiectasia (HHT).

• Contrast study examinations performed include sinograms, micturating cystograms, antegrade/retrograde pylograms, herniograms, and barium specific studies including enemas, meals, swallows, and proctograms. Videofluoroscopy is also provided for Speech and Language Therapy. The radiology department participates in clinical multi-disciplinary team meetings for vascular surgery, general surgery/GI and urology, general medicine, geriatrics, oncology, paediatrics, and neurology, and we are an approved training site for the national diagnostic radiology training programme.

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 23 August 2022	09:30hrs to 15:55hrs	Maeve McGarry	Lead
Tuesday 23 August 2022	09:30hrs to 15:55hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection took place at Mercy University Hospital on 23 August 2022 to assess compliance with the regulations and to follow up on the outcomes of an inspection carried out in 2019. The previous inspection identified that considerable improvement was required with respect to the level of involvement of a medical physics expert (MPE) in the service, and also gaps in compliance were found in relation to Regulations 11, 13 and 16.

Overall inspectors found that progress had been made since the last inspection in relation to the allocation of MPE responsibility by the undertaking. A full time MPE was now employed by the hospital and was supported by an external radiation protection advisor, who was also an MPE. While acknowledging the significant work required to come into compliance with the regulations and how aspects of this work were still in progress, inspectors were satisfied that an MPE was appropriately involved in the service. Radiology staff and management informed inspectors that the service had benefited significantly from increased MPE input and on-site presence.

Furthermore, improvements were evident in relation to the system in place for policy development, oversight and approval at the hospital. Policies and procedures reviewed by inspectors were found to have been approved and were within the expected review dates. However, inspectors identified the opportunity to update the justification policy to ensure that it reflects the day-to-day practices as described by clinical staff in relation to justification of high dose procedures.

Inspectors were satisfied that only those entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at the hospital. In addition, all medical exposures for ionising radiation at the hospital were carried out under the clinical responsibility of an individual entitled to act as a practitioner as required by Regulation 10. Inspectors were satisfied from reviewing a sample of referrals and speaking with staff, that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4. However, further assurance was required by the undertaking to ensure that the referrer was clearly identifiable for referrals for CT procedures, regardless of the referral pathway.

Inspectors found that there was effective leadership, governance and management arrangements in place to facilitate the safe delivery of medical exposures at the hospital. The local Radiation Safety Committee (RSC) was supported by an operational Radiation Safety Action Group (RSAG) which was in place since 2019. The hospital was in the process of updating membership to the RSC at the time of the inspection, to ensure adequate representation from relevant clinical services and teams.

Overall, inspectors were satisfied that Mercy University Hospital had demonstrated a

commitment to ensuring the radiation protection of service users by progressing aspects of these regulations since the previous inspection. Some areas for further improvement are outlined under the Safe Delivery of Medical Exposures below.

Regulation 4: Referrers

Records of referrals reviewed on the day of inspection were found to be in line with the requirements of this regulation.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Mercy University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation and spoke with staff and management in relation to the governance arrangements in place for the radiation protection of service users. Inspectors were satisfied with the oversight arrangements for medical exposure to ionising radiation at the hospital. However, the undertaking should review the nominated designated manager to ensure it aligns with HIQA guidance and is at an appropriate level to ensure oversight of compliance of the regulations and relevant services.

The Operations Director of the hospital was a member of the RSC, which was chaired by a radiologist and this was the main forum for the oversight of radiation protection of service users. The RSC reported directly to the undertaking and also to the hospital's Clinical Governance Group which in turn reported to the Executive Management Board (EMB). Inspectors found that the terms of reference of the RSC should be updated to clarify the frequency of meetings. Inspectors were informed that additional clinical representatives from outside the radiology department had been recently co-opted onto the RSC and were due to attend future meetings. The hospital should continue to progress this to ensure adequate representation from relevant services. The RSC was also supported by the Radiation Safety Action Group (RSAG), which was an operational sub-group of the RSC.

The practical aspects of medical exposures were only carried out by practitioners at the hospital and the presence of radiographers was retained in areas where medical exposures were conducted outside the radiology department. The allocation of responsibility for justification of medical exposures was shared between radiologists and radiographers. Inspectors found that this allocation should be more clearly outlined in policy as per the day-to-day practices outlined, particularly in the context of high dose procedures such as nuclear medicine, where multiple practitioner groups were involved in justification.

The process of referrals and justification for CT services conducted outside of core working hours were outlined to inspectors. For all records reviewed, a referrer as per Regulation 5 was identifiable. However, greater assurance was required by the undertaking to ensure that unique logins are being utilised by all referrers, and that processes are consistent with local policy and compliant with the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that all individual medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. There was evidence that practitioners and MPEs were involved in the optimisation of medical exposures and examples of optimisation were provided to inspectors by members of the multidisciplinary team. Only those recognised as practitioners conducted medical exposures at Mercy University Hospital.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and from reviewing documentation that there were arrangements in place to ensure the continuity of medical physics expertise at the hospital. Inspectors were informed that there was one MPE based permanently at Mercy University Hospital who was supported through a formal arrangement with an external MPE, who provided RPA services to the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Documentation reviewed by inspectors and discussions with management and staff indicated that the MPE had contributed to aspects of this regulation including optimisation, diagnostic reference levels (DRLs), quality assurance (QA) of medical radiological equipment, acceptance testing of new medical radiological equipment and patient dosimetry. Furthermore, an MPE was involved in education and training of practitioners in relevant aspects of radiation protection and contributed to the analysis of radiation incidents with advice and dose calculations.

Judgment: Compliant

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

Inspectors were satisfied that an MPE was appropriately involved in medical radiological practices and that the level of involvement was commensurate with the radiological risk posed by services at the Mercy University Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Since the previous inspection in 2019, progress was evident with aspects of the regulations assessed under the safe delivery of medical exposures. For example, the hospital had progressed work on DRLs and updating the inventory of medical radiological equipment. However, gaps in compliance were evident, including for Regulations 13(2) and 16 which were also found during the previous inspection. Action is required by the undertaking to come into and to sustain compliance with these regulations.

In relation to Regulation 13, written protocols were in place for standard medical radiological procedures carried out at the hospital. In addition, inspectors reviewed audits carried out which included monitoring adherence with local policies. Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. While the hospital has put an interim measure in place, this did not meet requirements of this regulation and a long term solution to meet compliance with the regulation has not yet been progressed by the undertaking. Mercy University Hospital, the undertaking for this service, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures

are implemented at the hospital in relation to Regulation 13(2).

Similar to the 2019 inspection, a non-compliance was again identified during this inspection regarding the inquiry about breastfeeding for nuclear medicine procedures. Inspectors were informed that changes to practice had been implemented, as per the previous inspection's compliance plan, however, records and documentation reviewed on the day of inspection found that these changes had not been sustained. Therefore the undertaking needs to take action to ensure that compliance with this regulation is maintained.

Overall, inspectors found that the hospital had a positive approach to incident management. There was evidence that senior management had oversight of the investigations following on from an accidental or unintended exposure, and the analysis of such events was found to be comprehensive and utilised appropriate multidisciplinary resources. Furthermore, on the day of inspection, records of justification in advance were available for review for all imaging modalities. However, the undertaking should ensure that requests for all medical exposures are accompanied by sufficient medical data to fully meet the requirements of this regulation.

An up-to-date inventory of equipment and QA reports were provided to inspectors which showed that an appropriate QA programme was in place. While QA testing had been performed on the majority of equipment, inspectors found that a minority of equipment was overdue QA testing due to the reorganisation of the QA schedule and prioritisation of resources. Since the previous inspection, inspectors found that significant work was done in relation to DRLs. While DRLs were now established for most common procedures carried out at the hospital, the methodology used to regularly review DRLs should be addressed to ensure that the approach is comprehensive and is in line with published guidance.

Regulation 8: Justification of medical exposures

Information in relation to the benefits and risks associated with medical exposures was available on posters and information leaflets in the waiting areas of the Radiology and the Emergency Department. Staff demonstrated to inspectors that previous diagnostic information from procedures carried out at Mercy University Hospital and some other hospitals in the region was available for review on the hospital's radiology information system. Inspectors found that the hospital had taken a proactive approach to the consideration of previous imaging conducted elsewhere through discussions with patients and relevant signage in the waiting areas.

The local justification policy document was reviewed by inspectors which outlined the overall approach to justification at the hospital. Inspectors spoke with practitioners on the day of inspection, who explained how medical exposures were justified in advance of the medical exposures. Inspectors reviewed a sample of records of medical radiological procedures and found that all referrals were in writing and a record of justification was available for review. However, in some

records reviewed for endoscopy and theatre procedures, the referrals for medical exposure stated the name of the procedure only and were not accompanied by sufficient medical data to allow the practitioner to consider the benefits and the risk of the medical exposures. The undertaking should ensure that requests for all medical exposures are accompanied by sufficient medical data to fully meet the requirements of this regulation.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors acknowledged that much work was done by the hospital in relation to DRLs since the previous inspection in 2019. The hospital had a "*Policy and Procedure for the Use of Diagnostic Reference Levels (DRLs) and Patient Dose Audit"* which was approved in October 2020. DRLs were now established for most key areas and procedures in the hospital. However, inspectors identified that the methodology around the annual review of DRLs should be reviewed. Inspectors were informed that CT1 DRLs were reviewed in December 2021 but this review was based on a small sample size and the resultant values were then compared to the previous year's data, which were accepted for use. The hospital should ensure that the review of DLRs is comprehensive, uses contemporary data and is in line with HIQA guidance. Furthermore, staff informed inspectors that DRLs for paediatrics had not been established for all areas due to low patient numbers but that data collection was underway. The hospital should continue to progress the work on DRLs to fully meet the requirements of this regulation.

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. Inspectors reviewed a sample of clinical audits conducted at the hospital which included audits which monitored adherence to local policies on patient identification, CT timeouts, pregnancy checks and documentation of dose metrics.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. At the time of the previous HIQA inspection in 2019, the hospital were seeking to address this non-compliance through engagement with a system vendor with a timeframe set of March 2020. However, inspectors were informed that subsequently, the hospital's radiology system was significantly impacted by a cyber-

attack. While in the interim, a statement has been added to the reports indicating where dose information can be found, a long-term solution to address this gap in compliance has yet to be found by the hospital. Implementation of appropriate measures to ensure compliance with Regulation 13(2) is the responsibility of the undertaking, Mercy University Hospital, and needs to be addressed in order to ensure full compliance with Regulation 13.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in advance of the inspection. Since the previous inspection in 2019, the hospital had progressed updating some ageing medical radiological equipment on the basis of clinical priority. Inspectors were informed that any remaining computed radiography (CR) systems were upgraded or replaced by digital radiography (DR) systems. The undertaking should continue to progress and update medical radiological equipment to ensure that any ageing equipment which is on the hospital risk register is prioritised for replacement.

Policies for quality assurance and performance testing were provided to inspectors in advance of the inspection and inspectors noted that in general the equipment was kept under strict surveillance regarding radiation protection. Quality assurance, including regular performance testing for all equipment was carried out, as per local policy in the majority of cases. However, inspectors noted that the timing of annual QA for some of the mobile X-ray units was outside the time line indicated in local policy, and inspectors were informed this was due to an overall update of the schedule and competing priorities. The undertaking should ensure that all QA is prioritised to provide assurance around the safe delivery of medical exposures.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Posters were displayed in waiting rooms and public places to raise awareness in advance of medical exposures of the special protection required during pregnancy. These posters, in a variety of languages, alerted patients to inform staff of their pregnancy status.

This regulation requires that where appropriate, an inquiry is made about both pregnancy and breastfeeding status. Furthermore, for nuclear medicine, special attention should be give to justification and optimisation of a breastfeeding individual, depending on the procedure. In the 2019 inspection, inspectors found

that individuals were not routinely asked about breastfeeding prior to a nuclear medicine examination. The hospital submitted a compliance plan to HIQA which indicated that changes had been made to address this finding. However, during this recent inspection, from a sample of records reviewed for nuclear medicine examinations, inspectors found that inquiries made included pregnancy status, but not breastfeeding status. Therefore, inspectors were not assured that the measures implemented following the 2019 inspection had been sustained and the undertaking should rectify this gap in compliance to ensure that inquiries made include breastfeeding status where appropriate, as per the regulations.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

The hospital was found to have a system in place for the recording and analysis of accidental and unintended exposures. Furthermore, processes were in place to ensure that significant events were reported to HIQA within the required time frame. The analysis of reported events was found to be comprehensive, had multidisciplinary involvement and were overseen by senior hospital management. Inspectors were informed about how a previous incident, which was reported to HIQA, was followed up and how changes to practice had been put in place to minimise the probability of this type of event taking place again. In this example, the review team used relevant hospital-wide resources including a pharmacist from outside of Radiology to contribute to the review of this incident. This was deemed a positive initiative by the hospital to ensure that the study of risk involves the appropriate expertise.

The hospital was found to have arrangements in place to minimise the probability and magnitude of accidental and unintended exposures. Inspectors were satisfied that there was a good culture of reporting which was proactively encouraged by management and staff consistently reported the mechanism in place to report near misses and incidents. While potential and actual incidents were reported and recorded, from discussions with staff there was opportunity to improve the levels of reporting, particularly for low risk events such as where local procedures were not adhered to. While compliant with this regulation, there is potential to further expand reporting at the hospital to develop intelligence to minimise the probability and magnitude of accidental and unintended exposures.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
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	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	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mercy University Hospital OSV-0007403

Inspection ID: MON-0035869

Date of inspection: 23/08/2022

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: i. The Undertaking acknowledges the feedback regarding the 'Designated Manager' role and is aware of the guidance from HIQA. Due to personnel changes currently underway in the Executive Management roles in MUH, the Designated Manager role is to be transferred to the Operation's Director, who will also continue to act as Undertaking Representative until the Deputy CEO post is appointed – whereby this person will assume the Undertaking Representative role. ii. The 'frequency of meetings' as described in the Radiation Safety Committee's own 'Terms of Reference' (TOR) has been added as an agenda point for the next committee meeting. Any change to the current meeting frequency will be communicated to the Undertaking, and reflected in the TOR, and all other documentation as appropriate. iii. Amendments to the current Justification Policy will be made to specifically reflect the actual operational practice of justification within the relevant modalities. This will capture the allocation of practitioner responsibility (pertaining to justification of high-dose examinations), and under what conditions/parameters the allocation can occur. iv. A communication will be issued to all referrers reiterating the requirement to only use their personal login as issued when placing electronic radiological requests involving medical exposures.	
Regulation 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of	

medical exposures:
In order to confirm that endoscopy and theatre procedure referrals for medical exposure have sufficient medical data to allow Justification by the practitioner, MUH will ensure the following:

• A reminder will be sent to MUH clinical teams who refer for endoscopic and theatre procedures involving medical exposures, reinforcing the requirement for compliance with Regulation 8.
• All practitioners (radiographers and radiologists) will be informed of the above communication, and that only referrals with sufficient medical information for these areas can be processed, as per the Justification Policy.
• An audit will be performed at the end of Q1 2023 to verify compliance with the Regulation.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
i. HIQA Guidance regarding sample size will be fully implemented for the requisite scheduled annual local DRL review. These will then be signed-off and displayed accordingly in the respective clinical area(s).
ii. Local DRLs for paediatric patients are currently available for some clinical areas/equipment. In order to further our compliance with Regulation 11, the MPE has commenced progression of local DRLs for paediatrics in the remaining areas/modalities (with known low paediatric activity), with cognisance that the sample sizes available are currently below ideal/recommended levels.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
The MUH RIS/PACS systems are currently part of a regional ICT upgrade, with project completion expected at some point in Q1 2023. Once completed, MUH can engage with the vendor regarding the implementation of potential automated solutions to bring us into full compliance with Regulation 13. In the interim, MUH Radiology will continue to insert the following statement into all radiological reports: 'Ionising Radiation Imaging dose reports are available on request'.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
i. The MPE and Radiology will be submitting an equipment list to MUH Procurement in Q4 2022 for inclusion on the MUH's 2023 Equipment Replacement Program submission to the HSE. The radiological equipment requiring replacement will be prioritised on a risk-basis and will consider equipment age, current performance, and ability for further optimisation of patient dose.

ii. To ensure that the timings of the MPA QA schedule remain within compliance, the on-site MPE will provide notification to the Undertaking Representative if the schedule cannot be met for operational and/or availability reasons. In this event, the Undertaking will engage with the back-up MPE to ensure the QA schedule remains on target. Additionally, the wording of 'annual' will be replaced by the phrase 'within 12 months of last QA date' in all relevant documentation pertaining to MPE QA.

iii. As an aid for the MPE QA Schedule, a colour coded Excel based QA schedule for testing medical radiological equipment will be created to include the following information: Due Date, Scheduled QA Date, Completion Date and Other Information such as Scheduling issues (details to be documented if and when they arise). This will ensure that all QA is prioritised to provide assurance around the safe delivery of medical exposures regarding scheduled testing of medical radiological equipment.

Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:
In order to come into compliance with Regulation 16, MUH will ensure the following:

• Focused training to Nuclear Medicine Radiographers will be performed by the Nuclear Medicine Clinical Specialist Radiographer(s) as a priority, ensuring all staff are aware of, and compliant with, the requirement for specific enquiries as per Regulation 16 and our existing policies and SOP.
• In order to ensure only the relevant documentation is available for use within the Nuclear Medicine area, all soft-copies and hard-copies versions of non-relevant forms will be removed/deleted to minimise any risk of reoccurrance.
• The Nuclear Medicine Clinical Specialist Radiographer(s) will perform a weekly compliance audit for an initial period of 1 month to ensure compliance with the Regulation. Providing the compliance is 100%, the frequency of this focused compliance

audit shall move to quarterly to provide ongoing assurance.

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	30/11/2022
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for	Not Compliant	Orange	30/11/2022

	requesting the particular procedure, and			
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	30/11/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	31/03/2023
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	31/03/2023
Regulation 14(2)(a)	An undertaking shall implement	Substantially Compliant	Yellow	30/11/2022

	and maintain appropriate quality assurance programmes, and			
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	Not Compliant	Orange	30/11/2022
Regulation 16(3)	In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.	Not Compliant	Orange	30/11/2022