



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:	17 December 2019
Medical Radiological Installation Service ID:	OSV-0007403
Fieldwork ID:	MON-0028226

About the medical radiological installation:

Mercy University Hospital is a public acute voluntary hospital in the South/South West Hospital Group (SSWHG) providing inpatient and outpatient radiology services with up to 75,000 examinations per year. The service supports general practitioners within the SSWHG region, local hospitals and supports community medicine. The Radiology department provides an extensive range of diagnostic imaging and interventional procedures. Out-of-hours emergency services are also provided by consultant radiologists and on-call radiographers. The facility is a training site within the national training scheme for radiology registrars. Imaging services currently provided include; plain-film imaging including mobile radiography, fluoroscopic imaging for theatre and endoscopy, computed tomography including CT guided interventions and biopsies, and vascular/interventional procedures. A range of nuclear medicine examinations are provided to children and adults, including technetium based examinations and single-photon emission computed tomography (SPECT) studies.

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
Tuesday 17 December 2019	10:00hrs to 17:00hrs	Kay Sugrue	Lead
Tuesday 17 December 2019	10:00hrs to 17:00hrs	John Tuffy	Support
Tuesday 17 December 2019	10:00hrs to 17:00hrs	Maeve McGarry	Support

Governance and management arrangements for medical exposures

Inspectors found that the governance structures for radiation safety at Mercy University Hospital were clearly documented in the hospital radiation safety procedures. These arrangements reflected the allocation of responsibilities in practice for the radiation protection of service users. The Chief Executive Officer (CEO) was the designated responsible person for radiation protection at the Mercy University Hospital. This responsibility was delegated to the undertaking representative who was the deputy CEO and day-to-day operational responsibility rested with the Operations Director. In discussions with inspectors, radiology staff clearly articulated the allocation of responsibility for the protection of patients. Radiologists and radiographers were the only practitioners recognised by the hospital and were also the only registered professionals delegated with carrying out the practical aspects of medical radiological procedures.

The hospital had a Radiation Safety Committee in place. Inspectors reviewed the committee terms of reference and standard agenda items that were discussed at three meetings conducted in 2019. This committee demonstrated an effective means to advise the undertaking on matters relating to radiation protection. The undertaking representative was a member of this committee and provided a direct reporting route to the CEO. An operational sub-group of the Radiation Safety Committee was formed in 2019 and inspectors were satisfied that the establishment of this group was a positive development for radiation safety at the hospital.

Inspectors found evidence of good oversight of local policies and procedures related to radiation protection by key personnel and senior management. Minutes of the Radiation Safety Committee from 2019 evidenced that radiation related policies were reviewed and approved as a standing agenda item at these meetings. Policies reviewed by inspectors had been recently approved or were in draft, awaiting sign off by the Radiation Safety Committee. Inspectors were also informed during discussions with staff that there was an overarching hospital Policy Procedure Protocol and Guideline Committee with responsibility for overseeing and final approval of all hospital documentation.

Inspectors found that the hospital had a system in place to identify risks within the Radiology Department. By way of example, the inventory of radiology equipment provided to inspectors categorised and prioritised equipment for replacement. While inspectors were satisfied that the hospital was compliant with Regulation 14, it was noted that a significant proportion of the radiological equipment were beyond nominal replacement dates. The undertaking representative told inspectors that the age profile of radiological equipment had been identified as a risk and recorded on the hospital risk register. This issue had also been escalated externally by the undertaking through appropriate channels within the Health Service Executive to request the necessary funding to address the age profile of the equipment.

Senior management informed inspectors that the hospital had acted to address

deficiencies in radiographer and medical physics expert (MPE) staffing resources in radiology. A formal arrangement was in place with a MPE on a temporary basis during 2019, but this contract had ceased in early October 2019. Inspectors were informed that the hospital was in the process of recruiting a whole time equivalent MPE. While noting this intention to recruit a MPE, inspectors determined that the arrangement at the time of inspection did not provide the necessary assurance that there was appropriate involvement of a MPE commensurate to the radiological risk posed by the services provided and as required by the regulations. It was also evident to inspectors that ongoing resource shortages were a contributing factor in the deficiencies in the established local diagnostic reference levels (DRLs) at the hospital. It is the undertaking's responsibility under the regulations to provide and allocate the resources necessary to ensure compliance with the regulations.

Regulation 4: Referrers

Local policy stated that registered medical practitioners, nurse prescribers and radiographers were entitled to refer service users for medical radiological procedures at Mercy University Hospital. Referrals were accepted in hard copy or electronic format. Internal and external referrals viewed by inspectors were in line with regulations and the referrer was consistently identifiable. The Irish Medical Council number for each referrer was recorded where appropriate.

Inspectors noted that the specific circumstances in which a radiographer might act as a referrer were not defined within local procedures. There was no evidence of radiographer referrals as part of day-to-day practice, but key personnel described that the provision for radiographer referrals was included in policy to accommodate certain circumstances. For clarity, those circumstances should be defined in local policy to reflect clinical practice.

Judgment: Compliant

Regulation 5: Practitioners

The list of practitioners demonstrated that only radiographers and radiologists were entitled to act as practitioner at the Mercy University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

The inspectors found that governance structures in place supported radiation

protection of service users. Staff who spoke to inspectors were aware of their allocated responsibilities which was consistent with documentation reviewed by inspectors. Strong communication links were evident between the Radiation Safety Committee and the CEO of the hospital via the undertaking representative, who was a member of the Radiation Safety Committee.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were informed that the chair of the Radiation Safety Committee was a consultant radiologist who had overall clinical responsibility for medical exposures at Mercy University Hospital.

Only radiologists and radiographers were delegated the practical aspects of medical radiological procedures as outlined in local procedures viewed by inspectors. Appropriate delegation of the practical aspects of medical exposure were consistently articulated by staff who spoke with inspectors. The undertaking had limited the delegation of practical aspects to practitioners only, which inspectors were informed provided assurances that regulatory requirements were met.

There was evidence in the documentation seen by inspectors and in discussion with relevant staff that justification and optimisation of medical exposures involved the practitioner, the MPE and those entitled to carry out the practical aspects of the exposure. Draft justification and optimisation policies had been recently developed and provided a positive template for application of the regulations in practice.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

During most of 2019, an MPE was available on site two days per week on a temporary basis; however, this contract had expired on 4 October. The hospital had identified the need to increase the MPE resourcing from two days per week to five days per week on a permanent basis. At the time of inspection, the hospital was in the process of recruiting a whole time equivalent MPE. Therefore, as a gap in the MPE service was evident at the time of inspection, inspectors found that a formal arrangement to ensure the continuity of medical physics expertise was not in place and the requirements of this regulation were not met. Inspectors noted that whilst arrangements were due to be put in place in early 2020 to rectify the gap in the MPE service, this was not evident at the time of inspection and this should be progressed as a priority by the undertaking.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors noted MPE involvement with aspects of this regulation including the provision of training of staff and analysis of incidents as defined in local policy. However, inspectors noted that there was an absence of locally established DRLs for general radiography and interventional radiology. Additionally in nuclear medicine, inspectors were informed that the clinical specialist radiographer performed and was responsible for daily quality assurance and there was a lack of evidence that an MPE took responsibility for dosimetry. Noting that the Mercy University Hospital was in the process of recruiting an MPE, the involvement of the MPE in the areas outlined above represents an area for necessary improvement following this inspection.

Judgment: Substantially Compliant

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

Inspectors were not satisfied that the involvement of an MPE in medical radiological practices, as outlined in the Regulations, was being met at Mercy University Hospital at the time of inspection. The inspection team were told by the undertaking representative and other senior management representatives that the MPE contract had ceased on 4 October 2019 and access to an MPE was not properly formalised at the time of inspection. Inspectors found insufficient evidence that the involvement of an MPE was commensurate with the radiological risk posed by the practice, which included high dose procedures such as nuclear medicine and interventional radiology practices. The hospital had identified the need for increased MPE resourcing and were working towards formalising a future permanent whole time equivalent arrangement which should be prioritised.

Judgment: Not Compliant

Safe Delivery of Medical Exposures

There was evidence of good examples of practice to help protect service users from potential risks from medical exposures at Mercy University Hospital. Justification for medical exposures was clearly documented in the local radiation safety procedures, which was in line with the process consistently described by staff in discussions with inspectors. The Mercy University Hospital identified only radiologists and

radiographers as practitioners. The practitioner who justified each medical exposure was clearly identifiable to inspectors on the radiology information system.

Inspectors reviewed the information provided to service users on risks and benefits of medical exposure. Good examples of practice were evident in relation to this regulatory requirement. The waiting areas for CT and nuclear medicine had posters specific to those modalities which included information on the relative risks of those types of procedure. The waiting rooms also had an information leaflet available which had been developed by Mercy University Hospital on radiation information for patients.

Inspectors observed that protocols were in place for each medical radiological equipment in use. Comprehensive protocols were available in hard copy in clinical areas such as in nuclear medicine. Inspectors reviewed the quality assurance (QA) programme for medical radiological equipment and found that the QA programme for all medical radiological equipment was up-to-date. Documentation viewed by inspectors demonstrated that appropriate daily quality control checks were undertaken. Records evidenced that equipment in use underwent acceptance testing and equipment was deemed suitable for use. There was evidence that the hospital had prioritised equipment replacement; however, the age of the equipment had been identified on the hospital risk register as a risk.

Inspectors were satisfied that there was an appropriate system for reporting radiation safety incidents to the radiation protection officer and other key personnel. Inspectors saw that reports on radiation incidents were discussed as a standing item in Radiation Safety Committee minutes and this was confirmed in discussions with the committee members. Evidence of the analysis of actual and near miss radiation incidents was reviewed by inspectors for 2019. Inspectors found there was potential to further develop the trending of such events to ensure that the probability and magnitude of accidental and unintended exposures was minimised. There was also scope to expand staff awareness on the learning gleaned from reported radiation incidents to all staff working in the Radiology Department to minimise the probability of recurrence across imaging modalities.

For most radiological procedures, the hospital had adopted national DRLs. Inspectors found that the hospital had taken recent steps to address this gap in the nuclear medicine and CT services. Data to update local DRLs for CT had been collected in 2019 and was due to be signed off at the next Radiation Safety Committee meeting. In nuclear medicine, an audit was carried out which assessed the amount of activity remaining in syringes after the injection took place. The result of this audit was an aid to optimise the activity drawn up in each syringe. However, the lack of established local DRLs for all procedures did not meet regulatory requirements. The establishment and review of hospital DRLs has been identified as a priority for the undertaking, not only to ensure compliance with the regulation but as an additional assurance on the optimisation of all medical exposures for service users.

Regulation 8: Justification of medical exposures

The local justification policy outlined that no medical exposure shall be carried out without prior justification by a practitioner. This policy stated that only radiographers and radiologists were entitled to perform justification. Staff consistently reiterated the process of justification in line with local policy. Records of medical exposures reviewed by inspectors affirmed that only radiographers or radiologists had performed justification in advance of the exposure and the practitioner was identifiable. In practice, inspectors found that CT examinations were justified by a radiologist and general X-ray by radiographers. This distinction in the allocation of responsibilities could be further clarified in the justification policy following this inspection.

All referrals reviewed by inspectors were in writing, either in hardcopy or electronic format. Referrals reviewed included the reason for the request and clinical data was available to the practitioner performing justification. The hospital had a system for the evaluation and possible rejection of referrals for medical exposures. Inspectors viewed a folder on the hospital intranet system to store referrals which were 'pending for discussion', which were grouped under each medical team. Each medical team was to actively manage and review this folder daily, discuss with the justifying practitioner as necessary and re-submit the request for the procedure as part of the process.

The waiting areas for CT and nuclear medicine had posters specific to those modalities which included information on the relative risks of those types of procedure. The waiting rooms also had an information leaflet available which had been developed by Mercy University Hospital on radiation information for patients. The information leaflet included a table comparing the doses received in common practices to natural background information. A further example of good practice in relation to optimisation was in relation to a draft procedure which was developed for the use of carers and comforters. The procedure included the provision of risk and benefit information to carers and comforters and included a specifically developed carers and comforters consent form.

The practitioners were able to demonstrate to inspectors the availability of previous diagnostic information from procedures which took place in Mercy University Hospital and the Cork University Hospital group sites.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors found that Mercy University Hospital did not meet the requirements of Regulation 11 with respect to establishing and regularly reviewing local DRLs. Inspectors viewed the DRLs applied and used within the installation and found those

in use were largely adopted from published national DRLs. The Mercy University Hospital had established DRLs for CT in 2018 and had commenced reviewing 2019 data for CT, but these had yet to be approved by the Radiation Safety Committee. Furthermore, in general radiography and interventional radiology, local DRLs had not been established. The hospital had established DRLs for nuclear medicine and conducted an audit of optimisation of the actual administered dose in respect of the national DRL and had updated dispensing practice to reflect the findings of the audit which was seen as a positive measure.

Judgment: Not Compliant

Regulation 13: Procedures

Inspectors noted hardcopy and electronic written protocols in place in all clinical areas. Staff informed inspectors that protocols varied depending on the equipment and these differences were outlined in the local procedures. In each clinical area, staff signed the protocols to confirm they were reviewed and understood. The justification and optimisation policies provided to inspectors were in draft and were due to be ratified at the next meeting of the Radiation Safety Committee.

A sample of reports of medical radiological procedures reviewed by inspectors did not contain patient exposure information as part of the report. Staff informed inspectors that occasionally the dose from nuclear medicine examinations forms part of the report but this was not evidenced in the documentation reviewed. To ensure full compliance with Regulation 13(2), information relating to the patient exposure must form part of all reports of medical radiological practice.

Referral guidelines were available on the hospital electronic system on the referral page. An example of good practice was apparent in relation to accessibility of referral guidelines. Staff informed inspectors that previously the guidelines were available on a separate tab but to improve accessibility the link was moved and was now embedded into the referral page itself as an example of good practice.

A list of three clinical audits conducted in 2019 was provided to inspectors. Inspectors found that there was potential to improve the system of selecting audits relating to radiation protection to ensure a proactive approach. Particularly there was scope to expand assurances on justification and optimisation processes. The hospital had initiated formalising the approval and centralisation of audits through the Quality and Risk Management Department.

Judgment: Substantially Compliant

Regulation 14: Equipment

Quality assurance (QA) reports for each piece of medical radiological equipment on the inventory provided were reviewed by inspectors. There was sufficient evidence to support that the requirements of the Regulations were met by the undertaking. All equipment was deemed suitable for clinical use, with some remedial actions required following QA testing. The hospital demonstrated commitment to the assessment of dose for service users as they prioritised the retrofitting of a dose area product (DAP) meter to one of the general X-ray units based on the activity level and patient demographics in this clinical area.

An inventory of all equipment was provided to inspectors which highlighted that five of the 13 pieces of equipment at the facility were beyond nominal replacement dates. Staff informed inspectors that the equipment in the Emergency Department was prioritised for replacement due to the high workload in that area which operated a 24 hour service and included paediatrics. Inspectors were informed by senior management that business cases had been submitted to the Health Service Executive (HSE) for replacements and the age of the equipment had been identified on the hospital's risk register.

Acceptance testing was reviewed for equipment commissioned in 2019 and was found to have met criteria of acceptability of equipment requirements.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors found pregnancy checks were performed consistent with local policy. Multilingual posters and notices were observed in patient waiting and changing areas to raise awareness of the need for special protection during pregnancy.

Examples of good practice were evident in patient information leaflets in the waiting rooms which included a section on X-rays during pregnancy. In addition, samples of radiology appointment letters were reviewed by inspectors which included information for female patients on risk associated with exposures during pregnancy.

Staff informed inspectors that patients were not routinely asked about breastfeeding prior to a nuclear medicine examination and there was opportunity to update information and process in the nuclear medicine area to include special protection during breastfeeding.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The radiation safety procedures document reviewed by inspectors outlined the local mechanisms for reporting radiation incidents. A hardcopy form was used for recording and reporting such events. Staff who spoke with inspectors could articulate the process of reporting potential and actual radiation incidents in accordance with local policy. A flowchart summarising the process of incident reporting was evident in all clinical areas visited by inspectors. Radiation incidents were a standing agenda item on the Radiation Safety Committee meeting and inspectors were informed that the monthly Radiation Safety Action Group meetings provided an opportunity to discuss such events in a timely manner.

Accidental and unintended exposures were classified in local policy as near misses, non-notifiable incidents and notifiable/significant incidents. A summary of actual and potential radiation incidents recorded between March and November 2019 was provided to inspectors, evidencing that there was a system in place for recording such events. The analysis recorded in this summary included cause of the incident, actions taken and in certain cases, evidence of MPE involvement. Evidence of the analysis of actual and near miss radiation incidents was reviewed by inspectors for a period in 2019. From this analysis, the majority of such incidents reviewed by inspectors involved non-adherence to the service user identification policy and staff told inspectors that an audit of this process was due to take place in January 2020. Inspectors were informed by staff in the clinical areas that feedback on radiation incidents was generally provided to staff who worked in that particular modality, for example feedback on an incident involving CT would be communicated to the CT staff. Inspectors found that there was scope to expand staff awareness on the learning gleaned from reported radiation incidents to all staff working in the Radiology Department to minimise the probability of recurrence across modalities.

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	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Not 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	Compliant

Compliance Plan for Mercy University Hospital OSV-0007403

Inspection ID: MON-0028226

Date of inspection: 17/12/2019

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 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:</p> <p>Regulation 19(9) An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.</p> <p>Mercy University Hospital (MUH) has established the requirement of 1 WTE full-time permanent Medical Physics Expert (MPE) - (named on the 'Register of Medical Physics Experts'). The recruitment process for the MPE is now at the 'offer' stage and we are awaiting confirmation of acceptance from the successful candidate.</p> <p>It is anticipated that the MPE will be in post by end of April 2020.</p> <p>In order to ensure a level of continuity and to mitigate against the risk of no cover during the interim period, MUH have engaged with the Radiation Protection Advisor (RPA) to provide additional support for certain MPE functions as required.</p> <p>The MPE is available for consultation by phone or email until such time as the WTE MPE is appointed.</p> <p>The MPE will attend the Radiation Safety Action Group monthly meeting and contribute to items involving patient protection raised during the meeting.</p> <p>The MPE is currently involved in establishing LDRs for all modalities in the department and is reviewing the QA programme with the RPO.</p>	

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:</p> <p>Regulation 20(1) - An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2 (Requirement In Relations to Medical Exposure), Part 4 (Education, Information, Training), Regulation 21 and point (c) of Article 22(4) of the Directive.</p> <p>The appointment of the MPE will ensure the current radiological service will have access to the appropriate level of expertise and advice in a timely manner. The MPE appointment is anticipated to be in post by the end of April 2020.</p> <p>Regulation 20(2)(a) - An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,</p> <p>As identified during the Inspection, the Clinical Specialist Radiographers currently have responsibility for the daily QA and aspects of dosimetry within the Nuclear Medicine service. On commencement of the role, the MPE will take responsibility for dosimetry in particular, in accordance with Regulation 20(2)(a).</p> <p>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:</p> <ul style="list-style-type: none"> (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; <p>and</p> <ul style="list-style-type: none"> (viii) the training of practitioners and other staff in relevant aspects of radiation protection. <p>MUH acknowledge that the generation of Local DRLs had not yet been established in all areas. On commencement of the role, a priority area will be for the MPE to contribute in generating Local DRLs for the Interventional and General radiographic procedures in</p>	

accordance with Regulation 11(5), 11(6), and 11(7).

Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
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Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:

Regulation 21(1) - An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.

The MUH, through the Radiation Safety Committee, has established that the required level of MPE input commensurate with the level of radiological service and radiological risk is 1.0 WTE (whole time equivalent) on a full-time and permanent capacity. This appointment has been prioritised at hospital level, and the recruitment process is underway. The current lack of a MPE is recorded on the MUH Corporate Risk Register, and remains in escalation until the appointment is finalised.

It is anticipated that the MPE role will be in post by end of April 2020.

Regulation 21(2)(b) - In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutic nuclear medicine practices as well as in radio diagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c), a medical physics expert shall be involved

All 'high dose' examination and procedures undertaken within the MUH to-date have had the involvement of the MPE and RPA to advise on justification and optimisation practices. The MPE (and RPA) have conducted radiation risk assessments pertaining to the Interventional Service, High-dose Fluoroscopy Examinations and Nuclear Medicine. Once appointed, the MPE will provide support to all radiological practice, and in particular those examinations termed as 'high dose'.

This particular MPE function will begin immediately following commencement of the MPE (anticipated as being in post by the end of April 2020).

Regulation 11: Diagnostic reference levels	Not Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

Specific to 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.

As identified during the Inspection, Local DRLs have been established and implemented for Nuclear Medicine procedures. Local DRLs have also been established for CT examinations. These are to be re-assessed and will be reviewed at the next Radiation Safety Committee meeting in March 2020.

DRLs specific to Interventional procedures are currently being generated. This process should be completed in time for review by the Radiation Safety Committee in March 2020.

The generation of DRLs for 'general' radiographic procedures is in progress. Due to variations in equipment and manufacturer type (CR and DR technologies), this process will need to be 'equipment specific' as well as 'examination specific'. As a start point, the review of DRLs specific to the 'Carestream DR' room has now commenced. It is anticipated that all general examinations will have equipment specific local DRLs by the end of Q3 2020. As an interim measure, the use of National DRLs will continue to be used (as as a reference guide only) to indicate typical expected radiation doses.

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.

As identified during the Inspection, an audit was performed in Nuclear Medicine to ensure compliance that the 'actual administered dose' did not exceed the Local DRLs in a sample selection of procedures. This audit process of dose compliance will be applied to all areas once the LDRLs are established. The audits will be on an annual cycle for each area. All results will be reported to the Radiation Safety Committee, and any improvement opportunities will be addressed through the Radiation Safety Action Group and The Radiation Safety Committee.

Re-audit of the Nuclear Medicine DRL compliance is due in Q4 2020. Initial audits of CT and Intervention DRLs are to be scheduled for Q3 2020. Audit of dose compliance for the general radiographic procedures will be confirmed once Local DRLs are established. The requirement of an 'Annual DRL Audit Program' will be tabled at the next Radiation Safety Committee meeting.

Regulation 11(7) - An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.

Agreed. All reviews pertaining to DRL compliance and any associated corrective actions will be recorded and held for a minimum of 5 years. This will be practically achieved by

all records being held by the Radiology Department's Radiation Protection Officer, and that a second record will be documented within the Radiation Safety Committee's minutes. These will be available on request.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:

Regulation 13(2) - An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

All patient doses associated with Nuclear Medicine (administered activity), CT, Interventional, Fluoroscopy, and DR procedures are manually captured as part of the permanent patient record in the RIS at the individual examination level. For modalities that generate full dose-reports, a dose-report image is also recorded within the patient's image folder. Despite patient radiation doses being permanently recorded within the PACS/RIS environment, the current system architecture does not allow the examination 'dose' to automatically populate the final medical radiological report. As of January 2020 we have commenced engagement with the system vendor regarding the feasibility of individual dose display in the report text.

There will be a request for a Radiology PACS/RIS representative to present an update of same at the next Radiation Safety Committee meeting (March 2020) in order to progress this issue.

Regulation 16: Special protection during pregnancy and breastfeeding

Substantially Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:

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.

A quality improvement plan has been devised to address this issue. The existing departmental 'Pregnancy Status Declaration' form has been redeveloped to be specific to the service user group undergoing Nuclear Medicine procedures. In addition to the

standard 'pregnancy status' check, there is now an added section to ascertain 'breast-feeding status' prior to injection of any radio-pharmaceutical. A draft version of this form is included as 'Additional Documentation - REG 16(3)' – copy attached to email.

The patient appointment letters specific to Nuclear Medicine have also been reviewed to provide assurance that information pertaining to breastfeeding patients is included and appropriate.

The Radiation Safety Action Group will review these improvements (February 2020), update the Radiation Safety Procedures document as required, and make a recommendation for Radiation Safety Committee approval (March 2020).

All Nuclear Medicine Radiographers will require a training session of the proposed improvements and will be required to 'sign-off' same. The Radiation Protection Officer and the area Clinical Specialist(s) will be responsible for implementation.

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	30/09/2020
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	Substantially Compliant	Yellow	30/09/2020

	consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	30/09/2020
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	Yellow	31/03/2020
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		31/03/2020
Regulation 19(9)	An undertaking	Not Compliant	Orange	30/04/2020

	shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.	Substantially Compliant	Yellow	30/04/2020
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals	Not Compliant	Orange	30/04/2020

	subject to medical exposure,			
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 specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving,	Not Compliant	Orange	30/04/2020

	<p>or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.</p>	Not Compliant	Orange	30/04/2020
Regulation 21(2)(b)	<p>In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred</p>	Not Compliant	Orange	30/04/2020

	to in Regulation 15(c), a medical physics expert shall be involved, and			
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