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:	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:	20 February 2024
Medical Radiological Installation Service ID:	OSV-0007396
Fieldwork ID:	MON-0039747

About the medical radiological installation:

The Mater Misericordiae University Hospital is a level 4 academic teaching hospital situated in Dublin's north inner city. The Mater Hospital provides a range of frontline and specialist services on a regional and national level including 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 Mater Misericordiae University Hospital is a teaching hospital for UCD and has close links with other academic institutes.

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. The Mater Misericordiae University Hospital conducts approximately 212,321 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)
- Magnetic resonance imaging (MRI)
- Interventional radiology and cardiology
- Fluoroscopy
- Nuclear medicine and PET/CT
- Mammography

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).

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 20 February 2024	09:00hrs to 16:30hrs	Kay Sugrue	Lead
Tuesday 20 February 2024	09:00hrs to 16:30hrs	Kirsten O'Brien	Support
Tuesday 20 February 2024	09:00hrs to 16:30hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the Mater Misericordiae University Hospital (MMUH) was carried out on the 20 February 2024 to assess compliance with the regulations. The previous inspection conducted on 13 February 2020, identified that compliance with Regulations 6, 8, 10, 11, 13, 16 and 17 needed to improve. The inspectors noted that corrective measures outlined in the compliance plan provided after the 2020 inspection had been implemented and the undertaking at MMUH now complied with Regulations 10(3)(a), 11, 16 and 17. However, despite the actions taken to come into compliance with the remaining regulations, inspectors found during this inspection that further action was needed by the undertaking to improve the allocation of responsibility required under Regulation 6(3) which had implications for compliance with other regulations including Regulations 4, 8, 10 and 14.

Inspectors visited several modalities during this inspection including nuclear medicine, computed tomography (CT), interventional cardiology, interventional radiology and mammography services. In addition, documentation and records from medical radiological procedures for a range of modalities within the radiology service were reviewed. Inspectors also spoke with staff and management working in each of the areas visited and senior management during this inspection.

Documentation and a chart that detailed the MMUH radiation management governance in 2024 was reviewed by inspectors. A radiation safety committee (RSC) was in place that reported upwards to the Chief Executive Officer (CEO) who was the chair of the RSC, the designated manager and the person with responsibility for the radiation protection of service users. The RSC terms of reference outlined a dual reporting structure as part of the Radiology Directorate that included regular reporting to the Hospital Executive and the Health and Safety Committee.

Inspectors found that the undertaking had ensured that medical physics experts (MPEs) were engaged for the radiology service and continuity arrangements were in place. The evidence gathered from discussions with staff and documentation reviewed satisfied inspectors that MPE involvement in medical radiological procedures was proportionate to the radiological risk associated with the practices at MMUH, therefore compliant with Regulations 19(9), 20 and 21. Inspectors were satisfied that practitioners, as per the regulations, were found to take clinical responsibility for medical exposures performed at the hospital in line with Regulation 5. Staff informed inspectors that a multidisciplinary approach was taken in the interventional cardiology service to discuss each planned procedure in advance in daily huddles. Inspectors found this to be an example of good practice as it offered an opportunity to discuss any potential issues that may arise when reviewing clinical history and provided additional assurance to the practitioner regarding the justification of each medical exposure.

However, notwithstanding the examples of good practice found on the day of inspection, areas of non-compliance were also identified by inspectors. Despite the

measures implemented to address the gaps in compliance with Regulation 6(3) since the last inspection, more action was required by the undertaking to ensure that responsibilities were appropriately assigned to individuals recognised in the regulations and that all aspects of the allocation of responsibilities were clearly defined. For example, inspectors identified a non-compliance regarding the allocation of responsibility for persons entitled to act as referrers at the hospital as detailed under Regulation 4. The findings in relation to Regulation 4 also impacted compliance with Regulation 10(3)(b) and had implications for the process of justification in advance of medical radiological procedures where the input of the referrer informs the justification process. The undertaking was required to submit an urgent compliance plan under Regulation 4 to address this non-compliance identified on inspection. The undertaking's response provided an assurance that the risk was adequately addressed.

Other areas regarding the allocation of responsibility also required improvements. For example, in each of the areas visited, inspectors were consistently informed by staff that radiographers and radiologists were the only recognised practitioners at the MMUH. However this did not fully align with the allocation of responsibilities for justifying procedures in the hospital policy viewed. In addition, while the practical aspects of medical exposures performed at the hospital were only carried out by persons recognised in the regulations, designated roles of MPEs delegated with some of the practical aspects in therapeutic nuclear medicine practices needs to be further defined and documented to meet the requirements of Regulation 10(5). Finally, steps initiated on formalising the pathway to review and approve new practices that require generic justification by HIQA should be implemented. A formalised approach should provide greater assurance to the undertaking that persons engaged or employed by it did not or do not carry out a new type of practice involving medical exposure unless it has first been justified by HIQA, as required by Regulation 7.

Overall, inspectors noted that there were several examples of good practices evident throughout this inspection that demonstrated the commitment of staff to the radiation protection of service users subject to medical exposures at the hospital, in a radiology service that has high activity levels and consistently provides complex safely delivered procedures each day. The assurances of management on the day and through the corrective actions outlined in the response to the urgent compliance plan received satisfied inspectors that appropriate actions would be taken to further improve compliance with the regulations and to ensure the continued radiation protection of service users attending the hospital.

Regulation 4: Referrers

Inspectors reviewed the document *Procedure for referrers of medical radiation exposure* as part of the review of documents requested in advance of this inspection. This document was approved for use on 7 December 2023 and outlined the systems and processes in place for referring patients for medical exposures

across a range of modalities in MMUH. Inspectors identified processes for referral in a number of settings within radiology services where the referral responsibility was allocated to personnel not allowed to act as a referrer as per the regulations.

Inspectors spoke to staff and management and reviewed records across several settings to verify compliance with regulations regarding referral practices. Inspectors noted that a referrer, as per the regulations, was identifiable in the majority of referrals viewed. However, in settings where the delegation of referral rights occurred such as the orthopaedic fracture clinic and the breast health unit, records viewed showed that a written referral from a referrer was not available for six medical radiological procedures carried out at the hospital. Staff confirmed to inspectors during discussions that orders were created on the electronic ordering system by staff members without a written referral from a person entitled to refer, therefore, did not comply with the requirements of Regulation 4(1). Consequently, compliance with Regulation 4(2) was also impacted as the records of medical radiological procedures viewed indicated that they were performed on the basis of referral from a person other than a referrer which was not in line with regulations.

Overall, inspectors found that referral practices as described in the procedure above and evidence seen in records during the inspection required immediate review and actions taken to ensure that the delegation of referral rights to persons not recognised under Regulation 4 is ceased immediately. In addition, greater assurance and monitoring is required by the undertaking to ensure that access rights to electronic ordering systems for medical radiological procedures is restricted to referrers recognised under the regulations. This non-compliance with the regulations was discussed with staff and management at the hospital on the day and appropriate assurance was provided that this issue would be addressed.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 5: Practitioners

Only those entitled to act as practitioners as per the regulations were found to take clinical responsibility for medical exposures in the radiology department on the day of inspection. Radiographers and radiologists were the practitioners for all medical exposures conducted in this facility.

Judgment: Compliant

Regulation 6: Undertaking

The governance, management and oversight arrangements in place for the radiation protection of service users at the MMUH were reviewed by inspectors. The MMUH was the undertaking for this facility and had a RSC in place that met twice a year. This committee was chaired by the CEO of the hospital who was also the designated manager and the person responsible for the radiation protection of service users at the hospital. A number of sub-committees reported into the RSC including the Radiation Protection Unit (RPU), Quality Control (QC) Radiology Committee, Radiology Nursing Meeting and Quality Assurance Committee.

RSC terms of reference and minutes from this committee's meetings, viewed by inspectors, showed that there was multidisciplinary membership with good attendance at each meeting. Inspectors were informed that the CEO, or representative, attended each meeting and was the communication link up to the board of the hospital. Inspectors were informed by senior management that the board of MMUH receives a report from the Radiology Directorate every four weeks that outlines radiology activities and risk register items and staff representing the Radiology Directorate also present a report to the board at allocated intervals. From the evidence gathered, it was clear to inspectors that there were direct and effective reporting structures in place for the communication of radiation protection issues to the undertaking. However, inspectors noted that documentation provided outlining the radiology governance arrangements should be updated to include the reporting line up the undertaking at MMUH.

Under this regulation, it is the undertaking's responsibility to provide a clear allocation of the responsibilities for the radiation protection of service users and the undertaking is also responsible for ensuring that employees engaged by it comply with the regulations. The undertaking had ensured that practitioner roles were allocated to the appropriate staff as per the regulations. There was also evidence to show that an MPE was engaged for the service with appropriate contingency arrangements for the continuity of MPE services provided by MPE resources in the medical physics team.

While inspectors found that some aspects regarding the allocation of responsibilities were evident, the following aspects regarding the allocation of responsibilities needed action to improve compliance with Regulation 6(3). As previously discussed under Regulation 4, the undertaking at MMUH had not ensured that responsibility for referring was only allocated to referrers, as recognised in the regulations, for all medical radiological procedures performed in the hospital. This finding also meant that more assurance was needed to ensure that a recognised referrer was involved in justification of each medical radiological procedure as required under Regulation 10(3) and that justification in advance is consistently recorded as required under Regulation 8. Additionally, inspectors noted improvements were required in documentation regarding the individual delegation of the practical aspects of responsibilities allocated to MPEs working in the nuclear medicine setting which were not evident during the inspection.

Finally, with regard to Regulation 7, the generic justification of new practices, inspectors noted that an application for a new practice had been made to HIQA.

Staff described to inspectors the processes applied for making this application. Inspectors were informed that all procedures were coded to track activities and new practices had to first be approved and reviewed by the radiology directorate team in advance of approval by the undertaking before submitting to HIQA. However, inspectors noted that the processes as described were not formalised or documented in local policy. In addition, inspectors noted no process was in place to review if any new practices had been implemented since the commencement of the regulations in January 2019. Inspectors were informed that a business case template was being developed for all future applications for new practices. Inspectors identified that a more formal approach was required at the hospital to determine if new practices need generic justification before being generally adopted into regular practice.

Overall, since the last inspection, and despite measures implemented by the undertaking to come into compliance with this regulation, more action needs to be taken to comply with all aspects regarding the allocation of responsibilities as per Regulation 6(3). Similar to the 2020 inspection, inspectors found established governance and management arrangements need to be strengthened to ensure greater oversight of medical radiological practices and compliance with the regulations.

Judgment: Not Compliant

Regulation 10: Responsibilities

During the 2020 inspection, inspectors found that all medical exposures took place under the clinical responsibility of a practitioner which was consistent with the findings of this inspection. Inspectors identified that the clinical responsibility for the medical exposure which formed part of a surgical or interventional cardiology procedure was allocated to a practitioner under the regulations. Inspectors noted that in the interventional cardiology service, a multidisciplinary approach was taken by staff to discuss the list of procedures during daily team huddles before justification of the medical exposure was carried out by a practitioner. Inspectors found this to be an example of good practice to ensure that all relevant clinical data and patient details were reviewed to inform the process of justification in advance of the planned medical exposure.

Inspectors were satisfied that practitioners and MPEs were involved in the optimisation process as per the regulations. The undertaking had taken action to address the gaps in compliance in relation to Regulation 10(3)(a) by ensuring that a recognised practitioner was present for all medical radiological procedures performed at the hospital. Inspectors found this to be an example of the commitment by staff to the radiation protection of service users. Improvements were also seen in which the practical aspects were now only delegated to individuals recognised in the regulations who had the appropriate training. However, to improve compliance further, improvements were required regarding the record of each

specific delegation of the practical aspects to an MPE required under Regulation 10(5). Additionally, corrective measures implemented to address Regulation 4 should also improve compliance with Regulation 10(3)(b).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

From speaking with staff and management, inspectors were satisfied that there was appropriate arrangements in place to ensure the continuity of medical physics expertise as needed at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Current MPE professional certification records were viewed by inspectors and demonstrated that a team of MPEs were involved and contributed to radiological practices and the radiation protection of services users at the hospital.

The inspectors were satisfied that MPEs took responsibility for dosimetry and contributed to a range of responsibilities relating to medical radiological practices within the hospital, as per Regulation 20(2). The evidence gathered demonstrated MPE involvement in the optimisation of medical exposures, their contribution to the quality assurance (QA) and acceptance testing of medical radiological equipment. MPEs contributed to the review and approval of facility diagnostic reference levels (DRLs) and had also initiated a review of DRLs in nuclear medicine following the publication of national DRLs in November 2023. Inspectors found this to an example of good practice and a proactive approach to ensuring facility DRLs aligned with national DRLs. Additionally, inspectors were satisfied that an MPE provided advice and dose calculation for radiation incidents. Inspectors noted MPE attendances and input at RSC and RPU meetings and also their contribution to staff training in relevant aspects of radiation protection.

Judgment: Compliant

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

From discussion with staff and documentation review, inspectors were satisfied that MPE involvement in medical radiological practices was proportionate to the level of

radiological risk associated with practices at MMUH and also focused on services associated with high doses. For example, an MPE resource was dedicated to therapeutic nuclear medicine practices and inspectors were informed that an MPE was also involved in interventional cardiology practices as per Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited a range of radiology services provided at this facility, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at MMUH. The evidence viewed showed that measures implemented by staff at the hospital since the previous inspection had resulted in compliance with Regulations 11, 16 and 17. Compliance was also found with Regulations 9 and 15, however, further work was needed to bring Regulations 8, 13 and 14 into compliance.

Examples of good practices were identified by the inspection team in relation to a clinical audit undertaken which was focused on the optimisation of medical exposures in relation to computed tomography of kidneys, ureters and bladder (CT KUB). Another area of good practice related to the processes in place to manage potential skin damage associated with procedures involving skin exposure to high radiation doses.

Inspectors were satisfied that facility DRLs were established and reviewed regularly and a proactive approach was taken to ensure that facility DRLs were aligned with national DRLs, thereby complying with Regulation 11. This approach was evident in a recently commenced review of the nuclear medicine procedures to ensure that facility DRLs in this service aligned with recently published national DRLs in nuclear medicine .

Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters in waiting areas and as part of patient information leaflets provided to patients undergoing certain procedures which were evident in areas visited such as the nuclear medicine service and interventional radiology procedures. Following the assessment of the justification processes, inspectors found gaps in the records of justification viewed, which was evident in a number of settings, thereby, not compliant with Regulations 8(8) and 8(15). More assurances was also required to ensure that each medical exposure was justified on the basis of a written referral from a recognised referrer as required in Regulations 8(10) and 8(11).

Inspectors found that staff at the hospital had implemented corrective measures to ensure that information relating to the patient exposure formed part of the report of medical radiological procedures. While the majority of reports viewed showed

evidence of compliance with this regulation, some did not. Therefore, more action was required by the undertaking to comply with Regulation 13(2).

In relation to Regulation 14, inspectors found some gaps in compliance in the evidence viewed. For example, an omission of one piece of medical radiological equipment from the quality assurance (QA) programme meant that annual QA by an MPE had not been completed since acceptance testing had been performed in April 2021, therefore, impacting compliance with Regulation 14(2)(a). As a example of the undertaking's commitment to addressing this issue, inspectors were informed that this gap was promptly addressed and QA was completed by an MPE while the inspection was ongoing. Other gaps were identified in relation to information provided in the inventory of medical radiological equipment that needed to be updated in line with the requirements of Regulation 14(10). Stronger oversight of hospital key performance indicators (KPIs) for regular quality performance testing of medical radiological equipment was also required to ensure that sub-optimal levels reported in 2023 are addressed and to comply with Regulation 14(3)(b). In light of these findings, inspectors found that greater assurance in relation to the strict surveillance to all medical radiological equipment was required to comply with Regulation 14 (1).

The measures implemented to address non-compliances found during the previous inspection demonstrated the undertaking's commitment to comply with the regulations. As a result, compliance had improved with some aspects of the regulations as previously mentioned. Management at the hospital provided assurances to inspectors that the necessary follow up corrective measures would be implemented to address additional gaps in compliance identified during this inspection. In addition, actions taken by staff on the day to address identified issues in relation to the QA of a unit of equipment again demonstrated the staff's commitment to the radiation protection of service users and to comply with regulations.

Regulation 8: Justification of medical exposures

Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters in service user waiting areas. Additional information was also provided in patient information leaflets for service users undergoing medical radiological procedures, such as, procedures performed in the interventional cardiology service. Inspectors were informed that a patient survey was underway in relation to the benefit of information to patients contained in patient information leaflets provided in the facility's nuclear medicine services

Inspectors reviewed the document titled *Procedure for Justification of Medical Radiation Exposure* that outlined the justification pathway and persons designated with the practitioner role of justifying each procedure. Inspectors were informed in each area visited, that radiologists and radiographers were the only persons entitled to justify a medical exposure in MMUH. While all staff listed were entitled to act as a

practitioner under Regulation 5, the allocation of the practitioner role for justifying procedures to non-radiologist consultants was not consistent with practices described to inspectors. Therefore, to provide greater clarity for staff, inspectors identified that the documented allocation of responsibility for the justification of medical exposures by a practitioner should be reviewed and clearly delineated to remove ambiguity.

As previously discussed under Regulation 4, a referral from a recognised referrer was not consistently evident to inspectors in some records viewed, therefore, full compliance with Regulations 8(10) and 8(11) was impacted. Furthermore, from the sample of records viewed across a range of settings in the radiology service, inspectors noted that justification in advance as required by Regulation 8(8) was not consistently recorded for all medical exposures in line with Regulation 8(15).

Judgment: Not Compliant

Regulation 9: Optimisation

Inspectors were assured, from documentation viewed and discussions with staff, that doses due to medical exposures were kept as low as reasonably achievable (ALARA) while also providing relevant information in relation to the diagnostic objective of the examination. The *Procedure for Optimisation of Medical Radiation Exposure* detailed standard approaches to the optimisation of procedures to be taken by staff during the practical aspects of medical radiological procedures.

Inspectors saw evidence that optimising radiation dose was a focus of clinical audit conducted in the computed tomography (CT) service. For example, an audit titled *Optimising radiation dose in computed tomography of kidneys, ureters and bladder (CT KUB)* outlined the results of a series of retrospective audits undertaken by a multidisciplinary team in relation to CT KUB studies between September 2020 and February 2024. The objectives outlined in the audit report viewed by inspectors aimed to assess the imaging techniques applied for the sample size reviewed, to quantify the effective doses associated with optimised and non-optimised studies and also quantify facility DRLs for KUB scans. The findings of the audits completed in February 2024 demonstrated that in 89% of the studies reviewed, a recommended scan range was applied by radiographers resulting in the optimisation of the radiation dose. Alternatively, in studies where non-optimal scan ranges were applied, the effective dose increased. The high level of compliance found in this audit had improved from the initial compliance found during the 2020 audit. Audit findings were shared with staff through email, educational posters displayed in CT clinical areas and short presentations. Staff at the hospital continued to monitor the optimisation of CT KUB studies as part of an audit and quality improvement cycle which was seen by inspectors as an example of good practice.

In the nuclear medicine service, staff commenced a project to review facility DRLs to ensure alignment with recently published national DRLs. An optimisation project was

underway which was focused on reviewing set doses of administered activity together with the patient weight to determine if radiation doses could be optimised further.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors noted that the actions taken by the undertaking following the 2020 inspection had resulted in compliance with Regulation 11. Facility DRLs were evident to inspectors in documentation viewed in advance of this inspection. Facility DRLs were displayed in control rooms visited for staff to reference against national DRLs when carrying out medical exposures and reviews were carried out as required.

Judgment: Compliant

Regulation 13: Procedures

Inspectors were satisfied from a review of documentation that protocols were available for each standard adult radiological procedure provided in each of the settings visited by inspectors, thereby, meeting the requirements of Regulation 13(1). As required by Regulation 13(3), inspectors saw that referral guidelines were available for staff and referrers on computer desktops located in control rooms in each radiological service visited.

Inspectors saw evidence of clinical audit and were informed that staff at the hospital had initiated steps towards establishing a clinical audit strategy that would incorporate the principles and essential criteria set out in the *National Procedures for Clinical Audit of Medical Radiological Procedures* into the hospital's established clinical audit programme.

In relation to Regulation 13(2), inspectors noted that staff had implemented measures to come into compliance with this regulation where a standard script that provided information relating to the patient exposure was auto populated into each report. A review of medical radiological reports however, found that while the majority of reports viewed had this script included, some did not. This indicated that more action was needed by the undertaking to achieve compliance with this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

Over the course of the inspection, the processes and procedures in place to ensure that all medical radiological equipment was kept under strict surveillance regarding radiation protection were reviewed by the inspection team. Inspectors spoke with staff involved in the regular QA and performance testing of medical radiological equipment and reviewed relevant records to demonstrate that regular performance testing and maintenance of equipment was carried out.

Inspectors found that a quality assurance program was implemented at the hospital. Adherence to the QA programme was monitored through a number of sub-committees that reported to the RSC which was evident in the minutes reviewed. There were also KPIs to monitor and trend regular performance testing of medical radiological equipment for each quarter, such as KPIs for QA by the physics team and QA by the radiation protection officer. Despite the multiple arrangements in place to ensure the strict surveillance of medical radiological equipment required by Regulation 14(1), some weaknesses were identified leading to gaps in compliance. For example, during a review of annual QA records, inspectors identified that all but one unit, a C-arm, had been subject to annual QA. Inspectors viewed acceptance testing for this unit which was completed in April 2021, however records demonstrating that QA by an MPE had been completed since 2021 up to the time of the inspection were not available. The omission of the C-arm from the MPE QA list was described by staff as an oversight and inspectors were informed this issue was promptly addressed and QA of the equipment was performed before the end of the inspection. However, inspectors identified that the QA programme should be reviewed to ensure the QA programme appropriately includes all units of medical radiological equipment in use at the hospital and to ensure full oversight and to comply with Regulation14(2)(a).

Other areas of improvement were also identified by inspectors. For example, quarterly 2023 KPIs reports, as mentioned above, were not achieved in three out of four quarters reported in that year. Assurances were provided by management that action would be taken to improve oversight and to ensure compliance with Regulation 14(3)(b). Additionally, the inventory of medical radiological equipment provided in advance of this inspection and reviewed on site, needed to be reviewed for accuracy and to ensure it is up-to-date to improve compliance with Regulation 14(10).

Overall, the evidence gathered by inspectors in relation to the QA and regular performance testing meant that action was needed by the undertaking at MMUH to ensure there is strict surveillance of medical radiological equipment required under Regulation 14(1) and that appropriate corrective actions are implemented to improve compliance with all aspects of Regulation 14.

Judgment: Not Compliant

Regulation 15: Special practices

Inspectors visited the interventional cardiology and interventional radiology services and spoke with staff involved in carrying out procedures there. Inspectors viewed the document *MMUH Procedure for Management of Potential Skin Burns* that outlined the steps to be taken to ensure that service users who had received a high skin dose during a procedure were appropriately followed up. This process was also described by staff to inspectors. Staff informed inspectors that a practitioner was present to optimise and monitor radiation doses throughout each procedure which provided assurance that potential high doses to the skin were identified and followed up as required. Inspectors viewed systems to record the justification of each procedure and the record of the radiation dose. An electronic dose log was evident with an inbuilt alert which was triggered when the radiation dose in a procedure had reached a threshold associated with an increased risk of tissue damage occurring following the procedure. In addition, a labelling system was evident to record the radiation dose for each procedure which also included a red label to clearly identify a high dose procedure where the Air Kerma had reached 5 Gray (Gy). Information leaflets were available to service users which contained information relating to potential skin reactions that may occur following high dose procedures.

Overall, inspectors were satisfied from reviewing the systems in place, and discussions with staff, that special attention was given to optimising medical exposures involving high doses to the patient as per Regulation 15.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors spoke with staff and reviewed the records relating to pregnancy queries undertaken prior to performing a medical exposure on female patients of childbearing age. Staff informed the inspectors that enquiries were made by a practitioner with input from a referrer. During the course of the inspection, the inspection team noted that multiple notices were displayed in service user waiting areas in services visited. The involvement of the practitioner and referrer in pregnancy enquiries made in several modalities visited was also evident in relevant medical radiological procedure records viewed by inspectors. The evidence gathered therefore, demonstrated compliance with this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Since the previous inspection, inspectors found that measures had been implemented by the undertaking to ensure that prescribed timelines for notifying HIQA of significant events and associated documentation were met. This was evident in the adherence seen to specified timelines for significant events received since the 2020 inspection.

Inspectors viewed the electronic system used for the reporting of radiation incidents and staff consistently described to inspectors how each incident was reported which was found to align with the processes outlined in the *MMUH Incident Management Policy* viewed in advance of this inspection. Inspectors noted that this document contained a radiation incident management pathway that outlined staff roles and responsibilities for the reporting and management of radiation incidents from staff working in the clinical area up to senior management via the Quality and Patient Safety Directorate. From the evidence gathered, inspectors were satisfied that the actions taken aligned with those outlined by the undertaking in its compliance plan following the last inspection and were sufficient to meet the requirements of Regulation 17.

While the undertaking at the MMUH demonstrated compliance with this regulation, inspectors determined that there was potential scope to improve the identification and reporting levels of non-reportable radiation incidents and potential incidents reported which were relatively low when considered in the context of the level of activity within the radiology service overall and the number of procedures associated with higher doses carried out at the hospital each year.

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	Not Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not 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	Not Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Not Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mater Misericordiae University Hospital OSV-0007396

Inspection ID: MON-0039747

Date of inspection: 20/02/2024

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 4: Referrers	Not Compliant
Outline how you are going to come into compliance with Regulation 4: Referrers: Amendments were made to Procedure PPC-RAD-RS-15 Procedure for Referrers of Medical Radiation Exposure to provide greater clarity on the process for referrals following review of workflow practices for gaps in compliance with legislation and implementation of measures, including additional verification step to assure compliance. This was updated to Procedure number PPC-RAD-RS-27 Procedure for Referrers of Medical Radiation Exposure and was approved by the chair of the Radiation Safety Committee on 18th March 2024 and circulated to staff via communique issued by CEO to all staff outlining the requirements for compliance with regulation. CA24-081 Referrer Compliance Audit will be completed twice yearly commencing Q2 2024.	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Amendments will be made to MMUH Policy PPC-RAD-RS-09 Radiation Protection of Patients improving documentation to reflect governance and responsibilities and to more clearly outline the Justification of New Practices (Regulation 7). This will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff. Amendment will also be made to Procedure PPC-RAD-RS-13 Procedure for Practitioners of Medical Radiation Exposure improving documentation regarding the individual delegation of the practical aspects of responsibilities allocated to MPEs. This will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff.	

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
Amendment have been made to Procedure PPC-RAD-RS-27 Procedure for Referrers of Medical Radiation Exposure to reflect more clearly the role of recognised referrer. This was approved by the chair of the Radiation Safety Committee on 18th March 2024 and circulated to staff.

Amendments were also made to Procedure PPC-RAD-RS-13 Procedure for Practitioners of Medical Radiation Exposure to include details of delegation of practical aspects to an MPE in Nuclear Medicine. A supporting procedure has been drafted PPC-RADNUCMED-26 MMUH Procedure – Roles and Responsibilities for MPE's in Nuclear Medicine. This document will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff.

Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Amendment have been made to Procedure PPC-RAD-RS-27 Procedure for Referrers of Medical Radiation Exposure to reflect more clearly the role of recognised referrer. This was approved by the chair of the Radiation Safety Committee on 18th March 2024 and circulated to staff.

Further amendments will be made to Procedure PPC-RAD-RS-16 Procedure Justification of Medical Exposures to reflect more clearly the role of recognised practitioner in the justification procedure. This document will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff.

CA24-029 Justification of ionising radiation imaging procedures audit will be completed twice yearly commencing Q2 2024.

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Amendments will be made to MMUH Policy PPC-RAD-RS-09 Radiation Protection of Patients improving documentation to outline more clearly the requirement for consistently recording information relating to patient exposure as part of the report of the medical radiological procedure. This will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff.	
Regulation 14: Equipment	Not Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Amendments will be made to Procedure PPC-RAD-RS-12 MMUH Procedure - Equipment Management of Medical Radiological Equipment to support compliance with the QA programme for all units of medical radiological equipment in use in the hospital. This will be approved by the chair of the Radiation Safety Committee on 17th May 2024 and circulated to staff.	

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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Red	18/03/2024
Regulation 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a practitioner unless	Not Compliant	Red	18/03/2024

	the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),			
Regulation 4(1)(c)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),	Not Compliant	Red	18/03/2024
Regulation 4(1)(d)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or	Not Compliant	Red	18/03/2024
Regulation 4(1)(e)	A person shall not refer an individual for medical	Not Compliant	Red	18/03/2024

	radiological procedures to a practitioner unless the person referring ("the referrer") is a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner.			
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	18/03/2024
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	Not Compliant	Orange	17/05/2024

	to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
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 specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Orange	17/05/2024
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Substantially Compliant	Yellow	17/05/2024
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 requesting the particular procedure, and	Substantially Compliant	Yellow	17/05/2024
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	Substantially Compliant	Yellow	17/05/2024

	data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).			
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	17/05/2024
Regulation 8(12)	The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposure.	Substantially Compliant	Yellow	17/05/2024
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	Not Compliant	Orange	17/05/2024

	Authority on request.			
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Substantially Compliant	Yellow	17/05/2024
Regulation 10(5)	An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	17/05/2024
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	17/05/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Orange	17/05/2024
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	17/05/2024
Regulation 14(3)(b)	An undertaking shall carry out the following testing	Not Compliant	Orange	17/05/2024

	on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	18/03/2024
Regulation 14(11)	An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	17/05/2024