



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Merlin Park University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	EC5, Old Dublin Road, Galway
Type of inspection:	Announced
Date of inspection:	20 March 2024
Medical Radiological Installation Service ID:	OSV-0008720
Fieldwork ID:	MON-0042756

About the medical radiological installation:

Merlin Park University Hospital delivers plain film, fluoroscopy, ultrasound, interventional radiology and orthopaedic services.

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
Wednesday 20 March 2024	10:00hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 20 March 2024	10:00hrs to 15:30hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection of the DXA and general X-ray departments at Merlin Park University Hospital was carried out on the 20 March 2024 to assess compliance with the regulations. On the day of inspection, inspectors reviewed documentation and records and spoke with staff.

Merlin Park University Hospital operates within the larger Saolta Hospital Group and the Health Service Executive (HSE) is the undertaking with overall responsibility for the radiation protection of service users in this hospital. Local responsibility for the radiation protection of service users lay with the Galway University Hospitals General Manager (GM). Staff at Merlin Park University Hospital used a radiation safety committee (RSC) to direct and enforce radiation safety policy in line with all relevant regulations and best management practices. A radiation protection unit (RPU) is also used for operational radiation safety issues.

While the relevant responsibilities and lines of communication regarding the protection of service users was consistently articulated during the course of the inspection some work was required to ensure that radiation safety documentation satisfied all regulatory requirements, used current regulatory language and reflected day-to-day practice at Merlin Park University Hospital. Also more work was required by the hospital to ensure that all areas using ionising radiation are present within the radiation safety platforms and communication pathways used by Merlin Park University Hospital to facilitate service improvement through improved regulatory compliance and the reduction of near miss incidents.

Following a review of documents and records, and after speaking with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Inspectors were also satisfied that where practical aspects of medical radiological DXA procedures were delegated, the associated professional registration records, radiation safety training records and record of delegation were available and met the requirements of Regulations 10(4) and 10(5).

After speaking to staff and reviewing radiation safety related documentation and records, the inspectors were assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided and satisfied the requirements of the regulations.

Overall, although some work was required by the undertaking to meet full compliance, the inspectors were satisfied that the areas for improvement did not currently pose a risk in relation to the radiation protection of service users at Merlin Park University Hospital.

Regulation 4: Referrers

Following a review of referral documentation and a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that Merlin Park University Hospital had systems and processes in place to ensure that only referrals from appropriately recognised referrers were accepted.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of radiation safety procedure documentation and a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures at Merlin Park University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

The HSE was identified to inspectors as the undertaking with overall responsibility for the radiation protection of service users at Merlin Park University Hospital. The inspectors were informed that Merlin Park University Hospital with University Hospital Galway comprise Galway University Hospitals which operates as part of the wider HSE Saolta Hospital Group. Inspectors were informed that the GM of Galway University Hospitals was the person with overall responsibility for the protection of service users at Merlin Park University Hospital and reported via the Chief Operations Officer (COO) of the Saolta Group to the HSE.

Inspectors noted from documentation that staff at Merlin Park University Hospital used a RSC to direct and enforce radiation safety policy in line with relevant laws and regulations. Inspectors were informed that a radiation protection unit (RPU) was also used as a more operational platform within the radiation safety structure of the hospital. Inspectors were also informed that the hospital's Quality and Patient Safety Committee served as another platform for the consideration of radiation safety issues as necessary.

While inspectors noted the ongoing work in the stewardship and update of radiation safety documentation at the time of inspection, some work was still required to define the clear allocation of responsibility for the radiation protection of service

users at Merlin Park University Hospital. For example, in the document *Policies, Procedures and Guidelines for the Safe Use and Application of Ionising Radiation including Standard Operating Procedures* inspectors noted the inclusion of a practitioner accepting referrals from non referrers. Inspectors were subsequently informed that this did not reflect day-to-day practice and should therefore be removed. Also, in the same document the responsibility for approving a new type of practice is assigned to professional bodies rather than HIQA, this should be updated to reflect the regulations. Document update is also required to ensure that responsibility for asking and recording pregnancy questions is assigned in line with regulatory requirements.

Inspectors also reviewed a number of clinical audits completed by Merlin Park University Hospital and while they were assured that clinical audit was in place the associated policies and procedures must incorporate HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*.

Finally, formalising communication pathways to include departments using fluoroscopy in the operating theatre setting would ensure radiation safety issues are considered in, and communicated to, all areas conducting medical exposures in the hospital. In particular, a clear line of communication with the orthopaedic department to facilitate and resolve issues identified under Regulation 8 and 17 is essential at Merlin Park University Hospital. Inspectors noted the ongoing work to record the number of near miss incidents and the ongoing efforts by staff at Merlin Park University Hospital to include all relevant parties at the RSC meetings. However, more needs to be done to address the associated non compliances.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Following a review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspectors were satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner.

Inspectors were informed that aspects of the medical radiological procedure were delegated by a practitioner to individuals registered with the Nursing and Midwifery Board of Ireland in the DXA scanning unit at Merlin Park University Hospital. Records of the delegation and associated professional registration was available and reviewed as part of the inspection.

The inspectors were assured by the training records supplied that Merlin Park University Hospital had a system in place to ensure that all training requirements, as specified by the Nursing and Midwifery Board of Ireland, were satisfied. Training

records were well maintained by the undertaking and staff and included initial training records and records in relation to continuing education after qualification.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to inspectors by staff and management and all evidence supplied satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at Merlin Park University Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, the inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing and the training of practitioners.

The inspectors were assured that the involvement and contribution of MPEs at Merlin Park University Hospital was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safe delivery of medical exposures to service users at this hospital.

Following a review of a sample of referrals, inspectors noted that a number of radiology records reviewed lacked both reasons for requesting the procedure and sufficient medical data. It is imperative that the undertaking ensures that all medical exposure procedure referrals are accompanied by the regulatory required information.

The inspectors were satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures. Novel processes to increase the reporting of near miss events were developed locally and used in the trending of near miss incidents. Inspectors were informed that this approach had achieved increased reporting levels since its implementation.

Inspectors were satisfied that the undertaking employed a systematic approach to ensure the special protection during pregnancy of the relevant service users. However, improvements were required to ensure that the appropriate staff were consistently involved in this process across all settings providing medical exposures and that regulatory requirements were consistently reflected in the associated radiation safety documentation.

Records of acceptance and performance testing for all radiological equipment at the hospital satisfied the inspectors that the undertaking had kept all medical radiological equipment under strict surveillance. Inspectors were satisfied that DRLs were established, used and reviewed at Merlin Park University Hospital, however some work was required by the undertaking to ensure full compliance with Regulation 11.

Overall, although some areas required further work by the undertaking to meet compliance, the inspectors were satisfied that the areas for improvement did not currently pose a risk in relation to the safe delivery of medical exposures at Merlin Park University Hospital.

Regulation 8: Justification of medical exposures

In the radiology department inspectors observed multiple posters, both general and hospital specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical

exposures. Merlin Park University Hospital also used a novel method to provide service users with information relating to the benefits and risks of medical exposures to ionising radiation by displaying quick response (QR) codes in poster format throughout the radiology department. Once the QR code is scanned using a smart phone or similar device the service user is directed to an online video explaining patient radiation dose.

Inspectors spoke with staff and reviewed a sample of referrals from a number of clinical areas on the day of inspection. Inspectors were satisfied that the sample of referrals for general and dental X-rays, DXA scans and interventional procedures were in writing, stated the reason for requesting the procedure and were accompanied by sufficient medical data to satisfy the practitioner that the procedure was justified. However, inspectors noted that for all orthopaedic fluoroscopic procedures reviewed on the day, the reason for requesting the particular procedure or sufficient medical data to enable the practitioner to carry out a justification assessment was not included on the referral. The inspectors were also informed that orthopaedic fluoroscopic procedures contributed significantly to the overall number of medical radiological procedures carried out at Merlin Park University Hospital. The undertaking is responsible for ensuring that any person employed or engaged by it complies with the regulations. It is therefore essential that this non compliance is addressed by the undertaking to ensure that all referrals to a practitioner for a medical radiological procedures meet the criteria laid out in Regulation 8(10).

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors reviewed documentation and records pertaining to DRLs and spoke with staff. Merlin Park University Hospital had established DRLs across all imaging modalities and had compared these local facility DRLs to national DRLs as required by the regulations.

In one instance where local facility DRLs exceeded national DRLs inspectors saw evidence of a high level optimisation plan. However records of associated investigations and corrective actions were not available on the day of inspection. When local facility DRLs consistently exceed national DRLs, the undertaking should retain detailed records evidencing that the appropriate reviews and corrective actions have been taken.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors reviewed written protocols for every type of standard medical procedure for each type of equipment and relevant patient categories. In this case, the requirements of Regulation 13(1) were met but inspectors noted the potential for improvement through the implementation of improved protocol document version control which was a work in progress by the undertaking at the time of inspection in relation to other radiation safety documentation and is detailed under Regulation 6.

Inspectors reviewed a sample of reports for general X-ray, theatre, DXA and interventional radiology medical radiological exposures and found that information relating to the patient exposure formed part of the report for all records reviewed.

Judgment: Compliant

Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This included the implementation and maintenance of quality assurance programmes including acceptance and regular performance testing by MPEs, radiographers and equipment manufacturers. While the inspectors were assured that the undertaking satisfied the requirements of Regulation 14, it was noted that delivery of the radiographer QA programme could be improved by implementing contingency arrangements for unforeseen staff absences.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Following imaging record review and after speaking with staff, inspectors noted that Merlin Park University Hospital had processes in place to ensure that appropriate service users were asked about pregnancy status and the answer recorded. This policy included the processes associated with DXA procedures. However, on review of the records, this questioning and recording of the answer, at the point of imaging, was not done by individuals recognised as practitioners under the regulations for a small subset of patients presenting to the DXA department.

Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing diagnostic and interventional medical exposures in this facility. Inspectors were satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Merlin Park University Hospital.

Evidence was available to show that incidents were discussed at the appropriate committee levels within the hospital and subsequently reported to the RSC, thus the undertaking had oversight of incidents in this facility. Inspectors also reviewed trending of near miss incidents at Merlin Park University Hospital and were informed and observed in RSC minutes that these were discussed. Inspectors noted the novel method developed by staff to maximise the reporting of such events using a QR code directing staff directly to a web based platform where such incidents could be quickly and easily recorded and reported. This approach had achieved its objective resulting in increased reporting levels by staff, and had identified a number of inadequate, incorrect or inappropriate requests for X-ray procedures which were subsequently escalated to the RSC. Inspectors were informed at the time of inspection that the issue was being considered by senior management and noted that some action had already been taken to attempt to improve communication pathways with the appropriate department.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	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 Merlin Park University Hospital OSV-0008720

Inspection ID: MON-0042756

Date of inspection: 20/03/2024

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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Documents to be updated to reflect current GUH practice and legislative and regulatory language with regard to:</p> <ul style="list-style-type: none"> • Staff GUH accepts referrals from • Approval of new types of practice • Asking and recording pregnancy questions <p>TARGET: END Q3 2024</p> <p>GUH SOP on Radiological Clinical Audit to be drafted and implemented incorporating HIQA National policy TARGET: END Q3 2024</p> <p>Orthopedics asked to select representative(s) to attend future RSC meetings to establish clear line of communication. TARGET: END Q2 2024</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: RPO to attend Orthopedic Team Meeting and deliver talk to referrers on trends of near-miss and HIQA findings.</p> <p>RPO to query systems of referral at meeting to ascertain whether any systematic change</p>	

can be made to improve referral quality. Any potential change to be implemented as soon as feasible.

TARGET: END Q2 2024

Audit of orthopedic referrals to be carried out to measure any difference in quality.

TARGET: END Q4 2024

Regulation 11: Diagnostic reference levels

Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

Existing optimisation plan template to be replaced by template with SMART characteristics and a higher level of detail.

TARGET: END Q2 2024

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:

DXA staff are currently completing education which satisfies NMBI requirements to be recognised as Referrers. Provisional date of qualification 23/05/2024. GUH will then recognise these staff as Referrers which will allow them legislative status to ask and record pregnancy questions.

TARGET: 23/05/2024

Section 2:

Regulations to be complied with

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

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

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	30/09/2024
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	30/09/2024

	specific objectives of the exposure and the characteristics of the individual involved.			
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,	Not Compliant	Orange	30/09/2024
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	Not Compliant	Orange	30/09/2024
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 data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	30/09/2024
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	30/06/2024

	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.			
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.	Substantially Compliant	Yellow	30/06/2024
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Not Compliant	Orange	23/05/2024
Regulation 16(1)(b)	An undertaking shall ensure that,	Not Compliant	Orange	23/05/2024

	<p>the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.</p>			
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