



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Mayo University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Westport Road, Curragh, Castlebar, Mayo
Type of inspection:	Announced
Date of inspection:	28 March 2023
Medical Radiological Installation Service ID:	OSV-0007362
Fieldwork ID:	MON-0038778

About the medical radiological installation:

Mayo University Hospital (MUH) Radiology Department provides a comprehensive range of general and specialised imaging services to our patients in a digital environment. Both adult and paediatric imaging are provided across a wide range of specialities. In particular radiology services, a very busy oncology and orthopaedic trauma and elective service as well as general practitioner (GP) and other consultant referrals. The Radiology department comprises of 5 general X-ray rooms, fluoroscopy and theatre imaging. There are 4 ultrasound (US) scanners in MUH and a further 3 located in community sites. The department has a computed tomography (CT) scanner installed in 2010 and a magnetic resonance imaging (MRI) scanner installed in 2011.

National Integrated Medical Imaging System (NIMIS) Picture Archiving and Communication System (PACS) and McKesson Radiology Information System (RIS) with Virtual Reality (VR) reporting were installed in November 2012. The service is delivered by 43 whole time equivalent (WTE) radiographers and 7 Consultant Radiologists primarily based in MUH. X-ray, CT, US, MRI, fluoroscopy & interventional radiology is provided to in-patients, out-patients and GP referred patients. We have long standing off-site general radiography services provided in Belmullet Community Hospital, Ballina District Hospital & Castlebar Primary Care Centre. Studies performed on these sites are reported and coordinated from the main MUH radiology department via NIMIS.

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 28 March 2023	09:30hrs to 16:00hrs	Lee O'Hora	Lead
Tuesday 28 March 2023	09:30hrs to 16:00hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

As part of this inspection, the inspectors reviewed documentation and visited the general X-ray and computed tomography (CT) departments in Mayo General Hospital and spoke with staff and management. On this inspection, the inspectors found effective governance, leadership and management arrangements for the protection of service users undergoing medical exposures.

Mayo General Hospital operated within the Health Service Executive (HSE) Saolta Hospital Group and the HSE was the undertaking with overall responsibility for the radiation protection of service users. Local responsibility for the radiation protection of service users lay with the Mayo Hospital General Manager (GM) who communicated through the hospital group Chief Operations Officer (COO) to the HSE.

Staff at Mayo General Hospital used a radiation safety committee (RSC) to oversee and ensure compliance with the statutory requirements regarding radiation protection across three community sites and Mayo University Hospital. The monthly radiology directorate meeting was also highlighted to inspectors as an important resource for the consideration and discussion of radiation protection of service users. The inspectors were assured that the undertaking had provided a clear allocation of responsibility for the protection of service users from medical exposures to ionising radiation. This allocation was well defined in documentation and consistently articulated by staff on the day of inspection.

Following a review of documents and records, and speaking with staff, the 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, the inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

The inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, the inspectors were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall the inspectors were satisfied that the allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at Mayo General Hospital.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that Mayo University Hospital only accepted referrals from appropriately recognised referrers.

In line with the regulations, radiographers and advanced nurse practitioners were also considered referrers in this hospital. The specific circumstances in which radiographers could act as referrers were clearly outlined in local policies and articulated to inspectors by staff. Information identifying individual nurse referrers and their area of speciality was observed by the inspectors and this information was made available to the relevant staff using a shared digital platform. The hospital's advanced nurse practitioners, their area of speciality and scope of practice was clearly and consistently articulated to inspectors by staff spoken with on the day.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of the radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that Mayo University Hospital had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures. Professions considered as practitioners were limited to radiologists and radiographers at this hospital. Inspectors noted that this information was clearly and consistently documented, understood and articulated by all staff spoken with on the day.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspectors outlined a clear allocation of responsibility for the protection of service users by the HSE operating at Mayo University Hospital. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspectors during the course of the inspection.

Mayo University Hospital operated as part of the wider HSE Saolta Hospital Group. Inspectors were informed that the GM was the person with overall responsibility for the protection of service users at Mayo University Hospital and reported directly to

the COO of the Saolta Group.

Inspectors were informed that staff in Mayo University Hospital used a RSC and a Radiology Directorate Committee to consider all matters pertaining to radiation safety. The Radiation Safety Committee had responsibility for compliance with the statutory requirements regarding Radiation Protection and the Radiology Directorate platform facilitated monthly consideration of relevant radiation safety matters. The GM was a member of both committees as was the Associate Clinical Director (ASD) and Quality and Risk Manager.

The RSC oversaw radiation safety of service users across three community sites and Mayo University Hospital. The unique operational management and radiation safety governance systems were clearly articulated to inspectors for each community facility. Inspectors were assured, despite complex operational governance arrangements, that the clear allocation of responsibility for the protection of service users from medical exposures to ionising radiation was maintained by the undertaking and Mayo University Hospital for all four sites.

Based on the evidence gathered as part of this inspection, inspectors were assured that the undertaking had provided a clear allocation of responsibility for the protection of service users from medical exposures to ionising radiation in Mayo University Hospital.

Judgment: Compliant

Regulation 10: Responsibilities

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

Inspectors were assured that the optimisation process involved the practitioner and the medical physics expert (MPE) in all aspects of optimisation. Similarly, inspectors were satisfied that the justification process for individual medical exposures involved the practitioner and the referrer at Mayo University Hospital following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff.

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. Mayo University Hospital was assigned a whole time equivalent MPE and associated arrangements for absence cover were articulated to inspectors. All evidence supplied satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, 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 DRLs, the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. Inspectors were assured that the involvement and contribution of MPEs at Mayo 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, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Mayo University Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspectors found that radiation protection processes implemented by staff at Mayo General Hospital ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals from a range of departments, inspectors were assured that the hospital had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded.

Information for service users on radiation risks was available throughout the radiology department on the day of inspection. The additional use of quick response (QR) codes and associated online radiation risk benefit information was seen as a positive use of Saolta Group resources to improve the amount and type of information relating to the risks and benefits of medical radiation doses available to service users.

The inspector reviewed records of acceptance and performance testing and service engineer reports for all radiological equipment at the facility and was assured that the hospital had implemented a QA programme and kept its radiology equipment under strict surveillance. The inspector was also satisfied that all service users, as appropriate, were asked about pregnancy status by a practitioner and the answer was recorded as required by Regulation 16.

Diagnostic Reference Levels (DRLs) were established, used and reviewed. For example, when doses were identified as above national figures, Mayo University Hospital had systems and process in place to appropriately investigate and optimise doses received by service users. The optimisation of patient protection through the implementation of diagnostic reference levels ensures that patient doses are as low as reasonably achievable for the clinical purpose of the examination.

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.

Although one area noted for improvement related to the establishment of written protocols for every type of standard medical radiological procedure, inspectors were satisfied that this did not pose an immediate risk to the safety, health or welfare of service users. Overall inspectors were assured that staff at Mayo General Hospital had effective systems in place to support the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded.

In line with Regulation 8, all referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff spoken with on the day consistently informed inspectors that previous diagnostic information was routinely sought to avoid unnecessary exposure.

Inspectors visited the clinical area and 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. Mayo 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 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.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of DRLs, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the clinical areas.

Where local facility DRLs exceeded national values, the records of associated audits and corrective actions were available for review. Inspectors were assured that for two CT procedures, when the local facility DRLs exceeded national values a multidisciplinary team were involved in the associated dose audits and the implementation of the corrective actions. At the time of inspection the undertaking had implemented corrective actions including staff information posters, reminders inserted into digital protocol pages and education sessions for staff involved. Inspectors were informed that the re-audit of the associated patient doses was underway at the time of inspection. This use of local DRL review to closely monitor, and in certain cases, potentially optimise service user radiation doses was seen as a positive use of regulatory required reviews to optimise service user outcomes. This was also seen as a good use of multidisciplinary audit and educational resources by Mayo University Hospital to address issues in relation to Regulation 11.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors found that written protocols were established and available for adult and paediatric general X-ray, CT and fluroscopy and interventional radiology procedures done in the radiology department. However, no written protocols were available for standard medical radiological theatre fluoroscopy procedures and this must be addressed by the undertaking for compliance with Regulation 13(1).

The specific referral guidelines used in this facility were documented in radiation safety documentation supplied in advance of this inspection and inspectors were informed and observed that these referral guidelines were made available digitally for the relevant staff on the hospital's intranet system.

Inspectors reviewed a number of examples of radiation safety related clinical audits completed by staff at Mayo University Hospital. These included audits relating to pregnancy policy, procedure justification, patient dose and radiation incidents. Evidence that relevant issues relating to radiation safety related audits were discussed by the RSC was reviewed which satisfied inspectors that Mayo University Hospital utilised audit structures and processes to help enhance regulatory compliance across a range of regulations.

Judgment: Substantially 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 had included the implementation and maintenance of a quality assurance programme incorporating appropriate acceptance and regular performance testing. Evidence was also available to show that any issues identified as part of MPE performance testing had been addressed by the relevant staff members and external engineers, documented appropriately and subsequently closed off. Inspectors were provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that staff at Mayo University Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Inspectors were informed that for theatre fluoroscopy cases, practitioners ensured service users were asked about pregnancy status on the ward before the patient went to theatre for their procedure. This was seen as a good measure to eliminate the possibility of the patient being anaesthetised before the relevant questioning could take place.

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

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing incident records, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at the monthly directorate committee within the facility and subsequently reported to the RSC, thus the undertaking had comprehensive oversight of incidents 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 Mayo University Hospital.

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	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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mayo University Hospital OSV-0007362

Inspection ID: MON-0038778

Date of inspection: 28/03/2023

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 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Written protocols for every type of standard medical radiological procedure will be established for each type of equipment for relevant categories of patients.</p> <p>Written protocol documents for adult and paediatric general X-ray, CT and fluroscopy and interventional radiology in department were reviewed. It was decided to mirror instruction booklet utilised in departmental fluoroscopy room to maintain consistency across similar units/examinations utilising fluoroscopy.</p> <p>All standard theatre radiological image intensified exams performed in MUH were identified for inclusion in document (by reviewing RIS/PACs Records). The RPO, Theatre Senior Radiographer & RIS Manager were responsible with a completion date of 21 April 2023.</p> <p>This draft document was reviewed and accepted by the RSM3 on the week commencing 15 May 2023. The subsequent updated protocol document was circulated to all theatre/general radiographers and uploaded in un-editable form to “radiographers shared drive” and is to form part of induction process for new radiographers to the department in future. The Hospital Manager was informed that issue was resolved by the RSM 3 on the week commencing 22 may 2023.</p>	

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 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	31/05/2023