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:	Castlebar Primary Care Centre X-Ray Service
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Moneen Road, Castlebar, Mayo
Type of inspection:	Announced
Date of inspection:	12 March 2025
Medical Radiological Installation Service ID:	OSV-0007339
Fieldwork ID:	MON-0046319

About the medical radiological installation (the following information was provided by the undertaking):

Castlebar Primary Care Centre officially opened on 10th November 2017.It is the largest primary care centre in County Mayo at 4,000 square metres with a planned extension due for completion in quarter three, 2026. It is situated on the outskirts of Castlebar town. Although physically located in Primary Care Services, the X-ray unit is staffed by and comes under the clinical governance of the Radiology Service at Mayo University Hospital (MUH). This service is operated under a hub and spoke model from MUH utilising the NIMIS RIS/PACS system. A senior manager from Primary Care Services and a Clinical Specialist Radiographer from Mayo University Hospital serving as the Radiation Protection Officer (RPO) sit as representatives of the Castlebar Primary Care Services X-ray unit on the Radiation Safety Committee. In relation to the Mammography service the clinical governance comes under the umbrella of the Breast service of Galway University Hospital. In terms of Radiation Safety the unit is governed by The Policies for the Safe use and Application of Ionising Radiation including Standard Operating Procedures for Mayo University Hospital, Ballina and Belmullet District Hospitals and Castlebar Primary Care Centre, issued by the Radiation Safety Committee of Mayo Hospitals.

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, as amended. 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] 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.

1. Governance and management arrangements for medical exposures:

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 12 March 2025	10:30hrs to 14:00hrs	Lee O'Hora	Lead

Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation and visited the X-ray and mammography rooms and spoke with staff and management. The inspector found that Castlebar Primary Care X-ray Service operated as part of Mayo University Hospital's radiology department and the Health Service Executive (HSE) was the undertaking with overall responsibility for the radiation protection of service users. The inspector was satisfied that robust communication pathways ensured effective communication between senior management within the Primary Care service and those responsible for the radiation protection of service users visiting the X-ray service at this Primary Care Centre.

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

After speaking to staff and reviewing radiation safety related documentation and records, the inspector was assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided at Castlebar Primary Care X-ray Service and satisfied the requirements of the regulations assessed on the day.

The inspector found effective governance, leadership and management arrangements were in place with a clear allocation of responsibility for the protection of service users undergoing medical exposures at this facility.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Castlebar Primary Care Centre X-ray Service only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Similarly, following record review and staff communication, the inspector was satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures at Castlebar Primary Care Centre X-ray Service.

Judgment: Compliant

Regulation 6: Undertaking

The inspector was informed that the X-ray department at Castlebar Primary Care Centre X-ray Service came under the radiation protection governance of Mayo University Hospital and the HSE was the undertaking with overall responsibility for the radiation protection of service users. Documentation review and staff communication established that the Castlebar Primary Care X-ray Service was governed by radiation protection structures established for Mayo University Hospital, Ballina and Belmullet District Hospitals and Castlebar Primary Care Centre, overseen by their Radiation Safety Committee (RSC). The inspector was informed that a senior manager from Primary Care Services and a Clinical Specialist Radiographer from Mayo University Hospital, serving as the Radiation Protection Officer (RPO) for this facility, were representatives of the Castlebar Primary Care Centre X-ray Service on the RSC.

While the inspector was informed that the mammography service came under the clinical governance umbrella of the Breast Service of Galway University Hospital, all regulatory requirements assessed in relation to the mammography service on the day were delivered by structures implemented under the Mayo University Hospital radiation protection governance structures. For example, all referrals were justified on site by a practitioner operating at Castlebar Primary Care Centre X-ray Service, imaging was provided by Castlebar Primary Care Centre X-ray Service, imaging reports were available on a shared Picture Archiving and Communication System (PACS) and imaging protocols, Diagnostic Reference Levels (DRLs), Quality Assurance (QA) of equipment records were all established and delivered by staff, structures and procedures of Mayo University Hospital (albeit, mammography imaging protocols were developed in conjunction with Galway University Hospital Mammography Service). The inspector was informed of and observed communication with the mammography service of Galway University Hospital, an arrangement which was also detailed in a Service Level Agreement (SLA) between the hospitals. All staff spoken with during the inspection confidently and consistently detailed this relationship, the communication pathways used and articulated a good understanding of this relationship and its practical day-to-day workings.

The General Manager (GM) for Primary Care Mayo/Roscommon was identified as the Designated Manager (DM) for this facility. The GM sat on the RSC and communicated via the Network Manager for Castlebar Primary Care with radiography staff on site. Primary Care senior staff articulated formal and informal communication pathways with radiography staff, the site assigned RPO, the MPE

and radiation safety platforms within Mayo University Hospital to the inspector, the formal components of which were captured in radiation protection documentation reviewed as part of this inspection. All relationships, responsibilities and communication pathways were clearly and consistently articulated to the inspector. While the GM of Mayo University Hospital was identified as being the person responsible for the radiation protection of service users visiting the Casltebar Primary Care Centre X-ray Service, the inspector was satisfied that the appropriate communication pathways were available to ensure effective communication between Primary Care Senior Management and those responsible for the radiation protection of service users visiting the X-ray service.

Overall, the inspector was satisfied that the undertaking had ensured a clear allocation of responsibility for the protection of service users at Castlebar Primary Care X-ray Service.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector reviewed radiation safety procedure documentation, a sample of referrals for medical radiological procedures and spoke with staff and was satisfied that all medical exposures at Castlebar Primary Care Centre X-ray Service took place under the clinical responsibility of a practitioner. The inspector was also assured that the optimisation process involved the practitioner and the MPE and that the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise were described to the inspector by staff. All evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at Castlebar Primary Care Centre X-ray Service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. From reviewing the documentation and speaking with staff, the inspector was assured that the MPE took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of DRLs, the definition of QA programmes including acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners.

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 and QA record review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Castlebar Primary Care Centre X-ray Service.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this service and noted a number of areas of good practice in relation to this.

Following a review of a sample of referrals for general X-ray the inspector was satisfied that Castlebar Primary Care X-ray Service had reliable and consistently applied 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.

The inspector was satisfied that DRLs were established, used and reviewed. Evidence that DRL review informed further investigation also highlighted processes used at this facility to reduce patient dose, optimise the service provided and enhance service user outcomes.

Records of acceptance and performance testing for radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained an appropriate QA programme.

The inspector was assured that this facility had appropriate systems in place to support the safe delivery of medical exposures and staff demonstrated a

commitment to the continual improvement of X-ray services provided by Castlebar Primary Care X-ray Service.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals across all clinical areas on the day of inspection. The inspector noted that Castlebar Primary Care Centre X-ray Service used a robust system to ensure that all medical exposures were justified in advance before service users arrived at the facility. Once the service user arrived at the facility the referral was reviewed again by the radiographer ensuring that each medical exposure was justified in advance and rechecked at the point of imaging which was considered a robust approach to justification. This was noted as an area of good practise reducing the potential for unnecessary imaging at Castlebar Primary Care Centre X-ray Service.

In line with Regulation 8, all referrals reviewed by the inspector 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 consistently informed the inspector that previous diagnostic information was routinely sought to avoid unnecessary exposure and robust justification procedures applied in the general X-ray and mammography departments formalised this process.

The inspector observed multiple posters which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of these posters were also available throughout the facility.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRL documentation, the inspector was satisfied that DRLs had been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. The inspector spoke to staff and reviewed records in relation to paediatric and adult service user dose audits initiated by dose trends noted during ongoing DRL reviews. While not exceeding national DRLs in either case, these dose audits resulted in patient dose optimisation through service user dose reduction. This was seen a positive use of information gained through DRL review to reduce patient dose, optimise the service provided and enhance service user outcomes.

The inspector visited the clinical areas and observed examples of local facility DRLs displayed in both the general and mammography rooms.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for all adult and paediatric standard medical radiological procedures. These were reviewed for all clinical areas. Staff in the clinical areas who spoke with the inspector clearly articulated how these protocols were made available to them and demonstrated extensive knowledge of these.

The inspector spoke with staff and reviewed a sample of imaging reports from all clinical areas on the day of inspection. The inspector observed that information relating to patient exposure formed part of all reports reviewed.

Judgment: Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory which was verified on site. From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance at Castlebar Primary Care Centre X-ray Service. The undertaking had implemented and maintained a QA programme, including appropriate acceptance and regular MPE and radiographer performance testing as well as manufacturer suggested equipment service. Evidence was also available to show that any issues identified as part of radiology equipment service had been followed up in a timely manner.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspector that processes were in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Multilingual posters were observed in all clinical areas to increase awareness of individuals to whom Regulation 16 applies.

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, as amended. 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	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant