



**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:	Belmullet Community Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Aras Deirbhile, Belmullet, Mayo
Type of inspection:	Announced
Date of inspection:	12 June 2024
Medical Radiological Installation Service ID:	OSV-0007345
Fieldwork ID:	MON-0042964

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

Belmullet District Hospital was built in 1936 with an extension added to the south in 1985. The capacity at the facility is currently 13 beds which can cater for stepdown, respite and palliative care. Belmullet is located on the Erris Peninsula, an area the size of County Louth but sparsely populated. It is 80 kilometres from the nearest acute Hospital, Mayo University Hospital and 64 kilometres from Ballina District Hospital, the nearest short stay step down facility. The Xray unit installation began in 2005 and became operational in 2007. It provides a general Xray service to patients referred by GPs in the area. Occasionally inpatients within the hospital are also X-rayed here. It is operated approximately one day a week, in keeping with service requirements, by a radiographer. Although physically located in Older People 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 Older People Services and a senior radiographer from Mayo University Hospital serving as the Radiation Protection Officer (RPO) sit as representatives of the Belmullet Xray unit on the Radiation Safety Committee. 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 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 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 June 2024	10:00hrs to 14:30hrs	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 department and spoke with staff and management. The inspector found that Belmullet Community Hospital X-ray department 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. Local responsibility for the radiation protection of service users lay with the General Manager for older persons services who communicated through the Mayo University Hospital radiation safety committee (RSC) to the HSE.

Belmullet Community Hospital's X-ray department used the Mayo University Hospital RSC and radiation protection unit (RPU) and utilised other communication pathways within the governance structure to ensure that radiation safety related issues could be considered and escalated appropriately. The inspector was assured that the Belmullet Community Hospital radiation safety officer (RSO), the Mayo University Hospital's radiography services manager (RSM) and the General Manager for older persons services had established both formal and informal communication pathways to ensure the consideration and communication of all relevant radiation protection related issues. Although the inspector found effective governance, leadership and management arrangements were in place, it was noted that the clear allocation of responsibility for the protection of service users undergoing medical exposures could be improved through the consistent provision of up-to-date contact details of the relevant staff to HIQA and through the local implementation of appropriate solutions in relation to Regulation 13(2).

Following 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 Belmullet Community Hospital and satisfied the requirements of the regulations.

Regulation 4: Referrers

Following a review of referral documentation and a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was assured that

Belmullet Community 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, the inspector was satisfied that systems were in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The inspector was informed that the X-ray department at Belmullet Community Hospital, while located in Older Peoples Services, came under the clinical governance of radiology services at Mayo University Hospital. The General Manager for older persons services for CHO area two was identified as the person with overall responsibility for the radiation protection of service users presenting for X-ray at Belmullet Community Hospital. However, the inspector was informed that the General Manager for older persons services delegated their responsibilities via direct communication with the RSM and the Belmullet RSO and communicated all relevant information to the Mayo University Hospital General Manager via the Mayo University Hospital RSC which he or his delegate also attended. The inspector was informed that staff at Belmullet Community Hospital also used the Mayo University Hospital RPU and this information was validated through meeting minutes provided which showed that the Belmullet Community Hospital RSO sat on both the RSC and RPU.

While the relevant staff and lines of communication were articulated to the inspector on the day, recent changes in the designated manager, and the individual highlighted as having overall responsibility for the radiation safety of patients at Belmullet Community Hospital had not been communicated to HIQA in a timely manner. This change in key personnel was only communicated to HIQA after announcement of this inspection. It is imperative that undertakings ensure that any changes to the undertaking's details or related personnel changes are made known to HIQA via the prescribed channels as soon as possible to ensure maintenance of a clear allocation of responsibility. HIQA must have accurate and up-to-date contact details for the undertaking, undertaking representative and designated manager.

The inspector was informed that staff at Belmullet Community Hospital were currently updating the relevant documentation to incorporate HIQA's national procedures for clinical audit (NPCA) of radiological procedures involving medical exposure to ionising radiation and were incorporating all radiation safety audits into the wider shared structures, platforms and resources within Mayo University Hospital. It is essential that all undertakings review the NPCA and incorporate these into their local audit approach.

Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector was informed that generic patient dose information templates developed and distributed by the HSE, as the undertaking, had not been adopted by staff responsible for reports at Belmullet Community Hospital. Although staff spoken with during the inspection were aware of the regulatory requirements and the relevant resources shared by the HSE, local responsibility for their implementation was not clearly allocated or articulated to the inspector. It is imperative that solutions developed by the HSE in relation to Regulation 13(2), or alternative local solutions, are implemented as a matter of urgency to ensure compliance with this Regulation.

Judgment: Substantially 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, the inspector was satisfied that staff at Belmullet Community Hospital ensured that all medical exposures took place under the clinical responsibility of a practitioner.

The inspector was assured that the optimisation process involved the practitioner and the MPE in all aspects of optimisation. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer 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 the inspector by staff and management and all evidence supplied satisfied the inspector that the undertaking had the necessary arrangements in place to ensure continuity of medical physicist expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The medical physicist's professional registration was reviewed by the inspector and was up to date.

From reviewing the documentation and speaking with staff at the hospital, the inspector was satisfied that arrangements were in place to ensure that the medical physicist 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 inspector was assured that the involvement and contribution of the medical physicist 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 inspector established that the involvement of the medical physicist was both appropriate for the service and commensurate with the risk associated with the service provided at Belmullet Community Hospital.

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 one area of non-compliance relating to Regulation 13(2), namely that the information relating to the patient exposure did not form part of the patients' reports as required.

Following a review of a sample of referrals for general X-ray the inspector was satisfied that Belmullet Community 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.

The inspector was satisfied that DRLs were established, used and reviewed. The inspector reviewed documentation and records of accidental and unintended exposures and significant event near misses. The inspector was assured that the undertaking had developed and implemented a system to identify and record such events and trending data provided also enabled both local and collective consideration of accidental and unintended exposures and significant event near misses.

Records of acceptance and performance testing for radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained a quality assurance (QA) programme.

Notwithstanding the gap in relation to Regulation 13, the inspector was assured that Belmullet Community Hospital had appropriate systems in place to support the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals on the day of inspection. The inspector was satisfied that the sample of referrals for X-rays 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. Evidence reviewed also 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.

The inspector visited the clinical area and observed multiple posters and QR (quick response) codes, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation and records pertaining to DRLs and spoke with staff. Belmullet Community Hospital had established DRLs and had compared these local facility DRLs to national DRLs as required by the regulations. The inspector was assured that in all cases where local facility DRLs exceeded nationally established DRLs the appropriate multidisciplinary investigations had taken place satisfying all requirements of Regulation 11.

A DRL dose audit completed by staff had taken a comprehensive approach to the optimisation of patient doses and DRLs at Belmullet community Hospital, this has

included a multidisciplinary review of equipment, protocols and practice which subsequently yielded patient dose reductions for a range of X-rays and this was noted as an area of good practice.

The inspector also visited the clinical area and observed multiple examples of local facility DRLs displayed.

Judgment: Compliant

Regulation 13: Procedures

Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for general X-ray medical radiological exposures and found that information relating to the patient exposure did not form part of the report on any of the records reviewed. The inspector was informed that at the time of inspection the national solution supplied by the undertaking had not been incorporated into reports generated for Belmullet Community Hospital. As information relating to patient exposure was not seen on any records reviewed, the Health Service Executive as the undertaking, must ensure that patient exposure information forms part of all reports to ensure compliance with this regulation.

Judgment: Not Compliant

Regulation 14: Equipment

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. All records reviewed detailed that all testing was up to date and appropriately followed up or closed off as required. The inspector was provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Following documentation and imaging record review and after speaking with staff, the inspector was satisfied that Belmullet Community Hospital had processes in place to ensure that pregnancy could be ruled out for all appropriate service users

and the answer recorded. While satisfying the requirements of the regulations it was noted that the current process and associated documentation may be further strengthened and this was discussed with staff during the inspection.

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 local incident records, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing diagnostic medical exposures in this facility. The inspector was 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 Bemullet Community Hospital. The inspector also noted that radiation incidents were discussed by all relevant staff at platforms including monthly Radiology Directorate meetings and Radiation Safety Committee meetings.

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	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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not 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 Belmullet Community Hospital OSV-0007345

Inspection ID: MON-0042964

Date of inspection: 12/06/2024

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, as amended.

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: On June 19, 2024 a NF201E (Notification Form, Change of designated manager) was completed and sent to The National Radiation Protection Office, HSE to update the name of the designated with immediate effect. A reply was received on June 20, 2024 to confirm the changes had been made.</p> <p>All future changes in designated manager in any of the community sites or MUH will be immediately notified to the chair of the radiation safety committee by the designated manager.</p> <p>The National Radiation Protection Office will be notified and they in turn will notify the changes to HIQA.</p> <p>Current records have been reviewed on all sites for accuracy and updated accordingly since inspection.</p> <p>The Radiation Safety Committee will monitor compliance with this going forward, via RPOs.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Generic patient dose information templates have been developed and now appear on all radiology reports at the Belmullet X-ray unit. This solution has been introduced across all Mayo Radiology sites and is being monitored to ensure uniform compliance.</p>	

Reports will be audited and reported to Radiation Safety Committee by RPOs in each of the four sites to ensure on-going compliance.

In future any national communications or agreed changes to process by undertaking will be communicated via the Radiation Safety Committee with time bound compliance plans.

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	Orange	20/06/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Not Compliant	Orange	09/07/2024

	radiological procedure.			
--	----------------------------	--	--	--