



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dungloe Community Hospital X-ray Service
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Gweedore Road, Dungloe, Donegal
Type of inspection:	Announced
Date of inspection:	19 September 2024
Medical Radiological Installation Service ID:	OSV-0008882
Fieldwork ID:	MON-0044710

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

Dungloe Community Hospital X-ray department is part of a five location community X-ray service for Donegal. It has one modern digital X-ray unit (Carestream) with links to the PACS/RIS system in Letterkenny University Hospital (LUH). It is integrated with the National Integrated Medical Imaging System (NIMIS) which allows for access to the previous patient reports and images. Reporting of the X-rays is undertaken by radiologists in Letterkenny University Hospital. It operates four days a week providing a service between 9:00 – 17:00hrs conducting an average of 3,500 X-ray exams a year. It is predominantly a GP service but acts as local X-ray imaging centre for hospital consultants at LUH and other centers nationally that operate within the NIMIS system.

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
Thursday 19 September 2024	09:30hrs to 13:15hrs	Emma O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of the medical radiological services at Dungloe Community Hospital X-ray service was completed on 19 September 2024 to assess the undertaking's compliance with the regulations. As part of this inspection the inspector reviewed documentation and visited the general radiography (X-ray) department and spoke with staff and management.

On the day of this inspection, the inspector reviewed the governance and management arrangements in place and the allocation of responsibility for the protection of service users undergoing medical exposures. Documentation viewed by the inspector in relation to governance arrangements demonstrated the dual reporting relationship from Dungloe Community Hospital X-ray service to Community Healthcare Cavan, Donegal, Leitrim, Monaghan, Sligo, referred to as Community Healthcare (CH) throughout the rest of this report, and Letterkenny University Hospital (LUH) and upward to the Health Service Executive (HSE) as the undertaking. The inspector was satisfied that there were appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day-to-day operations in the facility up to the undertaking.

A sample of electronic records for patients undergoing medical exposures were reviewed by the inspector during the inspection which showed that appropriate persons, as per the regulations, were involved in referring for medical exposures completed at the service. The inspector was also satisfied that only those entitled to act as practitioner, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

From the records viewed and discussions with staff, the inspector was satisfied that the undertaking had ensured contingency arrangements for the continuity of medical physics expert (MPE) expertise in the facility. The inspector saw strong evidence of MPE involvement in all areas of MPE responsibilities as per the regulations and was therefore satisfied that the level of MPE involvement was proportionate to the level of radiological risk posed by the service.

While the inspector was satisfied that responsibilities had been allocated for the protection of service users attending for medical radiological procedures at Dungloe Community Hospital X-ray service some improvements are required to strengthen governance of the document management system to ensure that all radiation safety policies, procedures and protocols go through a formal ratification process and include relevant information to assure staff that they are using the most up to date version of a document.

Regulation 4: Referrers

From discussions with staff and the sample of records of medical exposures reviewed on the day of inspection, the inspector was satisfied that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at this service. In Dungloe Community Hospital X-ray service, medical practitioners had been allocated the role of referrers, while radiographers as referrers could make adapted referrals for X-ray procedures.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from the day-to-day practice described by staff and the documentation viewed, that radiologists and radiographers were recognised as practitioners for this medical radiological facility thereby meeting the requirements of this regulation

Judgment: Compliant

Regulation 6: Undertaking

The inspector spoke with staff and management working at Dungloe Community Hospital X-ray service, and reviewed documentation and other records to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures. The HSE was identified to the inspector as the undertaking with overall responsibility for the radiation protection of service users, with a dual governance arrangement in place between CH and LUH. Operationally, the CH radiography services manager (RSM) reported to the general manager of CH, who in turn reported to the CH head of service. Clinical governance, including the oversight and the allocation of responsibilities for the radiation protection of service users, for Dungloe Community Hospital X-ray service was provided by LUH.

The medical exposures team was responsible for communication and discussion on all day-to-day matters relating to radiation safety. This forum met twice a year and was attended by the CH RSM, the radiation protection officer (RPO) and the MPE. The medical exposures team subsequently reported into the radiation safety committee (RSC), which was a cross-site meeting between the CH X-ray services and LUH. The RSC provided oversight for the radiation protection arrangements in the service, and met twice a year to discuss items such as radiation safety incidents, staff training and the radiological equipment quality assurance programme. Updates from the CH X-ray services was a standing agenda item at the RSC meetings. This

update was provided by the CH RSM and evidence of this was found in the minutes from recent RSC meetings. The inspector noted that these meetings were attended by, amongst others, a consultant radiologist, who was the chair of the committee, the radiation protection advisor (RPA), RPO, MPE, assistant general manager LUH, RSM's from LUH, the CH RSM, and the quality and patient safety manager.

While the inspector was satisfied that there were appropriate radiation safety platforms and lines of communication in place for the safe delivery of medical exposures in Dungloe Community Hospital X-ray service, the development and management of radiation safety documents was identified as an area for improvement. In some cases the format of policies was inconsistent and the ratification process was not fully evident. For example, and as further discussed under Regulation 17, the *Policy on incidents and near miss reporting and recording* document did not include information on approval dates, review dates or document owners. The undertaking is responsible for ensuring that staff and those engaged by the undertaking understand local systems and processes and are supported in carrying out their individual roles through the provision of regularly reviewed and ratified documented procedures, policies, protocols and guidelines.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Following a review of the radiation safety procedure documentation, a sample of referrals for medical radiological procedures and from speaking with staff and management, the inspector was satisfied that the undertaking 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. Similarly, the inspector was satisfied that the justification process for individual medical exposures involved the practitioner and the referrer, as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Dungloe Community Hospital X-ray service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector viewed the professional registration certificate of the MPE engaged by the undertaking to provide specialist advice to Dungloe Community Hospital X-ray service, as appropriate, on matters relating to radiation physics, and this met the requirements of Regulation 20(1). Evidence viewed in documentation and discussions with staff demonstrated to the inspector that the MPE fulfilled a range of responsibilities as per Regulation 20(2) relevant to the practice. These included optimisation, QA of medical radiological equipment and training of practitioners.

Judgment: Compliant

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

The inspector was satisfied that the MPE was appropriately involved in Dungloe Community Hospital X-ray service, and that the level of involvement was commensurate with the level of radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector found that Dungloe Community Hospital X-ray service had systems in place to ensure the radiation protection of service users undergoing medical exposures to ionising radiation.

A review of records on the day of inspection showed that there was a written referral from a recognised referrer for each medical radiological procedure which contained sufficient clinical information to inform justification in advance by a practitioner. Information about the benefits and risks associated with the radiation dose from a medical exposure was available to patients on posters and leaflets in the waiting area. 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.

The inspector viewed records of performance testing for the radiological equipment at the facility and was assured that the hospital had implemented a QA programme and kept the equipment under strict surveillance.

Written protocols were established for each type of standard adult medical radiological procedure provided by the facility, a sample of which were viewed by

the inspector. The inspector reviewed a sample of reports of medical radiological procedures and found that reports completed by two out of six radiologists in LUH did not contain information relating to patient exposure as required by the regulations. Staff were aware of this issue and provided evidence to the inspector that a solution to address this gap in compliance was in progress. The inspector was satisfied that clinical audits in this facility were carried out in accordance with the *National Procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, however, consideration should be given to the full clinical pathway when selecting audit topics in the future.

On the day of the inspection a number of examples of optimisation were found to be in place to ensure that medical radiological procedure doses were kept as low as reasonably achievable in this service. In particular, the inspector noted that diagnostic reference levels (DRLs) for adult X-ray procedures were established and reviewed regularly. The inspector also viewed evidence that corrective action was taken when local facility DRLs exceeded national DRLs and this was seen as an example of good practice in the radiation protection of service users at this facility.

While paediatric patients represented a very small number of the total number of X-ray procedures carried out at Dungloe Community Hospital X-ray service not all paediatric examinations had a written protocol established as required under Regulation 13. Also, DRLs had not been established for paediatric procedures as required by Regulation 11. Despite these gaps in compliance, the inspector was assured that all paediatric exposures were optimised and that doses were kept as low as reasonably achievable for this cohort of patients in the absence of paediatric protocols and DRLs.

Even though there were no incidents documented on the incident management system for this service the inspector was satisfied that there was an appropriate system in place for the record keeping and analysis of events involving accidental or unintended medical exposures. However, improvements are required to ensure that all near misses are recorded and analysed to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure in order to meet full compliance with Regulation 17.

Overall, the inspector was assured that Dungloe Community Hospital X-ray service had comprehensive systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

The inspector was satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to assist the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users, through posters and leaflets

available in the waiting area. The inspector viewed the *Community X-ray - Radiographer roles and responsibilities in justification and optimisation of radiology examinations* document and found that the procedure outlined for justifying X-ray examinations aligned with day-to-day practice in the facility. Records viewed showed that justification in advance was recorded by a practitioner on the referral which was then scanned up onto the radiological information system (RIS), thereby providing evidence of compliance with this regulation.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector observed that DRLs had been established for common adult radiological procedures completed at Dungloe Community Hospital X-ray service, and were comparable to national DRLs where established, and displayed in the clinical area. From a review of documentation the inspector noted that the local DRL for one procedure was marginally above the national DRL. On the day of the inspection the inspector was provided with evidence that a review of this DRL had been carried out in consultation with the MPE. This review included optimisation of the dose to the service user and resulted in the reduction of the facility DRL, without compromising the image quality of the exposure. These actions demonstrated a commitment to the optimisation of protection and safety of service users as per Regulation 11(6).

The inspector was informed that a low number of paediatric X-ray procedures were performed at Dungloe Community Hospital X-ray service, however, DRLs for these paediatric procedures had not been established. While the inspector was assured, from discussions with staff, that paediatric exposures were optimised, paediatric DRLs should be established and reviewed regularly in order to reach compliance with Regulation 11(5).

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspector was satisfied that the undertaking had ensured that referral guidelines for medical imaging were available to staff in the service as required by Regulation 13(3). Also, the inspector viewed the recently developed clinical audit strategy for the service as well as clinical audits that were recently completed, including last menstrual period (LMP), triple ID and justification in advance audits. While the inspector was satisfied that the undertaking had ensured that clinical audits are carried out in accordance with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, and were

appropriate for the size and scale of this service, future reviews of the clinical audit strategy should consider the scope and the full patient pathway.

On the day of inspection the inspector found that written protocols were established and available for all general X-ray procedures for adults. However, not all paediatric procedures carried out at Dungloe Community Hospital X-ray service had a written protocol. While the number of paediatric procedures is low, this gap in documentation should be addressed by the undertaking to ensure compliance with Regulation 13(1).

During the inspection staff explained to the inspector that the reporting of the X-ray procedures performed at Dungloe Community Hospital X-ray service is undertaken by radiologists in LUH. The inspector was also informed by staff that information relating to patient exposure was not yet available on reports from two radiologists, as these radiologists were relatively new to LUH. Records viewed by the inspector confirmed this, however, dose information was available on reports viewed from the other four radiologists working in LUH. Management were aware of this issue and provided evidence to the inspector that communication had been initiated with the Radiology Picture Archive and Communication System (PACS) manager to resolve this issue and work towards reaching compliance with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Dungloe Community Hospital X-ray service as required by Regulation 14(1). The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that an appropriate quality assurance programme was in place for equipment as required by Regulation 14(2). In addition, the inspector reviewed records of performance testing and was satisfied that testing was carried out on a regular basis as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The procedure for establishing the pregnancy status of women of child-bearing age was reviewed in the document *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* and verified by the inspector in discussions with staff. A sample of referrals and completed pregnancy declarations of relevant service users performed in advance of conducting a medical exposure were viewed and were consistent with this policy.

Posters were observed in the waiting area to help increase the awareness of the special protection required during pregnancy prior to undergoing a medical exposure. From the records reviewed, the inspector was satisfied that pregnancy inquiries involving the referrer and or practitioner were appropriately documented, ensuring that all reasonable measures were taken to prevent the unnecessary exposure of a foetus during a medical exposure of a pregnant individual.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The *Policy on incidents and near miss reporting and recording* document viewed outlined the process for reporting radiation incidents, and this process was also clearly articulated by staff and management to the inspector on the day of the inspection. However, this document did not clearly define what incident reporting system was used in this facility for the documentation of radiation safety incidents. Management spoken with on the day of the inspection clarified that the National Incident Management System (NIMS) was the system in use, however, there were no incidents or near misses documented for this service.

From discussions with staff the inspector was made aware of occasions when radiographers would adapt referrals where, for example, the left side was requested incorrectly for an image required on the right side on the primary referral from the medical practitioner. While this was seen as an example of good practice in the service these instances were not being captured as near miss events. The recording and analysis of near misses offers the potential to identify a hazard or risk and implement corrective actions to help prevent a more serious incident from occurring.

While the inspector was satisfied, from discussions with staff and management, that a system was implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, documentation should be updated to include the correct name of the incident management system in use in the facility. Also, improvements are required to ensure that all near misses are recorded and analysed to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure, as required by Regulation 17(1)(a).

Judgment: Substantially 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	Substantially 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	Substantially Compliant

Compliance Plan for Dungloe Community Hospital X-ray Service OSV-0008882

Inspection ID: MON-0044710

Date of inspection: 19/09/2024

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: The RSM will seek to re-instate the community PPPG committee for ratification of local PPPGs for the community X-ray service.</p> <p>The RSO will seek to submit shared PPPGs (including the Policy on incidents and near miss reporting and recording) for ratification through the PPPG committee in LUH.</p> <p>The Policy on incidents and near miss reporting will be updated to include clarification that the National Incident Management System (NIMS) is the platform for reporting incidents and near misses.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: The number of paediatric examinations remains extremely low. However a historic review of examinations will be undertaken with the results compiled into local DRLs.</p>	
Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
An amendment to the local Community X-ray - Radiographer roles and responsibilities in justification and optimisation of radiology examinations has been made to include paediatric protocols.

Dose reports were not displaying for two radiologists. This issue has been resolved for one radiologist and will be resolved in the near future for the other.

Regulation 17: Accidental and unintended exposures and significant events

Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

The Policy on incidents and near miss reporting will be updated to include clarification that the National Incident Management System (NIMS) is the platform for reporting incidents and near misses.

A system has been set up for the recording of near misses during the vetting phase and examination phases of a referral.

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	25/11/2024
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	15/10/2024

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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.	Substantially Compliant	Yellow	25/10/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	29/12/2024
Regulation 17(1)(a)	An undertaking shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,	Substantially Compliant	Yellow	25/10/2024