



**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:	Dungarvan Community Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Springmount, Dungarvan, Waterford
Type of inspection:	Announced
Date of inspection:	30 November 2022
Medical Radiological Installation Service ID:	OSV-0007951
Fieldwork ID:	MON-0038118

About the medical radiological installation:

Dungarvan Community Hospital is a 102 bed care facility providing beds for Alzheimer care, respite, rehab and long-term care of elderly and special needs patients. It is home also to a variety of community-based services such as physiotherapy, ophthalmology, dentistry, speech and language therapy and mental health services.

The one-roomed X-ray facility forms part of the community services section and it is a centre for out-patient GP referrals from the West Waterford/East Cork area. There is an occasional requirement for inpatient referral from the hospital for which the referral pathway is also through a locally-based GP.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA’s findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 30 November 2022	09:50hrs to 11:59hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations was carried out at Dungarvan Community Hospital X-ray facility on 30 November 2022. During the course of the inspection, the inspector spoke with staff and management of this general X-ray department and found that there were effective governance, leadership and management arrangements in place for medical exposures conducted there. The inspector was informed that this medical radiological facility was viewed as an additional X-ray room within the radiology services at University Hospital Waterford (UHW) and was under the governance and oversight of the UHW Radiation Safety Committee (RSC). The reporting lines of communication articulated by staff to the inspector were consistent with radiology structures detailed in documentation viewed. The designated manager who was also the general manager of UHW was a member of the RSC and was the point of contact for reporting upwards via the radiology governance structure and formal delegation systems to the undertaking; the Health Service Executive (HSE).

The inspector found that the undertaking had ensured that only appropriate professional persons as recognised by the regulations could refer and act as practitioners. However, the hospital should review radiation safety procedures to align with practitioner roles and responsibilities as described to the inspector and to ensure greater clarity for staff on the allocation of responsibility for this facility.

There was also sufficient evidence viewed to demonstrate that a medical physics expert (MPE) was engaged for the service, with continuity arrangements in place and the level of involvement proportionate to the radiological risk of the service.

Regulation 4: Referrers

A sample of referrals for X-rays completed were viewed by the inspector and demonstrated that these referrals were from referrers as defined in the regulations. The inspector was informed by staff that referrals were submitted electronically via health link or hard copy to this facility from general practitioners (GP) working in the locality. GP details and professional registration numbers were routinely included in each referral ensuring that the practitioner could easily identify the referrer in each case. The scope of a radiographer, as a referrer, was detailed in the hospital radiation safety procedures which aligned with what staff told the inspector on the day.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures. Further clarity was required regarding the specific practitioner roles and responsibilities at this facility as described under Regulation 6.

Judgment: Compliant

Regulation 6: Undertaking

The inspector viewed radiology governance structures in documentation provided prior to this inspection which were consistent with those described by staff and management on the day of the inspection. The inspector was informed in these discussions that this facility was an extended service provided by University Hospital Waterford (UHW). This meant that staff from UHW ran the general radiology service provided at Dungarvan Community Hospital two days a week and documentation related to the radiation protection of service users was developed and approved by an overarching UHW Radiation Safety Committee (RSC). The RSC met twice a year and reported into the UHW Quality and Patient Safety Committee. The designated manager was also the general manager of UHW, was a member of the RSC and was the link between the RSC and the UHW Quality and Patient Safety Committee. The designated manager was also responsible for communicating any issues relating to radiation protection to the UHW Executive Management Board and upwards through formal delegation processes and structures to the undertaking which was the HSE.

The role of the practitioner assigned to Dungarvan Community Hospital was not clearly identifiable to the inspector in documentation viewed prior to the inspection and in initial discussions with staff on the day. However, further discussion with staff identified that radiographers conducting medical radiological procedures at this facility were practitioners for this service. Following on from this inspection, the hospital should ensure that the allocation of responsibilities documented in local procedures is fully aligned with practitioner roles described to the inspector for this facility. In addition, MPE responsibilities outlined in the Radiation Safety Procedures should be reviewed to align fully with responsibilities as defined under Regulation 20 (2).

Staff described the processes in place for reporting radiation incidents and near misses to the inspector which demonstrated that there was a system in place for reporting and managing radiation incidents. The inspector was informed that common near misses such as referral issues relating to the wrong side requests were recorded on the triple identification forms and these were reviewed and collated by the radiology service manager and risk management.

Notwithstanding the gaps in documentation identified that need to be addressed for

full compliance, the inspector was assured of the overall oversight of the radiation protection of service users at Dungarvan Community Hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The inspector was satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. There was also evidence to show that practitioners and the MPE were involved in the optimisation process as per the requirements of this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documentation and spoke to the MPE and found that the Medical Physics Department of UHW provided MPE services at Dungarvan Community Hospital. On the day of the inspection, inspectors was assured that the undertaking had ensured the continuity of the MPE service at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records and documentation reviewed by the inspector demonstrated that an MPE provided specialist advice at Dungarvan Community Hospital as required. The roles and responsibilities as per Regulation 20 of the MPE were clearly articulated to the inspector. The inspector also viewed documentary evidence of MPE contribution to the quality assurance (QA) of the hospital's medical radiological equipment, optimisation and DRLs. The MPE informed the inspector that an MPE attended each RSC meeting and shared the role of training staff on matters relating to the radiation protection of services users with the Radiation Protection Officer (RPO). In addition and as required, an MPE was involved in advising on technical specifications of equipment and analysis of any accidental and unintended exposures should they occur.

Judgment: Compliant

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

From documentation reviewed and discussions with staff including an MPE, the inspector found that MPE involvement in all aspects of medical exposure to ionising radiation conducted at the hospital was proportionate to the level of radiological risk at this installation.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection, the inspector assessed the systems and processes in place to ensure that medical exposures for service users attending for X-ray at this facility were safe.

From documentation viewed and processes described by staff, it was clear to the inspector that there was an established process for justifying each medical radiological procedure. The processes observed provided assurance that evidence relating to justification in advance was recorded and maintained on the radiology information system.

The hospital provided an up-to date inventory of medical radiological equipment for this facility and also demonstrated that an appropriate QA programme was in place and maintained as per the regulations.

This facility was found to be compliant with Regulation 11 as diagnostic reference levels (DRLs) had been established, reviewed and were in use by staff working in Dungarvan Community Hospital. Evidence found also demonstrated compliance with aspects assessed in relation to Regulation 16 and Regulation 17.

While the inspector found the hospital was substantially compliant with Regulation 13 as they had protocols and referral guidelines available for staff and clinical audits were carried out, improved compliance was needed with regard to Regulation 13(2). Information relating to patient exposure was not evident in the reports of medical exposures reviewed by the inspector on the day of inspection. Management informed the inspector that measures to come into compliance with this regulation were under review in consultation with the undertaking with a potential solution expected to be implemented in mid 2023.

Overall, Dungarvan Community Hospital demonstrated a high level of compliance with the regulations which provided assurance to the inspector on the protection of

service users attending for X-ray at this facility.

Regulation 8: Justification of medical exposures

Dungarvan Community Hospital provides a general radiology service to the local community two days a week. The inspector reviewed a sample of records of medical radiological procedures conducted in this facility and spoke to staff responsible for this service. All referrals reviewed by the inspector on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient clinical data to inform the justification process. Justification in advance was recorded on a triple identification form and signed by the practitioner for each procedure. The completed form was then uploaded onto the radiology information system and retained as evidence of compliance as per regulations. Posters and information leaflets informing service users of the risks and benefits associated with exposure to ionising radiation from X-rays were displayed in the waiting area for service users.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector found that diagnostic reference levels (DRLs) for adult medical radiological procedures were established and used at Dungarvan Community Hospital. The process for the establishment, use and review of facility DRLs was documented in the UHW Radiation Safety Procedures which was viewed by the inspector. From discussions with staff and documentation viewed, the inspector was satisfied where a facility DRL was exceeded, appropriate corrective actions and follow-up monitoring was undertaken. For example, a dose audit conducted in March 2022 identified a drift upwards in facility DRLs. Further investigation following this audit identified an issue with the Automated Exposure Control (AEC) which required recalibration. Documentation viewed by the inspector showed that both the service engineer and the MPE were onsite during the maintenance of this piece of equipment. Once the technical issue was addressed, a re-audit was carried out and new DRLs for 2022 were established. The inspector noted from these DRLs that one procedure continued to remain above national DRLs at the time of the inspection. Staff, including the MPE, informed the inspector that this issue was no longer a technical issue but was a patient specific one. Therefore it would take time to address as the solution was reliant on sufficient numbers of these procedures taking place to improve optimisation if required.

Overall, the inspector was satisfied that evidence viewed demonstrated compliance with this regulation.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard procedure provided at Dungarvan Community Hospital were available to staff at this facility and viewed by the inspector. The referral guidelines- *iRefer*, were available to referrers and staff on desktop computers.

The inspector reviewed clinical audit reports undertaken at this facility. The inspector was satisfied that where compliance was less than satisfactory in audits conducted, follow-up actions were taken and a re-audit was conducted. This was evident in a justification audit where compliance in the initial audit was deemed poor but a re-audit demonstrated significant improvement. Staff informed the inspector that there was potential to improve the strategy and process for clinical audit of radiology services and this will be addressed in the future.

A sample of reports relating to medical exposures were viewed on the day of the inspection and demonstrated that information relating to the medical exposure did not form part of the report as required under Regulation 13(2). The inspector was informed that the hospital had communicated with the undertaking in relation to a proposed solution and associated time line to address this issue in order to ensure the requirements of Regulation 13(2) are met by the hospital. It was expected that a solution would be in place by mid 2023.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory of medical radiological equipment. Documentation reviewed by the inspector showed that an appropriate QA programme was in place, including regular performance testing. Quality control checks on the X-ray tube output were carried out by a radiographer one day each week. Documentation demonstrated that annual QA for medical radiological equipment in this facility had been completed in October 2021 and November 2022. Although the scheduled time line outlined in hospital policy was not met in 2022, there was sufficient evidence to demonstrate that X-ray equipment was kept under strict surveillance as per the regulations. The inspector was informed by the MPE that the equipment was subject to an extensive QA following the maintenance of equipment by a service engineer in June 2022 and therefore other competing demands on limited MPE resources were prioritised ahead of the QA due in October 2022. While the inspector was assured of the surveillance of the equipment by the evidence reviewed as part of this inspection, the hospital should review and update its QA policy to ensure QA of equipment by an MPE is aligned with documented

scheduled time lines.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector observed posters about pregnancy in the waiting area with the aim of increasing the awareness of service users to whom this regulation applied. Staff described the process in place for establishing the pregnancy status of relevant service users. The inspector noted that completed pregnancy declaration forms for relevant service users were uploaded to the radiology information system.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Following review of documentation and discussion with staff, the inspector was satisfied that there was a system in place to record all radiation safety incidents and there was also evidence of discussion at the UHW RSC. The inspector was informed that near misses such as laterality issues in referrals were recorded on the triple identification forms, all of which were reviewed by the radiology services manager.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	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 Dungarvan Community Hospital OSV-0007951

Inspection ID: MON-0038118

Date of inspection: 30/11/2022

Introduction and instruction

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe* to come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Radiation Safety Procedures have been amended to clearly define and fully align with the allocation of responsibilities to radiographers as practitioners in Dungarvan Community Hospital (DCH). To clarify; all radiographic procedures are carried out and reported on, under the clinical responsibility of a radiologist, as practitioner. However, for the routine procedures typically performed in DCH, which are not normally subject to vetting by a UHW radiologist, the authorisation/justification element of the practitioner role is delegated to the radiographer. Please note that Section 6.8.3 of the Radiation Safety Procedures have been amended to provide more clarity in this regard.</p> <p>Section 6.4 of the Radiation Safety Procedures have been amended to give more detail on the responsibilities of the MPE, including reference to Reg. 20(2) of S.I. 256 of 2018.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: The recording of patient exposure data is under review nationally pending further consultation with key stakeholders in the coming months. Recording of patient dose will be implemented immediately once guidance is issued.</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 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	01/01/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	01/07/2023

	procedure.			
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