



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Cahirsiveen Community Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	New St, Knockeens, Cahersiveen, Kerry
Type of inspection:	Announced
Date of inspection:	13 September 2022
Medical Radiological Installation Service ID:	OSV-0007952
Fieldwork ID:	MON-0037704

About the medical radiological installation:

The X-ray department in Cahersiveen is under the governance of University Hospital Kerry. On average 1000 X-ray examinations are performed annually in Cahersiveen. Cahersiveen is located 117km from University Hospital Kerry and provides plain X-rays radiography service to those who are unable to travel to Tralee. It is a GP demand driven service from primary care in the South Kerry region. It is open for referrals on a Tuesday and Thursday morning and is staffed by a senior radiographer. The X-ray images are linked to NIMIS (National Integrated Medical Imaging System) and are reported remotely by consultant radiologists. Images can be linked to any specialist sites that have NIMIS if additional treatment is required. The Carestream digital X-ray unit provides improved patient throughput and this digital technology means that patients in this remote location in South Kerry have access to X-ray imaging. The benefit of a community based X-ray service ensures swift access, improved efficiency and a better patient experience.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

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

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

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 13 September 2022	09:00hrs to 11:55hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

An inspection was carried out at Cahirsiveen Community Hospital on 13 September 2022. From documentation reviewed and speaking with staff and management, the inspector was satisfied that the hospital had a clear allocation of responsibility for the protection of service users undergoing medical exposures at the facility.

Documented radiology governance arrangements viewed detailed that University Hospital Kerry(UHK) had overall responsibility for the radiation protection of service users. Reporting structures were well defined and clearly articulated to the inspector on the day of inspection demonstrating that there were direct lines of communication via UHK to the Health Service Executive (HSE), the undertaking for this facility. However, the inspector found that the designated manager role for this facility should be reviewed to ensure the role is at the appropriate level of oversight to ensure regulatory compliance.

Following a review of documents and records, and speaking with staff, the inspector was assured 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. The hospital had ensured that a medical physics expert (MPE) was involved in medical radiological practices which was evident in documentation reviewed and in discussions with staff. Arrangements to ensure continuity of medical physics expertise were viewed and met regulatory requirements. The evidence gathered during the inspection satisfied the inspector that MPE involvement in medical radiological practices was proportionate to the radiological risk posed by the practice.

Overall, the inspector found that there was a good level of compliance with regulations at Cahirsiveen Community Hospital and was satisfied that there was a clear and effective allocation of responsibility for the protection of service users attending for X-ray at the facility.

Regulation 4: Referrers

The inspector was satisfied that referrals reviewed were from referrers as defined in the regulations. There was a finite list of general practitioners with professional registration numbers displayed on the notice board in the control area of the X-ray room. These referrers were easily compared with referrer details and professional registration numbers contained in each referral viewed by the inspector.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Staff and management informed the inspector that this service was an extended service provided by UHK. Radiology governance structures were reviewed as part of this inspection and the documentation reviewed showed clear lines of communication within corporate and clinical governance structures outlined. A Radiation Protection Compliance Committee was the operational sub-committee of the Radiation Safety Committee (RSC) that reported into the Radiology Governance Group, which in turn reported into the hospital Quality and Patient Safety Committee. The hospital Quality and Patient Safety Committee reported directly up to the UHK Executive Management Board and upwards to the undertaking which was the HSE. While the hospital had ensured the allocation of responsibility for the conduct of medical exposures, the inspector found the undertaking should review the nominated designated manager to ensure that it is at an appropriate level to ensure oversight of compliance with the regulations.

Judgment: 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 formal arrangements in place with a private MPE provider which provided assurance on the continuity of medical physics expertise as required. Additional MPE support from Cork University Hospital (CUH) was also provided.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Records and documentation reviewed by the inspector demonstrated that MPEs provided specialist advice at Cahersiveen Community Hospital as required. The roles and responsibilities as per Regulation 20 from both the private MPE and the MPE support from CUH were clearly articulated to the inspector. For example, MPEs from CUH carried out annual quality assurance (QA) testing as part of the hospital's quality assurance programme. This included acceptance testing which was evident in records viewed for new equipment commissioned for use in 2019. The private MPE responsibilities were focused on optimisation, DRLs, involvement in protocol and policy development and approval, and analysis of any accidental and unintended exposures. From training records reviewed, the inspector was satisfied that an MPE contributed and delivered training on various aspects of radiation protection, the contents of which, was also circulated to staff who were not in attendance.

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 there was appropriate involvement of an MPE in all aspects of medical exposure to ionising radiation conducted at the hospital, in line with the level of radiological risk at this installation.

Judgment: Compliant

Safe Delivery of Medical Exposures

Systems and processes in place to ensure the protection of service users undergoing medical exposures at the Cahersiveen Community Hospital were reviewed by the inspector during this inspection. Discussions with staff and management and documentation reviewed demonstrated to the inspector that the staff working in this

service had a strong commitment and local ownership for the radiation protection of the service user.

An up-to-date inventory and quality assurance reports were provided to the inspector which showed that an appropriate quality assurance programme was in place and provided assurance that medical radiological equipment was kept under strict surveillance.

Evidence gathered from documentation reviewed and from speaking with staff demonstrated several areas of good practice. For example, the process for justifying medical exposures at the hospital was reviewed during the inspection and met regulatory compliance. Records of justification in advance were evident and accessible on the radiology information system. There was evidence to demonstrate that facility diagnostic reference levels were established and regularly reviewed as per regulations. Due to low levels of paediatric X-rays carried out at the hospital, paediatric DRLs had yet to be established. However, the inspector was informed that work had commenced to develop weight based paediatric DRLs. Evidence of this collation of data was seen by the inspector on records of paediatric X-rays where the weight of each child was recorded on the image of the medical exposure.

The inspector found that there was a system in place for the reporting and analysis of accidental and unintended exposures and significant events ensuring that any radiation incidents and near misses were discussed at the relevant forums within the radiology governance structure. There was also a policy in place for the safe use of carers and comforters during medical exposures which aligned with practices described by staff. Similarly, there were appropriate measures in place to ensure that an enquiry as to the pregnancy status of service users was undertaken as relevant to Regulation 16.

One area of improvement identified by the inspector related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of the report and therefore this deficiency must be addressed to ensure the requirements of this regulation are met.

Notwithstanding the non-compliance with Regulation 13(2) identified in this inspection, the inspector was assured by the evidence gathered that Cahersiveen Community Hospital had effective systems and processes in place to ensure that service users undergoing medical exposures were safe.

Regulation 8: Justification of medical exposures

Cahersiveen Community Hospital provides a general radiology service to the local community two mornings a week. The inspector reviewed a sample of records of medical radiological procedures conducted in this facility and spoke to staff responsible for performing the X-rays there. 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.

Staff demonstrated how previous imaging could be accessed for individual service users at this hospital and UHK. There was also a process in place to ensure a record of justification in advance of each medical radiological procedure was retained and these were available as evidence of compliance as per regulations. Posters informing service users of the risks and benefits associated with exposure to ionising radiation from X-rays were displayed in service users waiting areas.

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 the hospital. A DRL policy underpinned the process for the establishment, use and review of facility DRLs which was viewed by the inspector. The inspector was informed that paediatric procedures performed at the facility were relatively low, therefore paediatric DRLs were not yet established however, work was underway to collate data to develop weight based paediatric DRLs. Staff showed the inspector how the weight of each child was recorded on the image of each paediatric medical exposure carried out at the hospital.

Judgment: Compliant

Regulation 12: Dose constraints for medical exposures

The hospital had a policy in place for the safe use of carers and comforters during medical exposures performed at the hospital and UHK which aligned with the procedure detailed by radiography staff. Records were kept for each time a carer or comforter was present for X-rays undertaken and uploaded on the radiology information system. A sample of these records was viewed by the inspector during the inspection.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard procedure provided at Cahersiveen 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 and found that there was evidence of good practice in this area. One audit undertaken focused on improving the justification of referrals for lumbar spine X-rays for lower back pain. An initial audit undertaken in July 2021 found that only 65% of referrals were justified based on recognised referral guidelines. As a follow-up action to address this finding, a communication was sent to referrers, namely GPs in the community, informing them of the audit results and signposting best practice for referring for this procedure using referral guidelines. A re-audit in November 2021 found that there was a significant improvement in justified referrals received for lumbar spine X-rays with compliance increasing to 87.5 %. This example of clinical audit demonstrated to the inspector the commitment of staff to the radiation protection of service users.

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). This non-compliance must therefore be addressed to ensure the requirements of Regulation 13(2) are met.

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 which had been implemented for general X-ray unit in line with the QA programme scheduled time lines. Records of the acceptance testing completed on the new unit was also viewed by the inspector.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector observed posters about pregnancy in the waiting area, including multilingual posters, 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. A prompt was generated for these service users on the printed triple identification form once individual details were entered onto the radiology information system as an additional safety measure.

These records 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 evidence of discussion at committees within the radiology and hospital governance structures.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 12: Dose constraints for medical exposures	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 Cahirsiveen Community Hospital OSV-0007952

Inspection ID: MON-0037704

Date of inspection: 13/09/2022

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 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: On-going communication with Change healthcare regarding timeline on dose report on Radiological Radiologist reports. 30.06.2023 In the interim, Radiologist continue to use template "Dose report on request" within the body of the radiological report.	

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	30/06/2023