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:	Arklow Community Diagnostic Service
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Arklow Health Centre, Wicklow
Type of inspection:	Announced
Date of inspection:	19 September 2024
Medical Radiological Installation Service ID:	OSV-0008311
Fieldwork ID:	MON-0043954

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

The Health Services Executive engages an external, private medical imaging company to provide and manage the X-ray service in Arklow Community Diagnostic Service from 09:00 to 17:00 Monday to Friday. Approximately 5000 medical radiological procedures (X-Ray) are completed annually from referrals received from a cohort of GP's in the area. The X-ray service in Arklow Community Diagnostic Service is a single general X-Ray room, staffed by the external company's staff and includes a senior X-Ray radiographer, who is supported by a Radiology Services Manager, a Radiation Protection Officer and a Head of Operations.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 19 September 2024	09:30hrs to 13:00hrs	Margaret Keaveney	Lead

Governance and management arrangements for medical exposures

On 19 September 2024, the inspector completed an inspection of the radiological service at the Arklow Community Diagnostic Service, to monitor the undertaking's compliance with the regulations. The inspector visited the service's single X-ray unit, spoke with staff and the management team, and reviewed a sample of service user records and documents that were developed to support staff on radiation protection measures. Overall the inspector observed that there was a good multidisciplinary approach to radiation protection in the service, however some action was required to come into full compliance with Regulations 14 and 16.

The inspector was informed that the undertaking, Health Service Executive (HSE), had engaged an external imaging company to provide the radiological service in Arklow Community Diagnostic Service. While overall responsibility for the radiation protection of service users remained with the undertaking, the inspector was informed that the external company resourced the service with radiography and radiology staff, developed many of the policies and procedures in use, and oversaw the day-to-day service operations including the receipt and vetting of external referrals for medical exposures. The inspector noted that there was good communication and collaboration between the various parties involved in the service. For example, a radiation protection training policy had been developed by the radiation protection officer (RPO) and medical physics expert (MPE), for use in training staff**.**

At the time of the inspection, the inspector was satisfied that there were appropriate governance and management arrangements in place for the radiation protection of service users. The undertaking had formed a radiation safety committee (RSC) which met every six months to discuss a range of relevant matters including the equipment quality assurance (QA) programme, clinical audits, new and revised policies and procedures, training and incidents. Key staff from both parties attended these meetings, including the designated manager (DM) for the service, who is a HSE General Manager, a member of the MPE team, the radiology services manager (RSM), the practitioner in charge who is a radiologist and the external company's Head of Operations. The meetings were chaired by the radiation protection officer, whose other responsibilities included completing clinical audits and equipment QA, and managing incident investigations. The RSC meetings facilitated communication between the DM and the external company, and informed the DM of key radiation protection matters in the service which they subsequently brought to the attention of the undertaking via HSE Quality and Safety Committee meetings.

The inspector noted the arrangements in place, which ensured that only referrals from appropriate persons as per the regulations were accepted and completed in the service. The inspector was also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

On the day of the inspection, the inspector spoke with one of the MPEs involved in the service. From this discussion and a review of documentation, the inspector noted the MPE's involvement in the service was proportionate to the radiological risk in the service. The inspector also noted that the undertaking had arrangements in place to ensure the continuity of their service.

Notwithstanding the actions required to comply with Regulations 14 and 16, the inspector was assured that the undertaking was providing safe radiological exposures to service users in Arklow Community Diagnostic Service.

Regulation 4: Referrers

The inspector was satisfied that referrals for medical radiological procedures to Arklow Community Diagnostic Service were made only from persons as defined in Regulation 4. A *Referrals Policy* stated that this role had been allocated to medical practitioners, and to radiographers who could make adapted referrals when required.

The inspector was informed that all referrals were received from external medical practitioners and that there was a system in place to ensure the referrer was identifiable and their professional registration up-to-date.

Judgment: Compliant

Regulation 5: Practitioners

From a review of a sample of medical exposure records and from speaking with staff, the inspector was satisfied that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in the service. The undertaking had allocated this role to appropriately registered medical practitioners and radiographers.

Judgment: Compliant

Regulation 6: Undertaking

As stated earlier in this report, the HSE as the undertaking had engaged the services of an external imaging company to operate the day-to-day radiological service in Arklow Community Diagnostic Service. From discussions with the management

teams of both parties, the inspector was assured that each party was aware of their roles and responsibilities in providing a safe service to service users.

Over the course of the inspection, the inspector also reviewed a range of documents that guided and supported radiography, radiology and medical physics staff on radiation protection matters, and included an allocation of their roles and responsibilities for the radiation protection of service users. During this review, the inspector noted that some documents required minor revision to ensure that all roles were clearly allocated and aligned with the current regulations. However, these minor revisions did not affect the undertaking's compliance with Regulation 6.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that there were systems in place to ensure that all medical exposures, carried out in Arklow Community Diagnostic Service, took place under the clinical responsibility of a practitioner.

During the inspection, the inspector viewed documentation and spoke with staff who demonstrated that the undertaking had processes in place to ensure that the referrer and the practitioner were appropriately involved in the justification of individual medical radiological procedures. Similarly, a practitioner and MPE were involved in optimisation of medical exposures as required by this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From discussions with staff and a review of documentation, including a service level agreement, the inspector was satisfied that the undertaking had arrangements in place to ensure access to and continuity of MPE services.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The professional registration certificates for the MPE team were available for review by the inspector. The inspector was also informed that one MPE had been assigned

the role of radiation protection advisor (RPA) in the service, which satisfied the regulatory requirement that the MPE and the RPA liaise as appropriate.

From a review of procedures and records, the inspector noted that the MPE team had been allocated a range of responsibilities across the service. For example, they were involved in the acceptance testing and quality assurance of medical radiological equipment, had contributed to the application and use of the DRLs established in the service and were also available to provide advice and dose calculation for radiation incidents when required.

The MPE also attended the RSC meetings, at which they provided and received updates on their responsibilities.

Judgment: Compliant

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

From documentation reviewed and discussions with a member of the MPE team and other staff, the inspector was satisfied that the level of MPE involvement in medical radiological exposures in Arklow Community Diagnostic Service was commensurate with the radiological risk in the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

Over the course of the inspection, the inspector noted that the management team had implemented a range of measures to ensure the radiation protection of service users. For example, systems for the use and review of diagnostic reference levels (DRLs) and for minimising the probability and magnitude of incidents occurring had been established in the service. However, the inspector noted that there were some gaps in adherence to the undertaking's equipment QA programme and pregnancy policy, which are further discussed under Regulations 14 and 16 respectively below.

The inspector reviewed a sample of referrals, and saw that each was in writing, stated the reason for the request and was accompanied by sufficient medical data to enable the practitioner to consider the benefits and the risk of these medical exposures. The justification of these medical exposures in advance, by the referrer and practitioner, was also evident in this sample.

The management team had developed written procedures for all common X-ray examinations completed in the service, and ensured that referral guidelines were available for use when required. The inspector also noted that the management

team placed good emphasis on the use of clinical audit as a tool in identifying areas for improvement and areas of good practice in the service. They had also implemented a clinical audit strategy to ensure that the local clinical audit programme met the requirements of the national procedures on clinical audit, published by HIQA, for a general X-ray service. In addition, the inspector observed that staff in the service had established and reviewed local DRLs for medical exposures, and that this data was reviewed by the MPE and discussed at the RSC.

The inspector reviewed documentation that evidenced good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation, and noted good oversight of any incidents that occurred in the service.

At the time of the inspection, the inspector was satisfied that there was an established QA programme for radiological equipment in the service, and the undertaking's management team had now implemented this programme as planned. However, a review of meeting minutes and records showed that the some regular performance testing had not been completed from January to November 2023, due to the unavailability of testing equipment. This is further discussed under Regulation 14 below.

The inspector observed that the undertaking had developed a process to determine the pregnancy status of service users, where relevant. However, a review of a sample of service users' records showed that this process had not been applied for some relevant service users. While acknowledging that the radiological risk from general X-ray exposures to the foetus is low, this gap in adhering to local processes must be actioned by the undertaking to achieve full compliance with Regulation 16.

Notwithstanding the gaps in compliance with Regulations 14 and 16, the inspector was satisfied that, overall, there were good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Information on the benefits and risks associated with the radiation dose from medical exposures was available by means of posters in the waiting areas of the service, and general X-ray specific information leaflets were also available to service users.

From a review of a sample of medical records, the inspector was satisfied that referrals for medical exposures were in writing and stated the reason for the request, and were accompanied by sufficient medical data to enable the practitioner to adequately consider the benefits and risks of the medical exposure. This review also demonstrated that the justification in advance process had been completed and recorded by practitioners. Practitioner staff also informed the inspector of how they obtained previous diagnostic information.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

From a review of documentation, the inspector was satisfied that DRL information for frequently completed X-ray examinations had been established and compared to national levels. The inspector noted that this information was prominently displayed in the equipment console area for easy reference by staff.

The inspector was informed that while the DRL for one examination type was below the national level, an additional audit and review of the DRL for this examination had been completed at the request of the RSC. Although this additional review established that no further action was required, this oversight and attention to radiation protection for service users was identified as an area of good practice within the service.

Judgment: Compliant

Regulation 13: Procedures

The inspector saw that written protocols for each standard radiological procedure had been developed and were available in the console area of the X-ray unit for easy access by staff. The inspector was also informed that referral guidelines were available to practitioners for use during the justification process.

During a review of a number of reports on medical exposures, the inspector saw that dose information relating to patient exposure was included in the reports.

A sample of clinical audits completed in the service were reviewed by the inspector. These included a *Practitioner on-site visit structure* audit that was completed by the service's practitioner in charge; process audits such as adherence to checking pregnancy status by staff, the justification process and incorrect referrals; and outcome audits such as image quality and reject analysis audits. The undertaking's management team had also developed a *Clinical Audit Strategy*, which included the oversight arrangements for clinical audits completed in the service. The inspector was satisfied that the undertaking's clinical audit programme in Arklow Community Diagnostic Service was appropriate for the radiological risk posed by the medical exposures completed in the service.

Judgment: Compliant

Regulation 14: Equipment

Prior to the inspection, the inspector received an up-to-date inventory of medical radiological equipment as requested. The inspector also reviewed acceptance testing records which had been carried out on equipment prior to the first clinical use. The inspector was informed that a multidisciplinary team had developed the equipment's QA programme, which included annual testing by the MPE and regular performance testing by the RPO and external engineers. From a review of QA records, the inspector saw that this programme had been effectively implemented since November 2023 with test timelines adhered to and the inspector was satisfied that the medical radiological equipment in the service was now under strict surveillance.

However, the review of records showed that prior to November 2023, due to testing equipment not being available, some performance testing had not been completed, and therefore the full QA programme had not been implemented and maintained. Although the inspector was assured that, during this period, the undertaking had measures in place to monitor the performance of the equipment and ensure the radiation protection of service users, due to the gaps in testing and records the undertaking was found to be not compliant with Regulation 14(2)(a) and Regulation 14(3)(b).

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking had implemented appropriate measures to minimise the risks associated with potential foetal irradiation, during medical exposures, of female patients of childbearing age. This included placing notices to raise awareness of the special protection required during pregnancy in advance of medical exposures in service user waiting areas and in changing rooms, and the development of a *Pregnancy Policy* outlined the roles and responsibilities for inquiring on and recording in writing the service user's pregnancy status where relevant.

However, during a review of a sample of records, the inspector noted that the pregnancy status inquiry process had not been completed for a number of relevant service users. Although the radiological risk from general X-ray exposures to the foetus is low, this gap in adhering to local processes, and the regulatory requirement to record in writing the answer to any such inquires and to hold such records for a period of five years, impacted on the undertaking's compliance with Regulation 16(1)(b).

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector reviewed the local *Guideline for Incident & Near Miss Reporting* policy, which outlined the process for the management of accidental and unintended exposures and significant events, and included the requirement to notify HIQA of certain reportable incidents. Staff who spoke with the inspector were able to describe the process of reporting an incident or near miss involving a medical exposure.

Records and investigation reports for one incident and one near miss, which had occurred in the service since it opened in January 2023 were available, and the inspector noted that they were discussed at the RSC meetings where investigation actions were agreed on. Additional records showed that, when the incident occurred, members of the undertaking's management team were immediately informed of the details and initial corrective actions implemented.

These oversight arrangements and documents assured that inspector that the undertaking had taken all reasonable measures to minimise the probability and magnitude of accidental and unintended exposures of service users occurring in the service.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Arklow Community Diagnostic Service OSV-0008311

Inspection ID: MON-0043954

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 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Regulation 14: The gaps in the QA were due to delays experienced with the purchasing a machine to measure Kv Output. We are happy that this was rectified from November 2023 and QA has been maintained in a timely manner since. We will continue to follow our QA schedule.	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: Regulation 16: Special protection during pregnancy and breastfeeding While the Radiology Department does undertake LMP audits, we acknowledge that gaps were identified on the day of inspection and addressed in regards to recording Pelvic examinations. The RSM has discussed this with all staff members the importance of recording LMP. The RPO will do an audit in 6 months to access compliance specifically in relation to pelvic LMP.	

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 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	30/11/2024
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	01/03/2025
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years	Substantially Compliant	Yellow	01/10/2024

	and provide such records to the Authority on request.			