

## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Alliance Medical @LAYA Health & Wellbeing Limerick
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Ennis Road, Shanabooly, Limerick
Type of inspection:	Announced
Date of inspection:	25 March 2025
Medical Radiological Installation Service ID:	OSV-0007907
Fieldwork ID:	MON-0044800

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

Alliance Medical Diagnostic Imaging (AMDI) work in partnership with Laya Healthcare and MyMedical providing x-ray and fluoroscopy services onsite at Laya Health & Wellbeing, Limerick. AMDI have been providing services onsite for over four years. The X-ray service is operational 365 days a year, supporting the Laya Minor Injuries Unit. A walk-in x-ray service is also provided. AMDI also operates an image intensifier providing fluoroscopy for a weekly pain injection list.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

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

<sup>4</sup> 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
Tuesday 25 March 2025	10:00hrs to 14:00hrs	Noelle Neville	Lead
Tuesday 25 March 2025	10:00hrs to 14:00hrs	Margaret Keaveney	Support

## Governance and management arrangements for medical exposures

An inspection of the undertaking Alliance Medical Diagnostic Imaging (AMDI) Ltd. at Alliance Medical @LAYA Health & Wellbeing Limerick was carried out on 25 March 2025 by inspectors to assess compliance with the regulations at this facility. As part of this inspection, the inspectors visited the general X-ray and fluoroscopy units, spoke with staff and management and reviewed documentation. The inspectors noted that the undertaking demonstrated compliance during this inspection with each regulation reviewed.

The undertaking, Alliance Medical Diagnostic Imaging Ltd., had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. The inspectors noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Alliance Medical @LAYA Health & Wellbeing Limerick and effective management structures were in place to ensure the radiation protection of service users.

### Regulation 4: Referrers

Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that medical exposures were only accepted from individuals entitled to refer as per Regulation 4 at Alliance Medical @LAYA Health & Wellbeing Limerick.

Judgment: Compliant

### Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Alliance Medical @LAYA Health & Wellbeing Limerick.

Judgment: Compliant

## Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including a governance structure organogram (organisational chart that shows the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Alliance Medical @LAYA Health & Wellbeing Limerick.

There was a radiation protection committee (RPC) in place at the facility. Inspectors reviewed the terms of reference for this committee, which had an approval date of May 2024, and noted that it had a multi-disciplinary membership. This membership included the unit manager who was also the designated manager of the facility, radiation protection officer, medical physics expert (MPE), radiologist, member of the senior management team, quality department member, clinical specialist radiographers and a representative from the pain clinic. The committee was incorporated into local governance structures, reporting to the undertaking's quality and patient safety department and senior management team demonstrating good communication and oversight structures in place for the radiation protection of service users.

Inspectors noted that information relating to Regulation 7: Justification of Practices, had been incorporated into the *Radiation Safety (ROI) Policy* in place at the facility in September 2024. This information included the allocation of staff responsible for the awareness of any new type or classes of practice involving ionising radiation and the next steps involved in relation to same.

Overall, inspectors were satisfied that the undertaking, Alliance Medical @LAYA Health & Wellbeing Limerick, had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the facility.

Judgment: Compliant

## Regulation 10: Responsibilities

Inspectors noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at Alliance Medical @LAYA Health & Wellbeing Limerick by individuals entitled to act as practitioners in the regulations. Practitioners and MPEs were found to be involved in the optimisation

process for medical exposure to ionising radiation. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were 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 Alliance Medical @LAYA Health & Wellbeing Limerick.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspectors reviewed the professional registration certificate of the MPE at Alliance Medical @LAYA Health & Wellbeing Limerick and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted that the MPE was involved in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Alliance Medical @LAYA Health & Wellbeing Limerick. The MPE was a member of the radiation protection committee in place at the facility and gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). The MPE carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relevant aspects of radiation protection. In addition, the MPE also acted as radiation protection adviser (RPA) for the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, inspectors were satisfied that the level of involvement of the MPE at Alliance Medical @LAYA Health & Wellbeing Limerick was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors visited the general X-ray and fluoroscopy units at the facility, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Alliance Medical @LAYA Health & Wellbeing Limerick. Inspectors noted compliance with each regulation reviewed.

For example, there was evidence showing that each medical exposure was justified in advance as required by Regulation 8. Facility DRLs were established, regularly reviewed and used for adult general X-ray and fluoroscopy medical exposures. Inspectors were informed that facility DRLs had not yet been established for paediatric exams due to the low number of paediatric procedures taking place at the facility. Inspectors reviewed a sample of reports for general X-ray and fluoroscopy medical radiological exposures and found that information relating to the exposure formed part of the report as required by Regulation 13(2). In relation to Regulation 13(4), inspectors found that a clinical audit policy and strategy was in place and was aligned to the national procedures established by the Authority. Staff at the facility ensured that medical radiological equipment was kept under strict surveillance as required by Regulation 14. In relation to Regulation 16, records of pregnancy inquiries for relevant service users were seen by inspectors. In addition, there was a process for identification, management, reporting, analysis and trending of radiation incidents and potential incidents as required by Regulation 17.

Inspectors were satisfied that systems and processes were in place at Alliance Medical @LAYA Health & Wellbeing Limerick to ensure the safe delivery of medical radiological exposures to service users.

## Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate 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 on posters displayed throughout the facility.

The undertaking at Alliance Medical @LAYA Health & Wellbeing Limerick had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was approved in September 2024. This document outlined the justification process in place at the facility and staff responsibilities in relation to same including the requirement for a practitioner to justify the medical exposure at both the vetting



stage and just before initiating the exposure. Inspectors reviewed a sample of records of general X-ray and fluoroscopy procedures and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The undertaking at Alliance Medical @LAYA Health & Wellbeing Limerick had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was approved in September 2024. This document set out the responsibilities in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. Inspectors found that facility DRLs had been established, regularly reviewed and used for adult general X-ray and fluoroscopy procedures having regard to national DRLs and were displayed prominently in the facility. Inspectors were informed that national DRLs were used for paediatric exams as it was not yet possible to establish facility DRLs due to the low number of paediatric procedures taking place at the facility.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols were in place at Alliance Medical @LAYA Health & Wellbeing Limerick for standard radiological procedures as required by Regulation 13(1). Regulation 13(2) states that an undertaking shall ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure. Inspectors reviewed a sample of reports for general X-ray and fluoroscopy medical radiological exposures and found that information relating to the exposure formed part of the report. Referral guidelines were also adopted at the facility and were available to staff and referrers as required by Regulation 13(3).

Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's national procedures document, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). The undertaking at Alliance Medical @LAYA Health & Wellbeing Limerick had a document titled *Radiation Clinical Audit Procedure*, the most recent version of which was approved in February 2025. This document outlined the audit strategy in place at the facility which is based on a risk assessment of areas including results from the previous year's annual radiation safety audit, non-compliances and the number and relative risk of previous year's

radiation incidents and near misses. The risk assessment forms a basis for categorising the facility as low, medium or high which then drives the number of audits that should be performed at a minimum. The document also outlined the process for radiation clinical audits at the facility including audit identification, approval, methodology, scoring, results and report. Inspectors reviewed a sample of audits carried out at the facility including an audit titled *AMDI Radiation Safety Audit 2024*. This audit included a range of topics including radiation safety governance, assessment of DRLs, compliance with procedures to establish pregnancy status and clinical justification of examinations in radiation modalities. Overall, inspectors noted that the undertaking was in compliance with Regulation 13(4).

Judgment: Compliant

### Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Alliance Medical @LAYA Health & Wellbeing Limerick as required by Regulation 14(1). The inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The undertaking had a document titled *Radiation Modality QA Procedure*, the most recent version of which was approved in November 2023 and a document titled *Ennis Road Laya Clinic Radiation QA Procedures Template*, approved in November 2023. These documents outlined staff responsibilities and the frequency of testing for each modality at the facility. The inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, the inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at Alliance Medical @LAYA Health & Wellbeing Limerick had a document titled *Patient Pregnancy Procedure Radiation (ROI)*, the most recent version of which was approved in November 2023. This document included information on the pregnancy procedures in place at the facility including the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed and discussions with staff, inspectors were satisfied that a referrer and practitioner

inquired as to the pregnancy status of service users and recorded the answer to the query in writing. In addition, inspectors noted notices in the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents that Alliance Medical @LAYA Health & Wellbeing Limerick had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The incident management process in place at the facility was outlined in two documents titled *Internal Incident Reporting Procedure*, the most recent version of which was approved in September 2024 and *Radiation Incident Procedure*, the most recent version of which was approved in November 2023. The latter document included information on the requirement to notify HIQA of certain reportable incidents.

Inspectors noted that two incidents had been reported to HIQA within the required timelines and aligned to the procedures in place at the facility since the commencement of the regulations in 2019. Inspectors were informed that the undertaking had established an academy for newly recruited radiographers covering topics such as legislation and safe working practices. As part of the corrective actions identified following the two reportable incidents, radiographer baseline competency is assessed and training needs are identified during this academy period to ensure patient safety. Inspectors noted the establishment of the academy as an example of good practice.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant