



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 @Cork University Hospital
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Wilton, Cork
Type of inspection:	Announced
Date of inspection:	10 July 2024
Medical Radiological Installation Service ID:	OSV-0005997
Fieldwork ID:	MON-0042283

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

Alliance Medical Diagnostic Imaging (AMDI) Ltd. are contracted on behalf of Cork University Hospital (CUH) to provide positron emission tomography/computed tomography (PET/CT), CT, MRI and dual energy X-ray absorptiometry (DXA) services on-site. AMDI have been providing services on-site for over 12 years. The PET/CT service operates four days per week, and is available to both in-patients and out-patients. The PET/CT service utilises two main isotopes, FDG and F-18 PSMA, providing access to CUH as well as external referrers from public and private regional hospitals. The CT, MRI and DXA operate five to six days per week and are available to out-patients and GP patients for MRI and DXA only. CUH is a Major Trauma Hospital and a Regional Cancer centre. The hospital has an extensive range of specialities referring to the AMDI modalities including paediatrics, oncology, neurology, orthopaedics, neurosurgery, geriatrics, respiratory, breast and prostate care.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

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

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

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

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

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 10 July 2024	09:00hrs to 12:25hrs	Noelle Neville	Lead
Wednesday 10 July 2024	09:00hrs to 12:25hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection of the undertaking Alliance Medical Diagnostic Imaging (AMDI) Ltd. at Alliance Medical @Cork University Hospital was carried out on 10 July 2024 by inspectors to assess compliance with the regulations at this facility. As part of this inspection, the inspectors visited the positron emission tomography/computed tomography (PET/CT) and dual energy X-ray absorptiometry (DXA) units, spoke with staff and management and reviewed documentation. The inspectors noted that the undertaking, Alliance Medical Diagnostic Imaging Ltd., demonstrated compliance during this inspection with Regulations 4, 5, 6, 8, 9, 10, 11, 14, 16, 17, 19, 20 and 21 and non-compliance with Regulation 13.

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 experts (MPEs) 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 strong culture of radiation protection was embedded at Alliance Medical @Cork University Hospital and clear and effective management structures were in place to ensure the radiation protection of services 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 @Cork University Hospital.

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 @Cork University Hospital.

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 @Cork University Hospital. Inspectors were informed that the undertaking was contracted on behalf of Cork University Hospital to provide a PET/CT, CT and DXA imaging service on the hospital campus.

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, a radiation protection officer, a radiologist, MPEs, members of senior management and the quality department, a clinical specialist radiographer and a representative from Cork University Hospital. 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 some information relating to Regulation 7: Justification of Practices, had been incorporated into the *Radiation Safety (ROI) Policy* in place at the facility in June 2024. This information included the allocation of staff responsibility for the awareness of any new type or classes of practice involving ionising radiation and the next steps involved in relation to same. While inspectors acknowledge the steps taken to initiate this process, there was scope to further clarify and formalise responsibilities in relation to the process for identifying and applying for approval from HIQA for new practices, as required by the regulations.

Overall, inspectors were satisfied that the undertaking, Alliance Medical Diagnostic Imaging Ltd., had clear and effective governance and management structures in place to ensure the radiation protection of service users and a strong 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 @Cork University Hospital 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 @Cork University Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspectors reviewed the professional registration certificates of the MPEs at Alliance Medical @Cork University Hospital and were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted that MPEs were involved in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Alliance Medical @Cork University Hospital. MPEs were members 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. MPEs were involved in optimisation, including the application and use of diagnostic reference levels (DRLs). MPEs 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, MPEs liaised with the radiation protection advisers (RPAs) at 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 MPEs at Alliance Medical @Cork University Hospital 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 PET/CT and DXA units at the facility, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Alliance Medical @Cork University Hospital. Inspectors noted compliance with each regulation reviewed with the exception of Regulation 13.

For example, there was evidence showing that each medical exposure was justified in advance as required by Regulation 8. For Regulation 9, inspectors noted that staff at Alliance Medical @Cork University Hospital demonstrated a strong commitment to optimisation and keeping doses to services users as low as reasonably achievable consistent with obtaining the required medical information. Facility DRLs were established, regularly reviewed and used for PET/CT and CT medical exposures and data collection was underway for DXA exams to allow for facility DRLs to be calculated. 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.

In relation to Regulation 13(2), inspectors reviewed a sample of reports for PET/CT, CT and DXA medical radiological exposures and found that while information relating to the patient exposure formed part of the report for DXA and the PET part of PET/CT exams, it was not available for CT exams or the CT part of PET/CT exams. As the majority of exams carried out at the facility involved CT, this meant that information relating to the patient exposure did not form part of the report for the majority of exams at Alliance Medical @Cork University Hospital.

In relation to Regulation 13(4), inspectors noted that clinical audits completed in 2023 identified quality improvement initiatives in relation to optimisation of medical radiological procedures at the facility. While inspectors noted that considerable work had been carried out by the undertaking in relation to clinical audit, there was scope for improvement in aligning the procedure in place with HIQA's national procedures.

Overall, despite the gaps identified in Regulation 13, inspectors were satisfied that systems and processes were in place at Alliance Medical @Cork University Hospital to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed 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. In addition, staff carried an information card to assist in providing meaningful information to service users in relation to the benefits and risks associated with the radiation doses from particular medical exposures.

The undertaking at Alliance Medical @Cork University Hospital had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was approved in June 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 in PET/CT, CT and DXA and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

Regulation 9: Optimisation

Inspectors noted several examples of good practice in relation to optimisation at Alliance Medical @Cork University Hospital. For example, a facility DRL was found to be higher than the national DRL for a particular CT exam. Staff at the facility identified that there was scope to optimise this exam with an aim of maintaining image quality. The scanning protocol for this exam was adjusted, dose data was collected and a new facility DRL was calculated. It was found that the facility DRL was reduced to below the national DRL while maintaining image quality.

Another example of good practice in relation to optimisation noted by inspectors involved a particular CT exam where staff identified that the facility DRL was below the national DRL and so there was scope to optimise the image quality. Staff adjusted the scanning parameter for the CT exam, collected data from exams using this new parameter and established a new facility DRL. It was noted that image quality was improved as a result of optimising this CT exam.

In addition, inspectors reviewed an audit conducted in PET/CT which was carried out with a view to amending and improving a clinical scanning protocol and workflows. The result was a reduced uptake time for a particular exam leading to reduced waiting times for service users and more service users having access to the exam.

Inspectors noted that staff at Alliance Medical @Cork University Hospital demonstrated a strong commitment to optimisation and keeping doses to services users as low as reasonably achievable consistent with obtaining the required medical information.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The undertaking at Alliance Medical @Cork University Hospital had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was approved in June 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 PET/CT and CT having regard to national DRLs and were displayed prominently in the facility. In addition, inspectors were informed that data collection was underway for the DXA service which began in February 2024 and local DRLs would be calculated once this data collection was complete.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Alliance Medical @Cork University Hospital for standard radiological procedures as required by Regulation 13(1). 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). Inspectors found that the undertaking and staff at Alliance Medical @Cork University Hospital had sought to align clinical audit practices with the national procedures and had updated a document titled *Radiation Clinical Audit Procedure* in June 2024. This document outlined the process for radiation clinical audits at the facility including audit identification, approval, methodology, scoring

and results. However, inspectors noted some gaps in aligning this document to the requirements of the national procedures.

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. Inspectors also noted that the results of clinical audits carried out during 2023 were displayed on posters in the department for staff and service users to view. While inspectors noted that considerable work had been carried out by the undertaking in relation to clinical audit, there was scope for improvement in aligning the procedure in place with HIQA's national procedures. For example, the development of an overarching clinical audit strategy, which should identify how clinical audit is prioritised, including based on risk and information from incidents or near misses. In addition, inspectors noted gaps in auditing the full clinical pathway of the service user, which should also be addressed in the clinical audit strategy.

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 PET/CT, CT and DXA medical radiological exposures and found that while information relating to the patient exposure formed part of the report for DXA and the PET part of PET/CT exams, it was not available for CT exams or the CT part of PET/CT exams carried out at the facility. As the majority of exams carried out at the facility involved CT, this meant that information relating to the patient exposure did not form part of the report for the majority of exams at Alliance Medical @Cork University Hospital.

Management informed inspectors that although the undertaking had a technical solution to meet the requirements of Regulation 13(2), this solution could not be implemented at this facility due to the external radiation information system/picture archiving and communication system (RIS/PACS) infrastructure in use by the host site, which also had to be used at Alliance Medical @Cork University Hospital. Inspectors were informed that the host site were in the process of progressing a technical solution to meet the requirements of Regulation 13(2) but a timeframe for this to be completed was not available. The undertaking, Alliance Medical Diagnostic Imaging Ltd., should ensure that information relating to the patient exposure forms part of the report for all medical radiological procedures to ensure full compliance with Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Alliance Medical @Cork University Hospital 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 at Alliance Medical @Cork University Hospital had a document titled *Radiation Modality QA Procedure*, the most recent version of which was approved in November 2023 and a document titled *CUH Radiation QA Procedures*, issued in June 2024. 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 @Cork University Hospital 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 discussion 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, the inspectors noted multiple 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 @Cork University Hospital 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 March 2023 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 11 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.

While the undertaking, Alliance Medical Diagnostic Imaging Ltd., demonstrated compliance with this regulation, inspectors determined that there was potential scope for improvement in relation to the identification and reporting of potential incidents, analysis and learning in the context of the number of procedures taking place at the facility each year and the low level of incidents and near misses being reported.

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 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not 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 Alliance Medical @Cork University Hospital OSV-0005997

Inspection ID: MON-0042283

Date of inspection: 10/07/2024

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 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Reg 13(4) Whilst documentation is in place for clinical audit, work has commenced on developing an overarching strategy to better align with the national procedure. This will include a framework for each site to assess and establish an audit cycle for the year which is commensurate with the service and risk for each site, and also to allow the full pathway of the service user to be audited. This will be implemented by the end of 2024 and will be measurable by way of relevant audits and reports.</p> <p>Reg 13(2) Information relating to the patient exposure is now present on all radiological reports at Alliance Medical @ Cork University Hospital.</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 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	22/08/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	31/12/2024