



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 @Mitchelstown Cork
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Fermoy Road, Brigown, Mitchelstown, Cork
Type of inspection:	Announced
Date of inspection:	08 February 2024
Medical Radiological Installation Service ID:	OSV-0007864
Fieldwork ID:	MON-0040110

About the medical radiological installation:

Alliance Medical in Mitchelstown offers rapid access to DXA, X-Ray and Ultrasound procedures. The radiology department is located within a primary care centre. All radiographers are highly qualified, CORU registered and imaging is reported by a consultant radiologist, approved by the Royal College of Surgeons.

The radiology department has been in operation within the primary care centre since 2009 and has offered a high-quality service to the local and wider community since that time. Referrals are predominately from general practitioners but referrals from consultants are also accepted.

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
Thursday 8 February 2024	10:00hrs to 12:45hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

Alliance Medical Diagnostic Imaging Ltd (AMDI) is the undertaking for Alliance Medical @ Mitchelstown, Cork. An inspection was completed at this medical radiological facility on 8 February 2024. The inspector spoke with staff and management, reviewed documentation and also visited the combined general radiography and dual-energy X-ray absorptiometry (DXA) room as part of this inspection.

The evidence gathered during this inspection demonstrated that all referrals were in writing, contained relevant details and clinical data to inform the process of justification by a practitioner. The inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer. From the documentation reviewed and discussions with staff and management, it was evident that the undertaking had ensured the appropriate involvement of a medical physics expert (MPE) in medical radiological practices which was proportionate with the radiological risk posed by the practice. In this facility, the allocation of responsibilities for medical radiological practices was in line with regulatory requirements. Staff who spoke with the inspector were not only clear on their individual roles and responsibilities but also demonstrated a strong commitment to the optimisation of medical exposures and radiation protection of service users.

Overall, the evidence showed that the undertaking complied with all regulations assessed during the course of this inspection.

Regulation 4: Referrers

The inspector found that there were established systems for accepting referrals at Alliance Medical @ Mitchelstown, the majority of which were received in electronic format. Local procedures viewed specified the information to be included in each referral for the referral to be accepted. The inspector was satisfied from discussions with staff and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Staff informed the inspector that any omissions or queries identified by a practitioner in referrals received were sent back to the referrer to be revised and re-submitted with the addition of a link and login details to available electronic referral guidelines. The inspector found this to be good practice by staff in promoting the access and use of referral guidelines to referrers as a reference point when referring service users for a medical exposure.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that medical exposures only took place under the clinical responsibility of a practitioner as recognised under this regulation.

Judgment: Compliant

Regulation 6: Undertaking

The inspector found that leadership, governance and management arrangements described by staff and management were consistent with structures outlined in the documentation viewed.

A radiation safety committee (RSC) was in place and met twice a year. This committee had multidisciplinary membership and was operationally accountable to the undertaking, AMDI, via established reporting lines. The inspector reviewed minutes from RSC meetings held in 2023 and January 2024 which were comprehensive and provided assurance that there was appropriate senior management representation and oversight of the radiation protection of service users. The inspector noted an example of good practice where the learning gained from previous HIQA inspections carried out on other sites under this undertaking was also shared at this forum with the aim of improving practices and compliance as appropriate, across all sites.

The inspector was informed by staff and management that points of note discussed at monthly governance meetings were discussed with the team at monthly staff meetings. A sample of minutes were viewed and the inspector was informed that staff were alerted by email when minutes were available to view. The inspector found that this forum offered a good medium for staff to convey queries or topics to be brought up for discussion in relation to radiation protection and also facilitated the sharing of information regarding audit outcomes and learning from radiation incidents.

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 practical aspects of medical radiological procedures were only carried out in this facility by persons entitled to act as practitioners as per the regulations. Similarly, practitioners

and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documentation and spoke with staff and management and was satisfied from the evidence gathered that AMDI had ensured the continuity of medical physics expertise at Alliance Medical @ Mitchelstown which was in line with regulatory requirements.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector viewed current professional certification for the MPE engaged by the undertaking for Alliance Medical @ Mitchelstown, thereby meeting the requirements of Regulation 20(1). There was also evidence to show that the MPE took responsibility for dosimetry, contributed to the establishment and review of facility diagnostic reference levels (DRLs) and was involved in the optimisation of medical exposures.

Overall the inspector was satisfied that MPE responsibilities set out under Regulation 20 were met by the undertaking of this facility.

Judgment: Compliant

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

From the evidence gathered from the review of documentation and speaking with staff and the MPE, the inspector was satisfied that the level of MPE involvement was proportionate to the radiological risk posed by the service provided at this facility, as per the regulations.

Judgment: Compliant

Safe Delivery of Medical Exposures

The systems and processes to ensure the safety of service users undergoing medical exposures at Alliance Medical @ Mitchelstown were reviewed as part of this inspection. The inspector found that the undertaking complied with all regulations assessed during this inspection. For example, there was evidence to show that each medical radiological procedure was justified in advance as per Regulation 8. Facility DRLs were established, regularly reviewed and applied in practice and reviews undertaken where facility DRLs were found to consistently exceed national DRLs, thereby, meeting the requirements of Regulation 11. Written protocols for standard procedures delivered were evident. The inspector saw evidence to show that information relating to the patient exposure was contained in reports viewed and referral guidelines were applied. Staff at this facility ensured that medical radiological equipment was kept under strict surveillance as required under Regulation 14. In relation to Regulation 16, records of pregnancy enquiries for relevant services users were evident and there was a process for the identification, management, reporting, analysis and trending of radiation incidents and potential incidents that complied with Regulation 17.

The inspector noted examples of good practice in clinical audits completed in 2023 with a focus on the optimisation of imaging carried out in the X-ray and DXA services. In the DXA service, the inspector found that staff involved in carrying out DXA scans were focused on ensuring that DXA imaging was reproducible and reliable through the application of standardised and consistent techniques when carrying out DXA scans. The inspector was informed that knowledge and experiences gained in this specialist setting was also shared with staff working in other medical radiological installations providing DXA services under the undertaking's remit which was considered by the inspector to be good practice.

Overall, the inspector was satisfied that staff and management had the systems and processes in place to ensure consistent practices for the optimisation and radiation protection of service users attending Alliance Medical @ Mitchelstown for diagnostic imaging.

Regulation 8: Justification of medical exposures

To assess compliance with this regulation, the inspector reviewed a sample of referrals and medical exposure records and spoke with staff. The records viewed showed that referrals were in writing and contained sufficient service user details and clinical data to facilitate justification in advance of each medical exposure by a practitioner. These records were retained on the radiology information system with the identification of the practitioner who had carried out justification evident to the inspector. Staff also described the process of justification which the inspector found

to be consistent with local policy. Posters detailing the risks and benefits associated with medical exposures were displayed on the walls in service user waiting areas.

The inspector was satisfied that the evidence gathered demonstrated the undertaking's compliance with the requirements of this regulation.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, the inspector was assured that Alliance Medical @ Mitchelstown had measures in place to ensure that all medical radiological procedures carried out in this facility adhered to the 'as low as reasonable achievable' (ALARA) principle. This was evident in local policies and procedures viewed by the inspector such as the *AMDI Mitchelstown Radiation QA Procedures Template*, the *Radiation Safety (ROI) Policy* and *Mitchelstown Radiation Local Rules*, all of which provided information about the process for optimising medical exposures.

Additionally, from discussions with staff, the inspector found an example of good practice in the DXA service where there was a strong emphasis placed on continued training and education in DXA scanning provided to staff performing DXA scans to ensure consistency in correct positioning and standards of care. Staff involved in DXA scanning service also shared their knowledge, learning and experience on the use of consistent practices and techniques more broadly across other facilities providing DXA services under the undertaking's remit. The inspector found this to be an example of good practice.

The inspector noted that clinical audits carried out in both the general X-ray and the DXA services were focused on optimisation. For example, in addition to the dose audit discussed under Regulation 11, an audit of pelvis procedures was performed in July 2023. This identified that improvements in patient positioning were required for these examinations. These learning points were communicated to staff from this and follow up completed audits of lumbar spine and pelvis examinations.

Recommendations provided to staff to improve the collimation and patient positioning had been acted on for these type of procedures and the inspector noted the commitment of staff to further optimise procedures and reduce doses received by patients.

Overall, the inspector found that there were effective systems and processes in place to ensure the radiation protection of service users attending for X-ray and DXA scans and to demonstrate the undertaking's compliance with the regulations assessed during this inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector saw evidence that DRLs for commonly performed examinations in general X-ray and DXA scanning had been established and reviewed. There was also evidence to show that appropriate reviews were undertaken in situations where the facility DRLs consistently exceeded national DRLs in general X-ray which had an analog X-ray system. For example, a dose optimisation study was performed to examine why facility DRLs for chest, lumbar spine and pelvic procedures consistently exceeded national DRLs. The corrective measures taken included adjustment to exposure settings, techniques, equipment service and maintenance and staff education which achieved a significant improvement in doses. However, some DRLs, although reduced, remained higher than national DRLs. The inspector noted that an image quality review was also conducted by a consultant radiologist to ensure that the diagnostic quality of the images was maintained. Staff informed the inspector that additional measures had been taken to further reduce these outlier DRLs within the confines of an analog system, the success of which would be determined during the ongoing monitoring and review of DRLs. From the recent actions taken as described by staff, the inspector was satisfied that a multidisciplinary approach had been taken and that appropriate measures had been implemented up to the time of the inspection to bring facility DRLs in line with national DRLs.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for each type of standard radiological procedure performed in this facility were evident and relevant to the categories of services users attending for X-ray at this facility.

To ensure compliance with Regulation 13(2), the undertaking had installed a software system that facilitated the transfer of the dose onto the report of each medical radiological report in general X-ray. Management informed the inspector that the transfer of the dose onto the reports of procedures carried out in the DXA service was still a work in progress but nearing completion. However, the inspector noted that the dose from each procedure was available on the image which formed part of the report that was issued to the referrer, thereby, complying with the requirements of this regulation.

The inspector was satisfied that referral guidelines were available and accessible on the computer desktop in the X-ray room. This medical radiological facility was located in a medical centre providing primary care services. Staff informed the inspector that the referrers working in this centre were provided with log in details

to access the electronic referral guidelines when referring service users to this facility for X-ray.

The inspector saw evidence that clinical audits were carried out at this facility in 2023 and were focused on multiple aspects relating to radiation protection such as the annual radiation safety audit, image quality in general X-ray and dose optimisation audits. Learning from audits conducted in 2023 was communicated to staff via a mobile phone application and regular staff meetings.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory was reviewed by the inspector prior to the inspection and verified as correct on the day of inspection.

Records viewed showed that annual quality assurance of medical radiological equipment was carried out by the MPE engaged for this facility in February 2023 and January 2024. Acceptance testing records for the DXA scanner were viewed by the inspector and demonstrated that acceptance testing of this equipment had been completed before its first clinical use in July 2023. The undertaking had replaced DXA equipment with similar equipment from the same manufacturer. This facilitated data to be imported and cross calibrated to ensure consistency in results, thereby, facilitating comparison between the previous imaging and new scans on service users returning for follow-up tests.

Staff informed the inspector that the volume of procedures performed on the general X-ray equipment was relatively low in the context of the age of the equipment, which was past its nominal replacement date. Records demonstrated that annual quality assurance (QA) and regular performance testing of this equipment were completed in line with the documented QA programme and the equipment was deemed safe for continued clinical use. Equipment vendors were engaged by the undertaking to provide system maintenance on the equipment on a regular basis and to address issues identified during annual QA and performance testing.

The inspector was satisfied that medical radiological equipment was kept under strict surveillance as per Regulation 14.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From a review of medical radiological procedure records, the inspector found that enquiries were made by a practitioner in advance of carrying out a medical exposure to determine the pregnancy status of the service user as relevant. The record of the enquiry was signed by the practitioner that had made the enquiry and uploaded on to the radiological information system.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The radiation doses from the medical exposures delivered at Alliance Medical @ Mitchelstown were relatively low and therefore were unlikely to meet the notification thresholds outlined in HIQA guidance. However, the undertaking had ensured that there was a system in place to identify, manage and analyse radiation incidents or near misses should they arise. This was evident in the trending and analysis reports of incidents and near misses viewed by the inspector. Staff who spoke with the inspector described how incidents were managed and reported which was aligned to local policy and procedure viewed by the inspector.

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 9: Optimisation	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