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:	Alliance Medical @Beaumont
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Beaumont rd, Beaumont, Co. Dublin
Type of inspection:	Announced
Date of inspection:	08 May 2024
Medical Radiological Installation Service ID:	OSV-0008193
Fieldwork ID:	MON-0039432

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

Alliance Medical Diagnostic Imaging (AMDI) Ltd are contracted on behalf of Beaumont Hospital to provide a computed tomography (CT) imaging service primarily for Out-Patients although In-Patients can be scanned. AMDI provide a staffed CT service, 5 days a week, located on the Beaumont Hospital Campus. Beaumont Hospital is a large academic teaching hospital, providing specialist medical services across the campus. As a result, AMDI receives referrals from Oncology, Respiratory, Neurology, Gastroenterology, ENT, National Transplant and Breast Care services.

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
Wednesday 8 May 2024	09:30hrs to 12:30hrs	Noelle Neville	Lead

Governance and management arrangements for medical exposures

An inspection of the undertaking Alliance Medical Diagnostic Imaging (AMDI) Ltd at Alliance Medical @Beaumont was carried out on 8 May 2024 by an inspector to assess compliance with the regulations at the facility. As part of this inspection, the inspector visited the computed tomography (CT) unit, spoke with staff and management and reviewed documentation. The inspector noted that the undertaking, Alliance Medical Diagnostic Imaging Ltd, demonstrated compliance during this inspection with Regulations 4, 5, 6, 8, 10, 11, 13, 14, 16, 17, 19 and 21 and substantial compliance with Regulation 20.

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 inspector noted involvement in, and oversight of, radiation protection by the facility's medical physics experts (MPEs) across a range of responsibilities. The inspector was 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, the inspector was satisfied that a culture of radiation protection was embedded at Alliance Medical @Beaumont and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

The inspector was satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was 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 @Beaumont.

Judgment: Compliant

Regulation 6: Undertaking

The inspector 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). The inspector reviewed documentation including governance structure organograms (organisational charts that show 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 @Beaumont. The inspector was informed that the undertaking was contracted on behalf of Beaumont Hospital to provide a CT imaging service on the hospital campus.

The facility had a radiation protection committee (RPC). The inspector reviewed the terms of reference for this committee, with an approval date of March 2024, and noted that it had a multi-disciplinary membership including 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 representatives from Beaumont Hospital. The committee was incorporated into local governance structures, reporting to the undertaking's quality and governance committee and senior management team demonstrating good communication and oversight structures in place for the radiation protection of service users.

Overall, the inspector was 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 culture of radiation protection was embedded at the facility.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector 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 @Beaumont 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, the inspector was also 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

The inspector was 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 @Beaumont.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificates of the medical physicists at Alliance Medical @Beaumont and was satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted MPE involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Alliance Medical @Beaumont. MPEs were members of the facility's radiation protection committee. MPEs 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). In addition, MPEs carried out dose calculations for any incidents relating to ionising radiation and an MPE acted as radiation protection adviser (RPA) for the facility and so met the requirements of Regulation 20(3). The inspector noted from discussions with staff and management that MPEs at Alliance Medical @Beaumont did not contribute to the training of practitioners and other staff in relevant aspects of radiation protection and so did not fully meet the requirements of Regulation 20(2)(c).

Judgment: Substantially Compliant

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

From documentation reviewed and discussion with staff, despite the gap identified in Regulation 20, the inspector was satisfied that the level of MPE involvement at Alliance Medical @Beaumont was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector visited the CT unit at the facility, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Alliance Medical @Beaumont. The inspector 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 at Alliance Medical @Beaumont as required by Regulation 11. The requirements of Regulation 13 were met at the facility including information relating to the patient exposure was contained in reports viewed by the inspector. 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 the inspector. In addition, there was a process for identification, management, reporting, analysis and trending of radiation incidents and potential incidents as required by Regulation 17.

Overall, the inspector was satisfied that systems and processes were in place at Alliance Medical @Beaumont to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

The inspector was 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 displayed on posters throughout the facility. In addition, information in relation to the benefits and risks associated with the radiation doses from particular medical exposures was available via a quick response (QR) code which could be scanned by service users.

The undertaking at Alliance Medical @Beaumont had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was issued in November 2023. This document outlined the justification process in place at the facility and staff responsibilities in relation to same. The inspector reviewed a sample of records in CT 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 @Beaumont had a document titled *Radiation Safety (ROI) Policy*, the most recent version of which was issued in November 2023. This document set out the responsibilities in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. The inspector found that facility DRLs had been established, regularly reviewed and used, having regard to national DRLs and were displayed prominently at the CT unit in the facility.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Alliance Medical @Beaumont for standard radiological procedures as required by Regulation 13(1). Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for CT medical radiological exposures and found compliance with Regulation 13(2). The facility had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3). In addition, the inspector noted a range of clinical audits which were ongoing and complete at Alliance Medical @Beaumont. These audits included an annual facility-wide radiation safety audit, DRL audit, justification audit and last menstrual period audit.

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Alliance Medical @Beaumont as required by Regulation 14(1). The inspector 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 @Beaumont had a document titled *Radiation Modality QA Procedure*, the most recent version of which was issued in November 2023. This document outlined staff responsibilities and the frequency of testing for each modality. In addition, a quality assurance procedure document was available at Alliance Medical @Beaumont and set out the different tests to be carried out as part of quality assurance checks. The inspector reviewed records of regular performance testing and was 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 inspector was 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 @Beaumont had a document titled *Patient Pregnancy Procedure Radiation (ROI)*, the most recent version of which was issued 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, the inspector was satisfied that a referrer or practitioner inquired as to the pregnancy status of service users and recorded the answer to this query in writing. In addition, the inspector noted multiple notices in the waiting area of 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

The inspector was satisfied from discussions with staff and management and a review of documents that Alliance Medical @Beaumont 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 issued in March 2023 and *Radiation Incident Procedure*, the most recent version of which was issued in November 2023. The latter document included information on the requirement to notify HIQA of certain reportable incidents. The inspector noted that two incidents had been reported to HIQA within the required timelines. Staff who spoke with the inspector described how incidents were managed and reported and this was aligned to local documents 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, 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	Substantially 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	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 @Beaumont OSV-0008193

Inspection ID: MON-0039432

Date of inspection: 08/05/2024

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 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: The MPE at Alliance Medical @Beaumont will now work collaboratively with the Designated Manager and RPO to design the content of the delivered training of practitioners and other staff in relevant aspects of radiation protection in accordance with the requirements of Regulation 20(2)(c). Training is delivered on commencement and annually as refresher – the training content will be reviewed prior to each annual update, to ensure it remains relevant and appropriate.	

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 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment;	Substantially Compliant	Yellow	13/06/2024

	(iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			