

## 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 @Kingsbridge Private Hospital Sligo
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Kingsbridge Private Hospital, Garden Hill, Sligo, Sligo
Type of inspection:	Announced
Date of inspection:	09 October 2024
Medical Radiological Installation Service ID:	OSV-0008088
Fieldwork ID:	MON-0043052

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

Alliance Medical Diagnostic Imaging (AMDI) Ltd. are contracted on behalf of Kingsbridge Private Hospital, Sligo to provide x-ray, MRI and fluoroscopy for pain clinic services on-site. The x-ray service operates five days per week and is available to out-patients and GP referred patients. All radiographers are qualified, CORU registered, and imaging is reported by a consultant radiologist, approved by the Royal College of Surgeons.

## 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
Wednesday 9 October 2024	10:00hrs to 15:00hrs	Lee O'Hora	Lead

## Governance and management arrangements for medical exposures

As part of this inspection, the inspector reviewed documentation, visited the X-ray department and spoke with staff and management.

Alliance Medical @ Kingsbridge Private Hospital operated as part of a larger company undertaking, namely Alliance Medical Diagnostic Imaging Ltd, which provided a radiological imaging service at this site. The inspector was informed that Alliance Medical @ Kingsbridge Private Hospital used a Radiation Protection Committee (RPC) and the relevant platforms, responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection.

Following a review of documents and records, and speaking with staff, the inspector was assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. However, the inspector noted that for a sub-set of medical exposures, the clinical evaluation of the outcome was not assigned to a practitioner. This must be addressed by the undertaking to ensure full compliance with Regulations 6 and 10.

After speaking to staff and reviewing radiation safety related documentation and records, the inspector was assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided at Alliance Medical @ Kingsbridge Private Hospital and satisfied the requirements of the regulations.

Notwithstanding the gaps in compliance under Regulations 6 and 10, the inspector was assured that service users were receiving a safe radiological service at Alliance Medical @ Kingsbridge Private Hospital.

## Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, the inspector was satisfied that Alliance Medical @ Kingsbridge Private Hospital only accepted referrals from appropriately recognised referrers. In line with the regulations, radiographer practitioners were also considered referrers in certain circumstances in this facility. The specific circumstances in which radiographers could act as referrers were clearly

outlined in documentation supplied and articulated by staff who spoke with the inspector on the day.

Judgment: Compliant

### Regulation 5: Practitioners

Following the review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals were considered practitioners at Alliance Medical @ Kingsbridge Private Hospital.

Judgment: Compliant

### Regulation 6: Undertaking

Documentation reviewed by the inspector outlined the corporate allocation of responsibility for the protection of service users by the undertaking at Alliance Medical @ Kingsbridge Private Hospital. Alliance Medical Diagnostic Imaging Ltd was identified as the company undertaking for X-ray and fluoroscopy service at Kingsbridge Private Hospital and the inspector was informed that the undertaking was contracted on behalf of Kingsbridge Private Hospital Sligo to provide a X-ray, fluoroscopy and MRI imaging service on the hospital campus.

Alliance Medical @ Kingsbridge Private Hospital used a Radiation Protection Committee (RPC), the aim of which was to develop, deliver, champion, implement and evaluate a quality and safe radiology service in Kingsbridge Private Hospital. The relevant platforms, responsibilities and lines of communication regarding the effective protection of service users were clearly articulated to the inspector during the course of the inspection.

However, some work was required by the undertaking to ensure the clear allocation of responsibility for the clinical evaluation of the outcome for fluoroscopic procedures carried out at this hospital. This area of non-compliance requiring the attention of the undertaking is further discussed under Regulation 10.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

Following a review of a sample of records for medical radiological procedures and by speaking with staff and management, the inspector noted that fluoroscopy reports, identified by staff as constituting the clinical evaluation of the outcome, were not signed off by staff entitled to act as practitioners. It is imperative that the undertaking ensures that all medical exposures take place under the clinical responsibility of a practitioner including clinical evaluation of the outcome. This was brought to the attention of management staff on the day of inspection.

Despite this, the inspector was assured that the optimisation process involved the practitioner and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer at Alliance Medical @ Kingsbridge Private Hospital.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to the inspector by staff and management and the details were available in a service level agreement (SLA) reviewed as part of this inspection. All evidence supplied satisfied the inspector that Alliance Medical @ Kingsbridge Private Hospital had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, the inspector was satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. The inspector noted that the medical physics staff played an important role in the content and delivery of face-to-face and virtual practitioner training at Alliance Medical @ Kingsbridge Private Hospital.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspector established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Alliance Medical @ Kingsbridge Private Hospital.

Judgment: Compliant

## Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this hospital. Following review of a sample of referrals for general X-ray and fluoroscopy the inspector was satisfied that Alliance Medical @ Kingsbridge Private Hospital had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. The inspector was satisfied that DRLs were established, used and reviewed.

The inspector reviewed documentation and records of accidental and unintended exposures and significant event near misses and was assured that the undertaking had employed measures to minimise the probability and magnitude of accidental or unintended exposures of service users. Records reviewed also satisfied the inspector that the appropriate systems were implemented for the record keeping and analysis of such events.

An area noted as not meeting the requirements of the regulations on this occasion was related to Regulation 13(2), namely that information relating to patient exposure did not form part of all patients' reports reviewed on the day of inspection. However, it should be noted that staff did articulate to the inspector that this issue had been identified and rectified by the undertaking and records reviewed did confirm this.

The inspector reviewed Alliance Medical @ Kingsbridge Private Hospital's approach to clinical audit and while not yet meeting the requirements of Regulation 13(4), the inspector noted the significant work ongoing by the undertaking to come into compliance which aligned with the compliance plan provided in relation to the same issue in another site recently.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. All records reviewed detailed that all testing was up to date and any issues identified were appropriately followed up or



closed off as required. The inspector was provided with an up-to-date inventory which was verified on site.

Overall, despite some areas noted for the attention of the undertaking, the inspector was satisfied that good systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users in Alliance Medical @ Kingsbridge Private Hospital.

### Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. In line with Regulation 8, all referrals reviewed by the inspector were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

The inspector visited the clinical area and observed multiple posters which provided service users with information relating to the benefits and risks associated with the radiation dose from X-ray and fluoroscopy. The inspector was also informed that this information was available in pamphlet format on request of the service users.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

Following a review of DRLs, the inspector was satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this hospital. In the clinical area multiple examples of local facility DRLs were displayed for staff. The inspector reviewed evidence highlighting that DRLs were a standing agenda point for the RPC under the heading of 'doses' and this platform, in conjunction with the MPE, was used to ratify DRLs by the undertaking.

Judgment: Compliant

### Regulation 13: Procedures

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.

The inspector reviewed a sample of reports for X-ray and fluoroscopy medical radiological exposures and found that while information relating to the patient exposure formed part of the report for all X-ray procedures reviewed, it was not available for a number of fluoroscopy reports reviewed. However, while not meeting compliance requirements on this occasion, staff informed the inspector that this was due to a short lived ICT issue, which had been identified, addressed and subsequently rectified by the undertaking.

The inspector reviewed documentation and spoke to staff and management about Alliance Medical @ Kingsbridge Private Hospital's approach to clinical audit. The inspector noted that while 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. Staff at Alliance Medical @ Kingsbridge Private Hospital informed the inspector that, as outlined in the compliance plan submitted to HIQA for another site under the remit of this undertaking, work had commenced on developing an overarching strategy to better align with the national procedures, including a framework for each site to assess and establish an audit cycle for the year commensurate with the service and risk, and incorporating the full pathway of the service user. The inspector reviewed meeting minutes and spoke with staff in relation to the undertaking's ongoing work on compliance with Regulation 13(4) and was assured that Alliance Medical Diagnostic Imaging Ltd was in the process of addressing this non-compliance and had made progress which aligned with the compliance plan previously submitted to HIQA.

On the day of inspection, the inspector found that written protocols were established for all medical radiological procedures. A sample of these were reviewed by the inspector. Staff spoken with in the clinical areas clearly articulated how these protocols were made available to them.

Judgment: Substantially Compliant

### Regulation 14: Equipment

The inspector was provided with an up-to-date inventory which was verified on site.

From the evidence available, the inspector was satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing.

Judgment: Compliant

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

Documentation and imaging records reviewed satisfied the inspector that Alliance Medical @ Kingsbridge Private Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Multilingual posters were observed throughout the department to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

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

From speaking with staff and reviewing local incident records and associated documentation, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at the RSC, thus the undertaking had oversight of incidents in this Hospital. The inspector was also satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained. The inspector noted that near miss and incident trending information was used to influence the clinical audit topics chosen by the undertaking which was seen as a positive use of incident trending to improve service quality.

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	Substantially Compliant
Regulation 10: Responsibilities	Substantially 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	Substantially 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 @Kingsbridge Private Hospital Sligo OSV- 0008088

Inspection ID: MON-0043052

Date of inspection: 09/10/2024

## 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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: A clinical evaluation of the outcome of procedures whereby fluoroscopy is utilised, will be included in the patient specific post-procedural documentation by the clinician undertaking the procedure.</p> <p>This will be completed by 10th January 2025.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: A clinical evaluation of the outcome of procedures whereby fluoroscopy is utilised, will be included in the patient specific post-procedural documentation by the clinician undertaking the procedure.</p> <p>This will be completed by 10th January 2025.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: 13 (2) – dose information on reports Whilst not meeting compliance requirements at the time of visit, this was due to a short</p>	

lived ICT issue, which had been identified, addressed and subsequently rectified by the undertaking by the day of inspection. This will continue to be monitored.

#### 13 (4) clinical audit

Whilst documentation is in place for clinical audit, work is underway to develop 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.

## 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 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	10/01/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	10/01/2025



Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	09/10/2024
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