



## 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, UPMC Kildare Hospital Clane
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Prosperous Road, Clane, Kildare
Type of inspection:	Announced
Date of inspection:	06 December 2022
Medical Radiological Installation Service ID:	OSV-0005996
Fieldwork ID:	MON-0037371

## About the medical radiological installation:

Alliance Medical at UPMC Kildare Hospital Clane provides outpatient diagnostic imaging procedures (X-ray, Dexa, CT, MRI, Ultrasound and theatre Fluoroscopy procedures) for self-paying and privately insured patients as well as performing scans for several HSE hospitals as part of their outsourcing waiting list initiatives in addition to ad hoc outsourcing of both inpatients and outpatients. Alliance Medical Diagnostic Imaging (AMDI) at UPMC Kildare Hospital Clane also participates in the HSE GP access to diagnostics scheme as a diagnostic imaging provider.

## 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 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:

### **1. Governance and management arrangements for medical exposures:**

---

<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.

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

**2. Safe delivery of medical exposures:**

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

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

**This inspection was carried out during the following times:**

Date	Times of Inspection	Inspector	Role
Tuesday 6 December 2022	09:30hrs to 14:00hrs	Noelle Neville	Lead

## Governance and management arrangements for medical exposures

An inspection was carried out at Alliance Medical, UPMC Kildare Hospital Clane on 6 December 2022 by an inspector to assess the facility's compliance with the regulations. As part of this inspection, the inspector visited the dual-energy x-ray absorptiometry (DXA) and computed tomography (CT) areas, spoke with staff and management and reviewed documentation. The inspector noted that Alliance Medical, UPMC Kildare Hospital Clane demonstrated compliance with Regulations 4, 5, 6, 8, 10, 11, 14, 16, 17, 19, 20 and 21 and substantial compliance with Regulation 13.

Alliance Medical, UPMC Kildare Hospital Clane had a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation. 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. In addition, the inspector noted medical physics expert (MPE) involvement in radiation protection across a range of responsibilities.

Overall, the inspector was satisfied that a culture of radiation protection was embedded at Alliance Medical, UPMC Kildare Hospital Clane and clear and effective governance and management structures were in place to ensure the radiation protection of service users.

### Regulation 4: Referrers

Alliance Medical, UPMC Kildare Hospital Clane had a document titled *Patient Pathway Procedure*, the most recent version of which was approved in April 2022. This document outlined who can refer for medical radiological procedures at the facility. The inspector was satisfied from reviewing a sample of referrals and speaking with staff and management that referrals for medical radiological exposures were only accepted at Alliance Medical, UPMC Kildare Hospital Clane 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, UPMC Kildare Hospital Clane.

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 and spoke with staff and management in relation to governance arrangements in place at Alliance Medical, UPMC Kildare Hospital Clane.

Alliance Medical Diagnostic Imaging Ltd. was the undertaking for Alliance Medical, UPMC Kildare Hospital Clane which had a radiation protection committee. The inspector reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership including radiologists, senior management and MPEs. The committee met twice a year and reported to the Department of Quality and Patient Safety which in turn reported to the Risk Management Committee and upwards to the managing director of Alliance Medical Diagnostic Imaging Ltd.

Overall, the inspector was satisfied that Alliance Medical Diagnostic Imaging Ltd., as the undertaking for Alliance Medical, UPMC Kildare Hospital Clane, had strong oversight and clear and effective governance and management structures in place to ensure the radiation protection of service users.

Judgment: Compliant

### Regulation 10: Responsibilities

The inspector was satisfied that all medical exposures for ionising radiation at Alliance Medical, UPMC Kildare Hospital Clane were carried out under the clinical responsibility of an individual entitled to act as practitioner as per Regulation 5. The inspector was also satisfied from a review of a sample of referrals, documentation and speaking with staff that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological exposures. The inspector also noted that the practical aspects of medical exposures were only carried out by persons entitled to act as practitioner. In addition, practitioners and the MPE were involved in the optimisation process for medical exposures.

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, UPMC Kildare Hospital Clane.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE at Alliance Medical, UPMC Kildare Hospital Clane and was satisfied that the MPE 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, UPMC Kildare Hospital Clane. The MPE was a member of the facility's radiation protection committee. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection.

The inspector noted that the MPE also liaised with Alliance Medical, UPMC Kildare Hospital Clane's radiation protection adviser as required by Regulation 20(3).

Judgment: Compliant

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

The inspector was satisfied that an MPE was appropriately involved at Alliance Medical, UPMC Kildare Hospital Clane, with the level of involvement commensurate with the radiological risk posed by the facility.

Judgment: Compliant

## Safe Delivery of Medical Exposures

The inspector visited Alliance Medical, UPMC Kildare Hospital Clane clinical areas including DXA and CT, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the facility.

In relation to Regulation 8, the inspector was satisfied that justification in advance was carried out by a practitioner and a record of this justification in advance was retained. The inspector was satisfied that DRLs were established, regularly reviewed and used as required by Regulation 11.

Alliance Medical, UPMC Kildare Hospital Clane had written protocols in place, had adopted referral guidelines and carried out a range of clinical audits as required by Regulation 13. Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for DXA and CT medical radiological exposures and found that while information relating to patient exposure was available for DXA, it was not yet available for CT. The inspector was informed by management that the implementation of a solution to come into full compliance with Regulation 13(2) was in the final stages and is expected to be operational imminently.

In relation to Regulation 14, the inspector was satisfied that equipment was kept under strict surveillance at Alliance Medical, UPMC Kildare Hospital Clane. In addition, the inspector was satisfied that a referrer and practitioner inquired as to the pregnancy status of service users as required by Regulation 16. The facility had also implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures as required by Regulation 17.

Overall, the inspector was satisfied that Alliance Medical, UPMC Kildare Hospital Clane demonstrated that systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users.

## Regulation 8: Justification of medical exposures

Alliance Medical, UPMC Kildare Hospital Clane had a document titled *Patient Pathway Procedure*, the most recent version of which was approved in April 2022. This document included the justification process for the facility. The inspector was informed that justification in advance was carried out by a practitioner as required by Regulation 8(8), and a record of this justification in advance was retained on Alliance Medical, UPMC Kildare Hospital Clane's radiology information system as required by Regulation 8(15). The inspector was satisfied from reviewing a sample of records that referrals were in writing and stated the reason for the medical radiological procedure. In addition, Alliance Medical, UPMC Kildare Hospital Clane provided risk and benefit information to service users in relation to medical radiological procedures and information posters were available in the waiting areas

of the facility.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The inspector reviewed a range of local DRLs in place at Alliance Medical, UPMC Kildare Hospital Clane for a variety of modalities, including fluoroscopy, general X-ray, CT and DXA. The inspector was satisfied that DRLs were established, regularly reviewed and used at the facility and these DRLs were displayed prominently in the clinical area.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols were in place at Alliance Medical, UPMC Kildare Hospital Clane for standard radiological procedures as required by Regulation 13(1). Alliance Medical, UPMC Kildare Hospital Clane 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 completed at Alliance Medical, UPMC Kildare Hospital Clane. These audits included an annual facility-wide radiation safety audit which covered areas including legislative compliance, pregnancy status, clinical justification and dose audits. The radiation safety audit results indicated high levels of compliance with the areas included as part of this audit. The inspector noted that Alliance Medical, UPMC Kildare Hospital Clane viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service users.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for DXA and CT medical radiological exposures and found that while information relating to patient exposure was available for DXA, it was not yet available for CT. The inspector was informed by management that the implementation of a solution to come into full compliance with Regulation 13(2) was in the final stages and is expected to be operational imminently.

Judgment: Substantially Compliant

## Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Alliance Medical, UPMC Kildare Hospital Clane as required by Regulation 14(1). Alliance Medical, UPMC Kildare Hospital Clane had quality assurance procedure documents for each modality in use at the facility which outlined staff responsibilities in relation to the quality assurance programmes in place. 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 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 inspector was satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry 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, UPMC Kildare Hospital Clane had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. Alliance Medical, UPMC Kildare Hospital Clane had two documents titled *Internal Incident Reporting Procedure*, the most recent version of which was approved in August 2021 and *External Incident Report Procedure*, the latest version of which was approved in July 2022. These documents outlined the process for incident reporting at Alliance Medical, UPMC Kildare Hospital Clane and included information for reporting significant events of accidental or unintended exposures to HIQA. The inspector noted that Alliance Medical, UPMC Kildare Hospital Clane had reported one

incident to HIQA since the commencement of the regulations in 2019.

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
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	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, UPMC Kildare Hospital Clane OSV-0005996

Inspection ID: MON-0037371

Date of inspection: 06/12/2022

## 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 and 2019.

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	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The new dose monitoring system, became live on the Alliance Medical radiology information system on 5th September 2022, during this process it was noted that CT examinations required further configuration. It was suspended to rectify the issue. The process has now been rectified and in the final phase of testing prior to resumption of providing the exposure information on the patient report. The estimated timeframe for completion is 17th February 2023.	

## 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).

<b>Regulation</b>	<b>Regulatory requirement</b>	<b>Judgment</b>	<b>Risk rating</b>	<b>Date to be complied with</b>
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	17/02/2023