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, Smithfield Dublin
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Block G, Smithfield Market, Dublin 7
Type of inspection:	Announced
Date of inspection:	04 August 2022
Medical Radiological Installation Service ID:	OSV-0005994
Fieldwork ID:	MON-0037368

About the medical radiological installation:

Alliance Medical, Smithfield Dublin provides the following out-patient diagnostic imaging procedures, dual-energy x-ray absorptiometry (DXA), general radiography (X-ray), computed tomography (CT), magnetic resonance imaging (MRI) and Ultrasound for privately insured and self-paying patients. Additionally Alliance Medical, Smithfield Dublin also performs scans for several publicly funded hospitals as part of their outsourcing initiatives. An X-ray service is also provided by Alliance Medical, Smithfield Dublin for the minor injuries unit located in the same building.

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[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. 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 4 August 2022	09:30hrs to 14:30hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of Alliance Medical, Smithfield Dublin was carried out on the 4 August 2022 to assess compliance against the regulations. As part of this inspection, the inspector visited the dual-energy x-ray absorptiometry (DXA), general radiography (X-ray) and computed tomography (CT) areas.

On the day of inspection, the inspector reviewed documentation and spoke with staff and management at the unit to assess the governance and management arrangements for medical exposures at Alliance Medical, Smithfield Dublin. Responsibility for the radiation protection of service users at the unit was found to be clearly allocated. A well defined line management and reporting structure for staff was in place, with regular unit team meetings held with upward reporting to the Alliance Medical Diagnostic Imaging Ltd (Alliance Medical) governance committee. Additionally, the terms of reference and minutes of the radiation safety committee (RSC) were also reviewed. The RSC was attended by members of the unit and a member of the undertaking's senior management. This provided an assurance to the inspector that the undertaking had arrangements in place to ensure the appropriate oversight of medical radiological procedures conducted at Alliance Medical, Smithfield Dublin.

The inspector was also satisfied that all medical radiological procedures took place under the clinical responsibility of a practitioner, and only written referrals from individuals entitled to act as a referrer, as defined in the regulations, were carried out at the unit. Referrers and practitioners were found to be involved in the justification of individual medical radiological procedures and radiographers, radiologists and a medical physics expert (MPE) were found to be involved in optimising medical exposures.

From speaking with staff and reviewing documentation and relevant records, the inspector found that the unit had access to an MPE to act and provide specialist advice in line with the level of radiological risk at the unit. The inspector was also assured that Alliance Medical had appropriate arrangements in place to ensure the continuity of access to medical physics expertise as required.

Regulation 4: Referrers

A sample of referrals for medical radiological procedures were reviewed on the day of inspection. Additionally, from speaking with staff and management, the inspector was satisfied that only referrals from individuals entitled to refer as per Regulation 4, were carried out at Alliance Medical, Smithfield Dublin.

Judgment: Compliant

Regulation 5: Practitioners

From a review of documentation and speaking with staff and management at the unit, the inspector found that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

A clear allocation of responsibility for the radiation protection of service users was found to be in place at Alliance Medical, Smithfield Dublin on the day of inspection. Inspectors reviewed documentation provided and spoke with staff and management who clearly communicated the management and oversight structure in place for medical exposures to ionising radiation at the unit.

The RSC was identified as the governance and oversight mechanism for ensuring the radiation protection of service users at the unit. The RSC met every six months and reported into the undertaking's senior management team governance and risk committee. Membership of the RSC included key members of staff and management at Alliance Medical and Alliance Medical, Smithfield Dublin including the designated manager, the quality manager, a member of the Alliance Medical senior management team, radiation protection officer for the unit, a radiologist and an MPE. The inspector also found that unit team meetings were held locally. These local unit team meetings reported up into the undertaking's governance committee which in turn reported to the undertaking's senior management team governance and risk committee. The inspector found that both clinical and administrative leads represented the unit at the governance committee meeting.

The terms of reference and minutes of the RSC and governance committee meeting minutes were reviewed by the inspector in advance of the inspection. This documentation provided an assurance to the inspector that the senior management at Alliance Medical had oversight of the radiation protection of service users at the unit. Additionally, the inspector found that a quality report was issued to the medical director of the company which included information about incidents and clinical audit. Additionally a clear line management and reporting structure was found to be in place.

Overall, the inspector was satisfied that Alliance Medical, Smithfield Dublin had governance and management arrangements in place to ensure the radiation protection of service users undergoing medical radiological procedures at the unit.

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. 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. Additionally, only persons entitled to act as a practitioner carried out the practical aspects of medical radiological procedures at the unit.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From communicating with staff and management, and from a review of records and other documentation, the inspector was assured that Alliance Medical had adequate arrangements in place to ensure the continuity of medical physics expertise at the unit. For example, while one MPE had primary responsibility for Alliance Medical, Smithfield Dublin, the undertaking had access to other MPEs, for consultation and advice as necessary, should the MPE with responsibility for the unit be unavailable.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector spoke with staff and management at the unit, including the MPE and senior management of Alliance Medical, about the involvement and contribution of the MPE at the unit. The MPE was found to take responsibility for dosimetry and was involved in the analysis of events involving, or potentially involving, accidental or unintended medical exposures. Additionally, the MPE carried out annual quality assurance and acceptance testing of medical radiological equipment at the unit and was also involved in the optimisation of medical exposures, including contributing to diagnostic reference levels (DRLs).

Overall, the inspector was assured that Alliance Medical had arrangements in place to ensure appropriate MPE involvement to act or give specialist advice as appropriate on matters relating to medical physics at the Alliance Medical, Smithfield Dublin.

Judgment: Compliant

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

On the day of inspection, Alliance Medical had ensured that appropriate arrangements were in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at Alliance Medical, Smithfield Dublin.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Alliance Medical, Smithfield Dublin. On the day of inspection, posters containing information about the benefits and risks associated with medical exposure to ionising radiation were observed in waiting areas at the unit. Multiple notices in a variety of languages were also observed in public places such as changing rooms and waiting areas to raise awareness, of the special protection required during pregnancy, in advance of medical exposure to ionising radiation.

All referrals reviewed were 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. Staff informed inspectors that a practitioner justified all medical exposures in advance and written records of justification in advance of medical radiological procedures were available for review on the day of inspection. The unit accepted referrals from a number of sources and the inspector found that the unit proactively sought previous imaging and other relevant information from external facilities.

The inspector reviewed documentation and records, and spoke with staff and management, and was satisfied that Alliance Medical had measures in place to ensure that all doses due to medical exposures were kept as low as reasonably achievable consistent with obtaining the required medical and diagnostic information. For example, the unit had formalised training and induction pathways in place for general X-ray where each new member of staff would have a nominated senior radiographer assigned to them for the first two weeks of their employment. Additionally, an assessment of dose, a review of DRLs and other clinical audits were carried out annually at the unit.

The inspector reviewed the written protocols available in general X-ray, CT and DXA

and an area of improvement was noted with regards to the general X-ray written protocols. While the written protocols for general X-ray included exposure parameters and appropriate projections for different clinical indications, they should be reviewed with a view to including additional information, for example, patient preparation and positioning, for completeness. The inspector also reviewed a sample of reports for DXA, general X-ray and CT medical exposures and found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2). However, management informed the inspector that the implementation of a solution to come into compliance with this regulation was in the final stages of testing before being deployed.

Alliance Medical had identified referral guidelines for medical imaging for referrers on their website. The inspector was also satisfied that medical radiological equipment was kept under strict surveillance and a quality assurance programme, including performance and acceptance testing, was in place for medical radiological equipment at Alliance Medical, Smithfield Dublin.

Alliance Medical had processes in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. A sample of records of incidents and potential incidents for the unit were reviewed as part of this inspection and the inspector found that a root cause and corrective action was identified for incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation at the unit. The inspector also found that Alliance Medical recognised the importance of promoting the reporting and analysis of potential accidental and unintentional exposures locally which was noted as an example of good practice.

Notwithstanding the areas for improvement found on inspection, the inspector found that Alliance Medical, Smithfield Dublin demonstrated a commitment to ensuring the safe delivery of medical exposures to ionising radiation.

Regulation 8: Justification of medical exposures

Alliance Medical, Smithfield Dublin accepted referrals from a number of external sources and the inspector found that the unit proactively sought previous imaging and other relevant information from facilities, both internal and external to Alliance Medical. Staff provided information to the inspector about the process for requesting previous imaging from other facilities and the use of a software solution which allows for the secure electronic transfer of imaging records with other facilities that are not part of Alliance Medical.

All referrals reviewed by the inspector as part of the inspection were found to be 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 spoke with practitioners who explained how medical exposures are justified in advance of the medical exposure. The record of

justification of medical radiological procedures in advance by a practitioner was available for all medical radiological procedures reviewed over the course of the inspection.

Information about the benefits and risks associated with the radiation dose from medical exposures was available in the form of posters in the waiting area. Staff communicated the inspector how they provide information to patients as required, and that a leaflet was also provided to patients where additional information about radiation doses from medical radiological procedures was requested.

Judgment: Compliant

Regulation 9: Optimisation

The inspector reviewed documentation and records, and spoke with staff and management, about the measures in place to ensure that all doses due to medical exposures were kept as low as reasonably achievable consistent with obtaining the required medical and diagnostic information.

Alliance Medical, Smithfield Dublin had a number of measures in place to ensure the consistent production of adequate diagnostic information which were noted as examples of good practice. For example, the unit had formalised training and induction pathways in place for general X-ray where each new member of staff would have a nominated senior radiographer assigned to them for the first two weeks of their employment. Additionally, the radiation protection officer carried out training with all staff members to raise awareness of radiation protection at the unit.

The inspector reviewed documentation and spoke with staff about measures in place to ensure that the medical radiological procedures were optimised. An annual audit which included an assessment of dose, adherence to checking pregnancy status and an audit of clinical justification of medical exposures was performed**.** The unit had also ensured that a programme of quality assurance of medial radiological equipment was established and maintained, including the conduct of regular performance testing by staff and annual service of equipment by its vendor. The MPE reviewed and signed off on monthly quality control results which was seen as an additional assurance that any issues with equipment performance could be identified promptly.

The unit had guidance on the exposure of carers and comforters which was reviewed by the inspector. The inspector also reviewed the form which is signed by individuals who intend to act as a carer or comforter at the unit. This form included information about the benefits and risk for the carer or comforter associated with the radiation dose from the medical exposure. The inspector was also informed that the individual carer or comforter was given the opportunity to ask questions about the medical exposure before the medical radiological procedure was performed.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Alliance Medical, Smithfield Dublin had established DRLs for medical radiological procedures carried out in its general X-ray, CT and DXA areas. The inspector observed DRLs clearly displayed in all control rooms in poster format. All DRLs were found to be reviewed annually and signed off by the unit manager, lead radiologist and MPE for the unit.

The inspector also noted that a comparison of local facility DRLs and typical doses across Alliance Medical's facilities had been conducted by the undertaking previously and this was identified as an example of good practice. This provided Alliance Medical with an opportunity to ensure that doses for medical exposures are adequately optimised across their facilities.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector reviewed the written protocols available for standard medical radiological procedures and found that written protocols were available in each area where medical exposures were conducted. The written protocols for all areas included the exposure parameters and the different projections to be conducted for different clinical indications. However, while the written protocols for CT and DXA included information about field of view, patient preparation and positioning, the written protocols for general X-ray were found not to contain this information and this was noted as an area for improvement.

The inspector also reviewed a sample of reports for DXA, general X-ray and CT medical exposures and found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2). However, management informed the inspector that the implementation of a solution to come into compliance with this regulation was in the final stages of testing before being deployed.

Alliance Medical had identified referral guidelines for medical imaging for referrers on their website. The inspector was also satisfied that clinical audit was carried out at the unit. The results of clinical audits were fed back to staff and opportunities for learning discussed at unit team meetings.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was satisfied that an appropriate quality assurance programme, which included an assessment of dose, was in place to ensure that medical radiological equipment at the unit was kept under strict surveillance. An up-to-date inventory was provided to the inspector and documentation reviewed on the day of inspection demonstrated that regular quality control, including equipment service by equipment vendors and acceptance testing by an MPE before first clinical use, was carried out.

The inspector also found that Alliance Medical had an medical radiological equipment replacement scheme in place. The presence of a proactive replacement scheme for radiological equipment that is past its nominal replacement date ensures that opportunities for the further optimisation of medical exposures in line with technological advancements in medical radiological equipment are availed of where appropriate. Examples of how such technological advancements were being used to further optimise medical radiological procedures, following the recent replacement of the CT scanner at the unit, were communicated on the day of inspection by staff.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices in a variety of languages were observed in public places such as changing rooms and waiting areas to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. Radiographers were found to take responsibility as practitioners for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations. The inspector reviewed a sample of referrals and found that an inquiry regarding the pregnancy status of these patients had taken place, where required, and was recorded in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector found that arrangements were in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. All incidents and potential incidents were recorded using an electronic incident management system which automatically notified management, such as the quality manager, of incidents.

Similarly, the inspector was satisfied that Alliance Medical, Smithfield Dublin had

arrangements in place to ensure that HIQA is notified of the occurrence of a significant event and had implemented measures to minimise the probability of re-occurrence of significant events, where necessary, as required by the regulations.

The inspector found that Alliance Medical had a good culture of reporting and placed an emphasis on the importance of reporting and analysing potential accidental and unintentional exposures. The inspector reviewed a sample of records of incidents and potential incidents at the unit and found that a root cause and corrective action was identified for incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Another example of good practice identified at Alliance Medical was the selection of reporting of near-misses as the topic of the month to highlight its importance to all staff across the company in February 2022.

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	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, Smithfield Dublin OSV-0005994

Inspection ID: MON-0037368

Date of inspection: 04/08/2022

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:
Regulation 13 (1) Protocols
Protocols for general x-ray have been reviewed and expanded upon so that they are of the same level of detail as in the other radiation modalities.

S
Develop x-ray protocols to include required field of view and anatomy, patient positioning and technique.
M
Will be evident for use and display within the x-ray room and on departmental SharePoint.
A
This will be completed by the newly appointed, x-ray Clinical Specialist Radiographer.
R
This task is high priority for the x-ray Clinical Specialist Radiographer.
T
This is to be completed by the end of October 2022.

Regulation 13 (2) Patient exposure on report
The new dose monitoring system, Qaelum, became live on the Alliance Medical RIS/PACS system on 5th September 2022. Doses now appear at the bottom of patient examination reports. Further to this, any radiation doses resulting from examinations undertaken in the future on the Alliance Medical RIS/PACS system will be stored within the patient profile as a "Dose Passport."

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	13/09/2022
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	05/09/2022