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:	Affidea Tallaght
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Unit 1, Tallaght Cross East, Dublin 24
Type of inspection:	Announced
Date of inspection:	25 October 2023
Medical Radiological Installation Service ID:	OSV-0005988
Fieldwork ID:	MON-0040822

About the medical radiological installation:

We provide General Radiography, Computed Tomography, Dual-energy X-ray absorptiometry and C-arm Fluoroscopy at Affidea Tallaght. We accept referrals for medical exposures to ionising radiation from general practitioners and consultant specialists.

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
Wednesday 25 October 2023	09:30hrs 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 dual-energy X-ray absorptiometry (DXA), computed tomography (CT), general radiography and fluoroscopy rooms and spoke with staff and management.

On the day of inspection Affidea Diagnostics Ireland Ltd was the undertaking with overall responsibility for the radiation protection of service users and employed a national radiation safety committee (RSC) to provide oversight for radiation protection across all facilities, including Affidea Tallaght. On this inspection, the inspector found effective governance, leadership and management structures for the protection of service users undergoing medical exposures, however, some work was required to ensure responsibility for clinical evaluation of the outcome of medical radiological procedures was consistently taken by a practitioner as defined in the regulations. Also radiation safety documentation should reflect local practices at Affidea Tallaght and clearly identify the professions considered referrers and practitioners to ensure that day-to-day practices and local policy are aligned, unambiguous and consistent. Furthermore the undertaking must ensure that all documentation is up to date and reflects current regulations and associated terminology.

The inspector reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Evidence of professional registration and arrangements to ensure continuity of MPE expertise was also supplied to the inspector. From the documentation reviewed, the inspector was assured that the level of involvement of the MPE was proportionate to the level of radiological risk at the installation and that the MPE took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, although some work was required by the undertaking to meet compliance, the inspector was satisfied that these areas for improvement did not pose a risk in relation to the radiation protection of service users at Affidea Tallaght.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and from speaking with staff, the inspector was satisfied that Affidea Tallaght only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Documentation submitted in advance of the inspection was reviewed by the inspector who also spoke with staff involved in the conduct of medical exposures in a range of clinical areas. A sample of medical radiological procedure records, including referrals, images and reports were reviewed by the inspector. While clinical responsibility for individual medical exposures was found to be taken by an individual entitled to act as a practitioner for the majority of records reviewed, in some instances responsibility for clinical evaluation of the outcome was not taken by an individual entitled to act as a practitioner, as per the regulations. This is discussed further under Regulations 6 and 10.

Judgment: Not Compliant

Regulation 6: Undertaking

On the day of inspection, the inspector spoke with staff and management and was informed that Affidea Diagnostics Ireland Ltd was the undertaking with overall responsibility for the radiation protection of service users. The inspector was informed that the person with overall responsibility for the radiation protection of service users was the Country Manager who was also the undertaking representative for Affidea Diagnostics Ireland Ltd. The inspector was also informed that the Clinical Services Manager for Affidea Diagnostics Ireland Ltd was the designated manager for all national facilities and acted as a radiation safety representative for the undertaking. A RSC was also in place which met twice a year. Terms of reference and minutes for the RSC were reviewed by the inspector in addition to speaking with staff and management. The RSC provided an oversight mechanism for radiation protection across Affidea Diagnostics Ireland Ltd's facilities. Membership of the RSC included the Medical Director who was also the chairperson; the Country Manager and national designated manager; the MPE and the facility radiation protection officers.

The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection, however, documentation in relation to the allocation of responsibility and definitions of referrers and practitioners needs to be updated to ensure consistent inclusion of the appropriate professions and reference to relevant regulations. For example in the document *Affidea Referral Policy For Diagnostic Imaging* outdated terminology such as 'prescribers' and reference to regulations such as 'S.I No. 478/2002' should be updated to reflect current regulations and associated terminology. Similarly, the document *Radiation Safety Procedures - Medical Radiology* must also be reviewed and updated removing outdated terminology and regulations. Also in the document *Radiation Safety Procedures - Medical Radiology,* the consistent inclusion of all professions considered referrers and practitioners, within this facility, would provide a documented, consistent and

clear allocation of responsibility as required by the regulations. Finally, the responsibility of the referrer as described in the document *Radiation Safety Procedures - Medical Radiology* should be amended to reflect actual practice within this facility. This document currently suggests that all referrers are limited to secondary referrals. On discussion with staff the inspector was satisfied that this did not reflect day-to-day practice and was an error.

Furthermore, some aspects of responsibility for the clinical evaluation of the outcome, as pointed out in Regulation 5 and 10, must be addressed by the undertaking. In order to come into compliance with this regulation it is imperative that the undertaking ensures that each individual who takes responsibility for the clinical evaluation of the outcome is always an individual entitled to act as a practitioner as per the regulations and that systems and processes are established and maintained to ensure ongoing compliance in relation to this matter.

Judgment: Not Compliant

Regulation 10: Responsibilities

As discussed under Regulation 5 and 6, following review of a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector noted that not all medical exposures took place under the clinical responsibility of a practitioner, specifically not all responsibility for clinical evaluation of the outcome was taken by a practitioner as defined in the regulations. Examples of this included internally generated fluoroscopy reports and outsourced X-ray and CT reports being signed off by staff not entitled to act as practitioners as per the regulations. This was brought to the attention of management on the day of inspection.

Despite this, the inspector was assured that the optimisation process involved the practitioner as recognised in the regulations and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer.

Practical aspects of medical radiological procedures were delegated to individuals registered with the Nursing and Midwifery Board of Ireland for a small subset of medial exposures to ionising radiation at Affidea Tallaght. The associated professional registration, radiation safety training records and record of delegation was reviewed as part of the inspection process satisfying the requirements of Regulation 10(4) and 10(5).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the facility 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 the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspector and was up to date. From reviewing the documentation and speaking with staff at the facility, 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 and the training of practitioners. The inspector was assured that the involvement and contribution of MPEs at Affidea Tallaght was in line with the requirements of Regulation 20.

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 Affidea Tallaght.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector found that radiation protection processes implemented by Affidea Tallaght ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals for general X-ray, DXA, CT and fluoroscopy the inspector was satisfied that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded.

One area for improvement noted was the establishment of protocols for fluoroscopic procedures and the consistent approach to the stewardship of protocol documentation. The inspector was satisfied that DRLs were established, used and reviewed internally. However, improvements in the timely review of local facility DRLs by the MPE need to be implemented by the undertaking to satisfy the requirements of Regulation 11.

Records of acceptance and performance testing for all radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained a QA programme and kept all radiology equipment under strict surveillance.

Notwithstanding the areas identified with respect to Regulation 11, and 13, overall, the inspector was assured that Affidea Diagnostics Ireland Ltd had appropriate systems in place to support the safe delivery of medical exposures at Affidea Tallaght.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals from all clinical areas 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 using the radiology information system (RIS) protocoling function.

In line with Regulation 8, all referrals reviewed by the inspector on the day of inspection 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. Staff who spoke with the inspector on the day consistently articulated that previous diagnostic information was routinely sought to avoid unnecessary exposure. The inspector observed records at the referral stage and pre-imaging stage detailing that the undertaking had systems in place to ask and record if patients had had previous imaging.

The inspector visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following 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 facility. However, while no local facility DRLs exceeded national diagnostic reference levels there was a protracted delay in the MPE's annual review, namely DRLs established in December 2022 were not signed off by the MPE until October 2023. In order to ensure that appropriate reviews and corrective actions, where necessary, are taken without undue delay the undertaking must ensure that MPE DRL reviews are completed in a timely manner.

Judgment: Substantially Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for standard medical radiological procedures in DXA, general radiography and CT, however no written protocols for fluoroscopy were available. The inspector also noted that document stewardship could be improved for the protocols provided. For example, protocols provided did not consistently have document references, types, titles, effective dates, versions, document owners or purpose clearly stated on the cover as did all other radiation safety related documents reviewed as part of this inspection.

The inspector spoke with staff and reviewed a sample of imaging reports from all clinical areas on the day of inspection. The inspector observed that information relating to patient exposure consistently formed part of the report for medical imaging procedures.

Judgment: Substantially Compliant

Regulation 14: Equipment

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

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspector that Affidea Tallaght 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 reviewing documents, speaking with staff and reviewing local incident records, 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 all incidents were considered by the appropriate staff within the facility and subsequently reported to the RSC, thus the undertaking had oversight of incidents in this facility.

The inspector was 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 by the undertaking at Affidea Tallaght.

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	Not Compliant
Regulation 6: Undertaking	Not 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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Substantially 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 Affidea Tallaght OSV-0005988

Inspection ID: MON-0040822

Date of inspection: 25/10/2023

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 5: Practitioners	Not Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: Regulation 5 (B) – As per regulation only medical practitioner with appropriate Irish Medical council (IMC) number can report on Ionising examination. A meeting was arranged with the undertaking and the third party on the 6th November 2023 and arrangement had been agreed for only IMC registered practitioners to report on Ionising exams. The latter was implemented with immediate effect. Standard report generated for the purposes of fluoroscopy exams and outsource exams has been assigned to the appropriate responsible person as per Regulation 10. An IMC registered practitioner is responsible for signing of all ionising reports. The action been communicated to the IMC practitioner and admin team and implemented on the 5th December 2023. The latter is in line with regulation 10.	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Both Referral policy and Radiation Safety documents had been updated and old references to SI 478/2002 had been removed and replace with references to SI 256/2018. Outdated references to 'prescriber' had been removed from the referral policy and replace with 'referrer' The error of referrer for only secondary referrals had been removed from the Local Rules and radiation safety procedure document to reflect the daily practice. 15th December 2023 The undertaking assigns responsibilities to the registered practitioner as outline in compliance plan in regulation 5 and 10.	

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
As outlined in regulation 5 compliance plan only IMC registered practitioners are responsible for signing ionising reports. Generated reports for outsource ionising imaging and fluoroscopy exams are assigned to an IMC practitioner and appropriately signed by the IMC practitioner as per regulation 5 and regulation 10. The communication was shared with the practitioner by the undertaking on the 5th December 2023.
A meeting was arranged with the undertaking and the third party as outline in compliance plan regulation 5 the responsible person for signing of ionising examination will only be an IMC registered practitioner with immediate effect on the 6th November 2023. An agreement was reach between the undertaking and the third party with no delays.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Dose reference levels will be signed off by the MPE on the second week of January each new year. A teams calendar notification will be generated for the RPO 20th December and a reminder notification on the 4th of January of every year.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Protocols was created for fluoroscopy studies. Document stewardship amendments reflecting appropriate references, dates, document owner and version. Date implemented 15th December 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).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Not Compliant	Orange	15/12/2023
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	Not Compliant	Orange	15/12/2023

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Orange	15/12/2023
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Substantially Compliant	Yellow	15/12/2023
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	Not Compliant	Orange	18/12/2023

	relevant categories of patients.			