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:	UPMC AUT EVEN Affidea
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Freshford Road, Kilkenny, Kilkenny
Type of inspection:	Announced
Date of inspection:	12 June 2024
Medical Radiological Installation Service ID:	OSV-0008740
Fieldwork ID:	MON-0043806

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

Affidea Diagnostics Ireland Ltd provide Computed Tomography (CT) services at UPMC Aut Even Affidea, Kilkenny. Services are for medical radiological procedures only and referrals are accepted for medical exposures to ionising radiation from general practitioners (GPs) 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, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 12 June 2024	09:30hrs to 15:15hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of the computed tomography (CT) service provided by Affidea Diagnostics Ireland Ltd at UPMC Aut Even Affidea was carried out on the 12 June 2024. As part of this inspection, the inspector reviewed documentation and records and spoke with staff and management at the facility.

Overall, the inspector was assured that governance and management arrangements for medical exposures were allocated and understood at the facility. The undertaking for this facility, Affidea Diagnostics Ireland Ltd, is part of the Affidea Group. The country manager for Ireland was the chief executive officer (CEO) and undertaking representative and person with overall responsibility for the conduct of medical exposures carried out by the undertaking in Ireland. The designated manager for the facility was the clinical services manager who has responsibility for the day-to-day operation of all national facilities. The designated manager and the undertaking representative were members of the radiation safety committee (RSC), which is a sub-committee of the clinical governance committee. The medical director for diagnostics was the chairperson of the RSC.

All referrals reviewed on the day of inspection were from a registered medical doctor and clinical responsibility was taken by radiographers and radiologists. A medical physicist was also contracted by Affidea Diagnostics Ireland Ltd to provide medical physics expertise across its facilities including UPMC Aut Even Affidea.

The inspector also reviewed documentation and policies relating to the allocation of responsibility for different aspects of radiation protection at the facility. These documents included both facility specific and group-wide policies and procedures. The inspector recognised that work had been undertaken by management to address previous findings relating to documentation which was identified during inspections of other Affidea Diagnostics Ireland Ltd facilities. However, some improvement was still needed in order for the undertaking to achieve full compliance with Regulation 6.

Overall, on the day of inspection, the inspector found a good level of overall compliance, notwithstanding some ongoing issues with documentation which need to be addressed in order to come fully into compliance with the regulations assessed.

Regulation 4: Referrers

On the day of inspection, the inspector reviewed a sample of referrals and spoke with staff. From the evidence reviewed the inspector was satisfied that referrals for

medical radiological exposures were only accepted at the facility from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The allocation of responsibility for radiation protection within Affidea Diagnostics Ireland Ltd at UPMC Aut Even Affidea was reviewed over the course of the inspection. The inspector spoke with staff and management and reviewed policies, records and a diagram of Affidea Diagnostics Ireland Ltd's governance structures (organogram) for medical exposure to ionising radiation.

On the day of inspection, Affidea Diagnostics Ireland Ltd was found to have only allocated responsibility for radiation protection to appropriate individuals as required by the regulations. In addition, the governance and management arrangements to provide oversight of the delivery of medical exposures were clearly outlined in documentation and communicated to the inspector. The country manager was the CEO and the undertaking representative for Affidea Diagnostics Ireland Ltd. The clinical services manager was the designated manager and the person responsible for the day-to-day operation of the organisation's imaging facilities nationally. Affidea Diagnostics Ireland Ltd has an RSC in place which is a subcommittee of the Clinical Governance Committee which in turn reports into the executive board. The undertaking representative and designated manager were members of the RSC, which included representation from medical physics, the quality and operations managers and radiation safety officers from the undertaking's facilities.

However, the inspector found evidence that some documentation updates, as identified on previous inspections of Affidea Diagnostics Ireland Ltd facilities, were still needed. In particular, the inspector identified the need to review and update the *Policy on Protection of the Unborn Child Arising from Ionising Radiation* and *Standard Operating Procedure Radiology In-House Quality Assurance Checks.* As identified on previous inspections, the undertaking should review all documentation relating to the conduct of medical exposure to ionising radiation to ensure that it is up-to-date and accurately reflects the requirements of the current legislation and current practice in the facility with regards to the allocation of responsibilities for

radiation protection. In addition, this revision and update must also include Affidea Diagnostics Ireland Ltd's clinical audit documentation and policies as they relate to medical radiological procedures to ensure compliance with the requirements of Regulation 13(4).

Overall, while the inspector was satisfied that governance and management structures were in place at the facility, an area of improvement relating to some policies and procedures was identified to ensure clarity of roles and responsibilities regarding the safe delivery of medical exposures.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

All medical exposures for ionising radiation were found to be carried out under the clinical responsibility of an individual entitled to act as a practitioner. From speaking with staff and reviewing a sample of referrals and other documentation, the inspector was assured that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological procedures. The practical aspects of medical exposures were only carried out by a radiographer. Inspectors also found evidence that practitioners and a medical physicist were involved in the optimisation process for medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from communication with staff and management and a review of relevant policies, records and a service level agreement, that Affidea Diagnostics Ireland Ltd had adequate processes in place to ensure the continuity of medical physics expertise at the UPMC Aut Even Affidea.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, Affidea Diagnostics Ireland Ltd had appropriate mechanisms in place to ensure the appropriate involvement of medical physicists at UPMC Aut Even Affidea. The inspector spoke with staff and management and reviewed documentation and other records to establish the involvement and

contribution of medical physicists to areas such as diagnostic reference levels (DRLs), quality assurance (QA) programmes, acceptance testing and the analysis of events involving or potentially involving an accidental or unintended exposure to ionising radiation.

Judgment: Compliant

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

The inspector found that medical physicists were appropriately involved for consultation and advice on matters relating to radiation protection at UPMC Aut Even Affidea in line with the level of radiological risk at the facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at UPMC Aut Even Affidea. Written protocols were available on a shared drive for standard medical radiological procedures. Posters containing information about the benefits and risks associated with medical exposure to ionising radiation and to raise awareness of the special protection required during pregnancy in advance of medical exposures were observed in waiting areas and the changing room.

The inspector found that radiographers or radiologists justified all medical exposures in advance of each procedure and this was recorded in advance before a patient was given an appointment. A process was also in place to follow up with the referrer when more information was required to justify the medical radiological procedure. Radiographers inquired about the pregnancy status of individuals prior to the conduct of medical exposures, where appropriate. These inquiries were recorded in writing and staff could clearly describe this process to the inspector.

On the day of inspection, Affidea Diagnostics Ireland Ltd's strategy of clinical audit for medical exposures was assessed. While the inspector found that some elements of the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* were in place other requirements as required by the regulations, were not in place. Similarly, while the inspector found that medical physics and radiography staff carried out quality assurance (QA) tests, the undertaking's *Standard Operating Procedure Radiology In-House Quality Assurance* Checks must be updated to ensure that the QA programme is fully defined to ensure

that equipment is kept under strict surveillance with regards to radiation protection as required by Regulation 14.

On the day of inspection arrangements were found to be in place regarding the recording of events involving, or potentially involving, accidental and unintended exposures to ionising radiation. The inspector was also satisfied that the hospital had arrangements in place to ensure that HIQA was notified of the occurrence of significant events, as required by the regulations. Good practice regarding the oversight of accidental or unintended accidental and unintended exposures by the undertaking was also noted by the inspector.

While areas for improvement were noted during the inspection to come into full compliance, the inspector was satisfied that UPMC Aut Even Affidea had adequate systems in place to help ensure the safe delivery of medical exposure to ionising radiation on the day of inspection in line with the requirements of the regulations assessed.

Regulation 8: Justification of medical exposures

The inspector reviewed a sample of referrals for medical exposures on the day of inspection and also the referral policy. The inspector also observed information relating to the benefits and risks associated with medical exposures was placed in the waiting area and changing room in the form of posters.

Staff informed the inspector that medical exposures were justified by a practitioner, who was usually a radiographer, in advance of each medical radiological procedure. Where a query about justification arose, a radiologist could also justify the medical radiological procedure. Justification in advance was also found to have been recorded by a practitioner on the electronic radiology information system for all records reviewed on the day of inspection. All referrals reviewed were also 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 also noted that Affidea Diagnostics Ireland Ltd's radiology information system had a useful feature where patients' previous imaging information was available for the practitioner to review across all of the undertaking's Irish facilities. A formal process was also in place where imaging from other undertakings was requested by practitioners where needed as part of the justification process.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The CT service at UPMC Aut Even Affidea was a new service and data collection for diagnostic reference levels (DRLs) was found to be underway at the time of inspection. The inspector reviewed the data collected to date and spoke with staff regarding the process. The inspector also observed that the national DRLs were displayed in the control room as an interim measure until a sufficient amount of dose data was collected and local facility DRLs for UPMC Aut Even Affidea established.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical radiological procedures and could be accessed by staff electronically on a shared drive. From a sample of records reviewed, the inspector also found that information relating to patient exposure formed part of the report of all medical radiological procedures reviewed on the day of inspection.

As part of this inspection, the inspector reviewed the undertaking's implementation of the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* as required by the regulations. The inspector spoke with management about the current work being undertaken in relation to clinical audit of medical exposures at UPMC Aut Even Affidea and across its other facilities nationally. The inspector found evidence that some elements of the framework were in place which were located across a number of documents, such as the *Group Clinical Audit* policy. However, these were high level overarching policies covering all the organisation's activities both nationally and internationally and did not include or reflect the specific requirements relating to medical radiological procedures as required by Regulation 13(4).

The inspector noted that oversight structures for clinical audit through committees and the quality manager were in place at the undertaking more generally but these structures had not fully incorporated clinical audit of medical radiological procedures. The *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* requires that essential elements and criteria are included in a clinical audit strategy and these were not sufficiently included in the documents reviewed on the day of inspection.

In addition, the inspector reviewed a sample of clinical audits carried out at the facility related to medical exposures and found that all stages in the clinical audit cycle had not been included. For example, the identification of a standard, criteria or target or agreed actions for improving practice following the audit were not included**.** In order to come fully into compliance with Regulation 13, Affidea Diagnostics Ireland Ltd must ensure that a clinical audit strategy for medical

radiological procedures is implemented in line with the requirements of the national procedures published by HIQA.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of equipment was provided in advance of the inspection. The inspector also observed that the information about the dose automatically transferred to the record of the examination. The equipment had been recently installed and acceptance testing had been completed by a medical physicist before first clinical use. The inspector also found evidence that radiography staff carried out regular performance testing. Staff also communicated that a service contract with the equipment vendor was in place.

While the records of QA testing carried out prior to the inspection provided assurance to the inspector that staff kept the equipment under surveillance regarding radiation protection, documentation reviewed did not include details of the full QA programme. A QA document called *Standard Operating Procedure Radiology In-House Quality Assurance Checks* was available, in addition to a *QA Guide* for the model of CT scanner at the facility. However, details regarding the frequency of testing or individuals responsible for carrying out the testing were not included. Furthermore, other elements of the QA programme not carried out by radiography staff, such as servicing by the vendor or the annual QA by medical physics were not included in the policy.

The inspector did note that the record of daily QA contained an area to record faults or errors and that this was available on a shared drive which could be accessed by other senior staff to provide oversight. Staff could also communicate to the inspector examples of how issues with the equipment were followed up. The undertaking should also consider documenting these pathways to ensure all staff are fully aware of the processes to follow where issues with equipment are identified.

Overall, while the inspector was satisfied from evidence reviewed on the day of inspection that staff working at the facility carried out appropriate performance and QA testing on a regular basis to ensure the appropriate performance of the CT equipment, improvements in the documentation of the QA programme would provide an assurance that a formalised QA programme had been established and was fully implemented.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the waiting and changing areas at the facility. Radiographers took responsibility for carrying out the inquiry of patients' pregnancy status, where relevant. The inspector also reviewed a sample of referral records and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

UPMC Aut Even Affidea had a system in place to facilitate the reporting and recording of actual or potential accidental or unintentional exposures. The inspector spoke with staff and management about the process for reporting and was informed that no actual accidental or unintended exposures have been reported at the facility to date. The inspector noted that potential accidental or unintended exposures had been reported and recorded and this was seen as an example of good practice and a positive reporting culture.

The inspector also noted that a weekly incident review meeting took place which reported to the RSC and the clinical governance committee. These strong oversight mechanisms by the undertaking were noted as an example of good practice where examples of how the undertaking reviewed and discussed learning from previous incidents as an quality improvement mechanism had been implemented.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially 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 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for UPMC AUT EVEN Affidea OSV-0008740

Inspection ID: MON-0043806

Date of inspection: 12/06/2024

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: • The Radiology In-House checks SOP has been revised and a table created, outlining the frequency of the equipment QA and responsible persons. • Protection of the Unborn Child Arising from Ionising Radiation policy had been reviewed and amended to reflect the up to date accuracy of the current legislation.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: • Ionising Radiation Clinical Audit Strategy drafted, approved and implemented. • The Strategy outlines all aspects of the Clinical Audit strategy and includes the topics to be audited, the frequency of audit, the sample size, the target. • The oversight for audit is documented as the Clinical Governance Committee and the committee approve recommendations and actions from audits, and monitor the implementation of these recommendations/actions.	
Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
As outlined in regulation 6, the Radiology In-House checks SOP has been revised and a table created, outlining the frequency of the equipment QA and responsible persons.

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	31/07/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures	Not Compliant	Orange	31/07/2024

	established by the Authority.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	31/07/2024