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 Santry
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Building 1, Swift Square,, Northwood Park, Santry, Dublin 9
Type of inspection:	Announced
Date of inspection:	17 May 2022
Medical Radiological Installation Service ID:	OSV-0005987
Fieldwork ID:	MON-0036378

About the medical radiological installation:

Affidea Diagnostics Ireland Ltd provides a general X-ray, ultrasound,and magnetic resonance imaging service at its facility in Northwood, Santry, Dublin 9. Affidea Santry accepts referrals for X-ray imaging from a variety of referrers including general practitioners, consultant specialists and emergency care doctors from Affidea's ExpressCare minor injury and illnesses walk-in clinic, which is located on the same site.

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
Tuesday 17 May 2022	10:00hrs to 16:00hrs	Agnella Craig	Lead

Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations was conducted of Affidea Diagnostics Ireland Ltd at its facility in Santry, Dublin 9 on the 17 May 2022. On the day of inspection, the inspector visited and spoke with staff in the general X-ray department of Affidea Santry.

From the documentation reviewed and the information gathered, the inspector was assured that the undertaking, Affidea Diagnostics Ireland Limited leadership, had governance and management arrangements in place to provide appropriate oversight of its facility at Santry.

The undertaking had a Radiation Safety Committee (RSC) in place and membership of this committee included the undertaking representative and the designated manager. The medical director was the chairperson of this committee. The lines of reporting into this committee and from this committee upwards to the executive board of Affidea Diagnostics Ireland Ltd were outlined in documentation provided in advance of this inspection.

The inspector found that the undertaking had systems and processes in place to ensure that only the appropriate professional persons recognised by the regulations could refer, act as practitioners and carry out the practical aspects of medical radiological procedures. Similarly, the inspector was assured that clinical responsibility for medical exposures was taken by personnel entitled to act as practitioners as per the regulations. However, the documentation could be updated to remove ambiguity in relation to roles and responsibilities of all personnel involved in medical exposures in this facility, in particular the responsibilities of the radiographer as practitioner should be clearly outlined to ensure that the allocation of responsibility for the radiation protection of service users is clear.

A medical physics expert (MPE) service was contracted by Affidea Diagnostics Ireland Ltd. to provide advice on matters pertaining to radiation protection of medical exposures carried out in this facility. Arrangements in place to ensure continuity of medical physics expertise were also detailed and found to meet the requirements of the regulations. The level of involvement of the MPE was also found to be proportionate to the level of radiological risk posed in this facility.

Regulation 4: Referrers

Based on the discussions with staff at Affidea Santry and the sample of records reviewed on the day of inspection, the inspector was satisfied that only referrals for medical radiological procedures from persons defined in Regulation 4 were carried

out at this facility.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation were reviewed and the inspector found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Information about the governance structures in place for the radiation protection of services users was detailed in the documentation provided to the inspector in advance of this inspection. The terms of reference for the RSC and minutes of previous meetings were also reviewed. The medical director was the chairperson of this committee. The designated manager and the undertaking representative were members of the RSC. Topics on the agenda included radiation safety, training and education, quality assurance, incidents, and clinical audit. This committee reported to the executive board through the clinical governance committee. Minutes of the last three clinical governance committee meetings were also provided and the inspector noted that membership included the designated manager and the undertaking representative. The inspector was satisfied that issues relating to the radiation protection of service users were also discussed at this committee's meetings.

Some information on the allocation of roles and responsibilities of personnel was included in the document titled *'Radiation Safety Procedures- Medical Radiography'*, however, this document lacked specific details and the radiographer's role as a practitioner was not clearly outlined. However, radiography staff were able to explain their role in taking clinical responsibility, as a practitioner, for medical exposures and the specific circumstances where radiographers can act as referrers or adapt a referral.

Notwithstanding the update required to the documentation to reduce ambiguity, in particular around the role and responsibilities of the radiographer, the inspector was assured that the undertaking had appropriate governance and management arrangements in place regarding oversight of the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to have taken 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. Sufficient evidence was available to satisfy the inspector that referrers and practitioners were involved in the justification process for individual medical exposures. Additionally, the practical aspects of medical radiological procedures were only carried out at this facility by individuals entitled to act as practitioners as per the regulations.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector met with the MPE engaged by the undertaking to provide medical physics expertise at this facility. The process in place to ensure the continuity of medical physics expertise was discussed and included an arrangement to utilise the expertise of another MPE engaged by the undertaking for other Affidea Diagnostics Ireland Ltd sites, where and when necessary. Staff who spoke with the inspector reported that they had adequate access to medical physics expertise and the inspector was satisfied of the processes in place to ensure the continuity of medical physics expertise at this facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector was assured by the arrangements in place that the MPE had acted and given specialist advice as appropriate on matters relating to the radiation protection of service users at this facility.

From the documents reviewed in advance of the inspection, and from speaking with staff on the day of inspection, the inspector was satisfied that an MPE took responsibility for dosimetry and was involved in optimising medical exposures. Evidence was also available to demonstrate that the MPE had contributed to quality assurance and acceptance testing at this facility and provided training in the area of radiation protection. The documentation and records reviewed also demonstrated that an MPE had been involved in establishing, reviewing and advising on DRLs at

Affidea Santry.

Judgment: Compliant

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

On the day of inspection, mechanisms were in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk at Affidea Santry.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection the systems and processes in place to ensure the safety of service users undergoing medical exposures at this facility were reviewed by the inspector.

The process of justifying medical radiological procedures and recording justification in advance of carrying out medical exposures was explained by staff. The inspector was satisfied with the evidence of compliance with Regulation 8 available in the report of the clinical audit of justification.

The inspector found that an appropriate quality assurance programme had been implemented and maintained and that the necessary acceptance testing had been completed on new medical radiological equipment before it was first used clinically. The mechanisms to report and record incidents and near misses involving, or potentially involving, accidental or unintended exposure to ionising radiation, and the initiatives to promote learning from incidents and potential incidents were also explained to the inspector.

This facility was found to be compliant with Regulation 11 as diagnostic reference levels (DRLs) had been established, reviewed and were in use by staff working in Affidea Santry. The MPE also communicated that image quality audits were conducted to ensure the images produced are of sufficient quality to provide the required medical information.

Similarly, Affidea Santry was found to be compliant with Regulation 13 as they had protocols and referral guidelines available for staff. Information relating to patient exposure was included on all reports of medical exposures reviewed by the inspector on the day of inspection. The process to ensure that information about the patient exposure was included in reports was manual at the time of inspection but the inspector was informed of the steps being taken to move to an automated process

and the implementation of this was imminent. Examples of clinical audit were also reviewed and showed increasing levels of compliance at the facility, specifically in relation to justification.

Although the undertaking had a policy and process in place to ensure that the referrer and or the practitioner inquired about and recorded pregnancy status, the measures in place to ensure the special attention to the justification of medical exposure for services users when pregnancy cannot be ruled out was not clearly detailed in the documentation and this is an area for improvement in order to become fully compliant with Regulation 16.

Notwithstanding the area for improvement identified above, overall, the inspector was satisfied that, at the time of inspection, Affidea Santry had effective systems and processes in place to ensure the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

All referrals reviewed by the inspector were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was observed in the form of posters in the waiting areas at this facility.

On the day of inspection, the inspector spoke with a practitioner 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.

Results of the *'Justification of X-ray referrals audit 2021'* carried out to examine the information included on X-ray referrals was reviewed by the inspector. This report, when compared with previous audits, showed an improvement in adherence to local policies and procedures and provided assurances that Affidea Santry had mechanisms in place to ensure that referrals were appropriately justified in advance by a person entitled to act as a practitioner in the regulations.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

As per the requirements of the regulations, DRLs have been established for radiodiagnostic examinations carried out at this facility. DRL charts were observed in the X-ray room and staff demonstrated an awareness of the use of DRLs in this

facility. Local DRLs were also found to be comparable to the national DRL levels and the inspector was informed of the image quality audits carried out to ensure that images produced at this facility provided the required diagnostic and medical information.

Judgment: Compliant

Regulation 13: Procedures

In line with Regulation 13(1), written protocols were viewed by the inspector for each standard radiodiagnostic procedures provided at this facility.

Information relating to patient exposure was included on all reports of medical exposures reviewed by the inspector. The inspector was informed of the manual process currently in place to ensure compliance with this regulation. However, the undertaking was in the process of implementing an IT solution to automate this process. This software had been tested and the implementation of this automated function was imminent at the time of inspection.

Clinical audits conducted at the facility included audits of the justification and the identification process. Referral guidelines were available to referrers and the staff who spoke with the inspector was aware of these guidelines.

Judgment: Compliant

Regulation 14: Equipment

An inventory of equipment was provided to the inspector in advance of this inspection. The inspector also noted that equipment and QA were discussed routinely at the RSC meetings. From the review of records and speaking with staff on the day of inspection, the inspector was assured that the undertaking had implemented and maintained a quality assurance programme. The inspector was also satisfied that the medical radiological equipment had undergone acceptance testing before first clinical use and subsequent quality assurance testing. Consequently, the inspector was satisfied that the medical radiological equipment was kept under strict surveillance by the undertaking.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, posters and leaflets in multiple languages were displayed in public areas to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures. The inspector was informed by staff of the process in place to inquire about pregnancy status and this aligned with the process described in the policy documents reviewed in advance of the inspection.

From the records reviewed on the day of inspection, the inspector was assured that a radiographer, as a practitioner, inquired about and recorded the pregnancy status in writing, as per the regulations.

However, while the 'Policy on Protection of Patients of Reproductive Capacity - LMP Policy' included some details of the process to be followed in situations where pregnancy cannot be ruled out for an individual service user, the inspector was not fully assured that the appropriate level of special attention was given to justification as required by the regulations.

One referrer who spoke with the inspector described a process they would follow in this situation before referring a patient for a medical radiological procedure at Affidea Santry. From communicating with staff the inspector found that the pregnancy policy should be strengthened, including improving the documentation of the individuals that should be involved in the justification process such as the referrer and the practitioner with clinical responsibility for the medical exposure. This improvement would provide an assurance for the undertaking that special attention is given to justification, particularly the urgency, and optimisation taking into account the individual service user and the unborn child subject to medical exposure to ionising radiation where pregnancy cannot be ruled out.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing the incident management policy and the forms available to record any incidents and near misses, involving or potentially involving accidental or unintended exposures to ionising radiation, the inspector was assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Staff who spoke with the inspector were also able to describe the process and this was in line with the local policy.

Although no significant events had been recorded, the inspector reviewed the near misses and other events identified as "good catches" and was satisfied that the processes in place to record and analysis events involving or potentially involving accidental or unintended exposures to ionising radiation. Initiatives undertaken at this facility to share learning from incidents and good catches was seen as good

practice to increase awareness and create a positive culture at Affidea Santry. Positive initiatives included weekly incident report meetings and using a 'memo-board' to 'spot-light' specific cases and lessons learned.
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	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	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Affidea Santry OSV-0005987

Inspection ID: MON-0036378

Date of inspection: 17/05/2022

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: See sections 1.2.6. and 3.1.6. of the procedures which deals with the role of the radiographer as a Practitioner In addition, the following changes will be made to our procedures (local rules) The Radiographer as a practitioner has clinical responsibility for an exposure which includes ensuring existing medical radiological and clinical information is available, protocolling, providing patients information regarding risks of ionising radiation, cooperating with practical aspects of radiological procedure, justification and optimisation.	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: Under section 3.3 of the procedures, we are adding the following: Any condition resulting in the loss of menstruation can be X-rayed outside of the 10-day rule or 28-day rule (DEXA) if the patient is happy to sign the LMP Waiver stating they are not pregnant", stating that; "In such a situation, the justification of the requested procedure will be reviewed, and particular care will be taken to ensure optimisation of the exposure through appropriate collimation etc. The justification process should include consultation with the Referrer and/or the Practitioner as to the urgency of the requested examination, taking into account the risk of pregnancy".	

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	31/07/2022
Regulation 16(2)	If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical	Substantially Compliant	Yellow	31/07/2022

	radiological procedure involved, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.			