



Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Affidea Waterford
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Holly House, Ardkeen, Waterford
Type of inspection:	Announced
Date of inspection:	30 September 2025
Medical Radiological Installation Service ID:	OSV-0005989
Fieldwork ID:	MON-0047710

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

Affidea Diagnostic Ireland Ltd. provide general X-ray services and dual-energy X-ray absorptiometry (DXA) scans at Affidea Waterford clinic. Services are for medical radiological procedures only. We accept referrals for medical exposures to ionising radiation from general practitioners, consultant specialists and advance nurse practitioners within their scope of practice.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Tuesday 30 September 2025	09:25hrs to 14:10hrs	Noelle Neville	Lead

Governance and management arrangements for medical exposures

An inspection of the undertaking Affidea Diagnostics Ireland Ltd. at Affidea Waterford was carried out on 30 September 2025 by an inspector to assess compliance with the regulations at this facility. As part of this inspection, the inspector visited the general X-ray and dual-energy X-ray absorptiometry (DXA) units, spoke with staff and management and reviewed documentation. The inspector noted that the undertaking demonstrated compliance during this inspection with each regulation reviewed, with the exception of Regulations 6 and 17, which were substantially compliant.

The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. In addition, the inspector was satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

The inspector noted some areas for improvement in relation to the clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation as required under Regulation 6(3). For example, in relation to Justification of Practices (Regulation 7), the inspector found that there was scope to document the allocation of responsibility for identification, oversight, management and approval of new types of practice and applications to HIQA, when required. In addition, the inspector noted that there was scope to improve communication with HIQA in relation to directory notifications, for example, ensuring that the correct service type is associated with the facility in the initial declaration of undertaking notification. In addition, any change of details notifications should be submitted in advance of changes being made to ensure that the HIQA directory is up-to-date, for example changes to a named designated manager.

Overall, despite the areas for improvement, the inspector was satisfied that a culture of radiation protection was embedded at Affidea Waterford and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

The inspector was satisfied from discussions with staff and management and from reviewing a sample of referrals that medical exposures were only accepted from individuals entitled to refer as per Regulation 4 at Affidea Waterford.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Affidea Waterford.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed documentation and governance structure organograms (organisational chart that shows the structures and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Affidea Waterford. A radiation safety committee (RSC) was in place at Affidea Waterford and this committee met twice a year. The inspector reviewed the terms of reference for this committee, dated 2024, and noted that it had a multi-disciplinary membership. This membership included the clinical services manager who was also the designated manager of the facility, chief executive officer, quality manager, radiation safety officers and medical physicists. The inspector noted that this committee had a standing agenda and items such as equipment, incidents and training were discussed. The committee was incorporated into local governance structures, chaired by the medical director at Affidea Diagnostics Ireland Ltd. and reported to the clinical governance committee which in turn reports to the executive board.

The inspector noted involvement in, and oversight of, radiation protection by the medical physics expert (MPE) at the facility across a range of responsibilities. From records reviewed and discussions with management and staff, the inspector was satisfied that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. The practical aspects of medical radiological procedures were only carried out by individuals entitled to act as practitioners and clinical responsibility for medical exposures was under the responsibility of a practitioner, as per the regulations.

The inspector noted some areas for improvement in relation to the clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation as required under Regulation 6(3). For example, in relation to the Justification of Practices (Regulation 7), the inspector found that there was scope to document the allocation of responsibility for identification, oversight, management and approval of new types of practice and applications to HIQA, when required. In addition, the inspector noted that there was scope to improve communication with HIQA in relation to directory notifications, for example, ensuring that the correct service type is associated with the facility in the initial declaration of undertaking

notification. In addition, any change of details notifications should be submitted in advance of changes being made to ensure that the HIQA directory is up-to-date, for example changes to a named designated manager.

Overall, despite some areas for improvement, the inspector was satisfied that a culture of radiation protection was embedded at Affidea Waterford and clear and effective management structures were in place for medical exposures to ensure the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at Affidea Waterford by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at Affidea Waterford.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the up-to-date professional registration certificate from the Irish College of Physicists in Medicine for the medical physicist at Affidea Waterford and was satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted that the MPE was involved in radiation protection across a range of responsibilities outlined in Regulation 20(2) at Affidea Waterford. The MPE was a member of the

radiation safety committee in place at the facility and gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). The MPE was available to carry out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relevant aspects of radiation protection. In addition, the MPE also acted as radiation protection adviser (RPA) for the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, the inspector was satisfied that the level of involvement of the MPE at Affidea Waterford was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector visited the general X-ray and dual-energy X-ray absorptiometry (DXA) units at the facility, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at Affidea Waterford. The inspector noted compliance with each regulation reviewed, with the exception of Regulation 17, which was substantially compliant.

For example, there was evidence that each medical exposure was justified in advance at the protocolling stage with additional checks on the day of the medical radiological exposure. Facility DRLs were established, regularly reviewed and used for general X-ray and DXA medical exposures. The inspector reviewed a sample of reports for general X-ray and DXA medical radiological exposures and found that information relating to the exposure formed part of the report as required by Regulation 13(2). In relation to Regulation 13(4), the inspector found that a clinical audit strategy was in place and was generally aligned to the national procedures established by the Authority. Staff at the facility ensured that medical radiological equipment was kept under strict surveillance as required by Regulation 14. The inspector noted records of pregnancy inquiries for relevant service users as required by Regulation 16. In relation to Regulation 17, the inspector determined that there

was potential scope for improvement in relation to the identification, reporting and analysis of potential incidents to meet compliance with Regulation 17(1)(c).

Overall, the inspector was satisfied that systems and processes were in place at Affidea Waterford to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

The inspector was satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users on posters displayed throughout the facility. The inspector reviewed a sample of records of general X-ray and DXA procedures and noted that justification in advance was completed at the protocolling stage. The inspector was also informed that, on the day of the medical radiological exposure, additional checks in relation to justification were completed by practitioners. However, the inspector noted to further strengthen compliance that there was scope to document these additional steps for clarity.

Judgment: Compliant

Regulation 9: Optimisation

The inspector noted an example of good practice in relation to optimisation at Affidea Waterford where staff carried out a reject analysis audit. The purpose of the audit was to determine the percentage of images in general X-ray that were deemed undiagnostic and that lead to a repeat exposure of the service user. One particular X-ray exam type was noted to have the most rejections and one of the possible reasons was noted as inadequate breathing in and out by the service user at the required times due to difficulties in hearing staff instructions. One action following this audit was the introduction of a lamp light for this particular exam. The lamp light was used to aid the service user in breathing in and out at the correct time when the light was switched on and off by staff in the equipment control area. The audit demonstrated a reduction in rejection rates in 2025 when compared to 2024. The inspector noted that staff at Affidea Waterford demonstrated a commitment to optimisation and keeping doses to service users as low as reasonably achievable consistent with obtaining the required medical information.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The undertaking at Affidea Waterford had a document titled *Standard Operating Procedure Radiology Dose Audit*, the most recent version of which was dated May 2022. This document set out the responsibilities in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. The inspector found that facility DRLs had been established, regularly reviewed and used for general X-ray and DXA procedures having regard to national DRLs and were displayed prominently in the facility.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Affidea Waterford for standard radiological procedures as required by Regulation 13(1). Regulation 13(2) states that an undertaking shall ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure. The inspector reviewed a sample of reports for general X-ray and DXA medical radiological procedures and found that information relating to the exposure formed part of the report. Referral guidelines were also adopted at the facility and were available to staff and referrers as required by Regulation 13(3).

Regulation 13(4) notes that an undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority. HIQA's national procedures document, published in November 2023, sets out the principles and essential criteria that undertakings must follow to ensure compliance with Regulation 13(4). The undertaking at Affidea Waterford had a document titled *Ionising Radiation Clinical Audit Strategy*, the most recent version of which was active since June 2024. This document outlined the audit strategy in place at the facility and noted that clinical audit topics are based on high-risk services and areas requiring specific attention. In addition, the inspector was informed that the clinical governance committee met monthly and provided oversight of clinical audit. While the inspector reviewed a sample of audits carried out of the facility including reject analysis, poster checks and patient identification/pregnancy check, it was noted that there was scope to further expand the range of audits completed to cover the full clinical pathway of the service user.

Judgment: Compliant

Regulation 14: Equipment

The inspector was satisfied that equipment was kept under strict surveillance at Affidea Waterford as required by Regulation 14(1). The inspector received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). The undertaking had two documents titled *Standard Operating Procedure Radiology In-House Quality Assurance Checks*, the most recent version of which was dated March 2023 and *Quality Assurance/Performance Testing for Medical Radiological Equipment*. These documents outlined staff responsibilities and the frequency of testing for each modality at the facility. The inspector reviewed records of regular performance testing and was satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults of issues arising if needed.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at Affidea Waterford had a document titled *Protection of the Unborn Child Arising from Ionising Radiation*, the most recent version of which was effective from May 2025. This document included information on the pregnancy procedures in place at the facility including the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed and discussions with staff, the inspector was satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to the query in writing. In addition, the inspector noted notices in several languages in the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector was satisfied from discussions with staff and management and a review of documents that Affidea Waterford had implemented an appropriate system for recording and analysis of events involving or potentially involving accidental or unintended medical exposures. An incident reports/good catch committee met weekly to oversee incident management and share learning and this committee reported to the RSC and the clinical governance committee.

The incident management process in place at the facility was outlined in two documents titled *Incident Management Policy*, the most recent version of which was effective from March 2024 and *Local Rules & Radiation Safety Procedures*, the most recent version of which was effective from March 2024. The latter document included information on the requirement to notify HIQA of certain reportable incidents. The inspector noted that no reportable incidents had been submitted to HIQA for this facility. In addition, the inspector noted that no incidents or near misses had been reported at Affidea Waterford for the last 12 months. However, several near misses or good catches were outlined to the inspector during the inspection which had not been recorded as such but were recorded instead as 'abandoned studies'. As a result, the inspector determined that there was potential scope for improvement in relation to the identification, reporting and analysis of potential incidents to meet compliance with Regulation 17(1)(c).

Judgment: Substantially 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 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Affidea Waterford OSV-0005989

Inspection ID: MON-0047710

Date of inspection: 30/09/2025

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Advance notification to the Authority of any changes for example new designated manager and equipment changes. Document revision and amendments to include application for justification of new services as stated under regulation 7.</p>	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: To ensure we are meeting the requirements for Regulation 17(1)(c), quarterly submission on the Incident management system of good catches, where studies are marked as abandoned. This will ensure 'good catches' or near misses trends are monitored.</p>	

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	04/11/2025
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of	Substantially Compliant	Yellow	04/11/2025

	events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			
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