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 Letterkenny
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Scally Place, Justice Walsh Road, Letterkenny, Donegal
Type of inspection:	Announced
Date of inspection:	07 December 2022
Medical Radiological Installation Service ID:	OSV-0005985
Fieldwork ID:	MON-0036814

About the medical radiological installation:

We provide dual-energy X-ray absorptiometry (DXA) and general radiography medical radiological imaging procedures at Affidea Letterkenny. We accept referrals for medical exposures to ionising radiation from a variety of referrers, including 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 7 December 2022	09:30hrs to 14:30hrs	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) and general X-ray 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 radiation safety committee (RSC) to provide oversight for radiation protection across all facilities. On this inspection, the inspector found effective governance, leadership and management arrangements for the protection of service users undergoing medical exposures, however, some update of the documented allocation of responsibility for radiation safety was found to be required to ensure complete regulatory compliance at Affidea Letterkenny.

Following review of documents and records, and speaking with staff, the inspector was assured 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. Similarly, the inspector was satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

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 documentation required update, the inspector was satisfied that the allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at Affidea Letterkenny.

Regulation 4: Referrers

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

Judgment: Compliant

Regulation 5: Practitioners

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was assured that Affidea Letterkenny had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: 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 also informed that the quality manager for Affidea Diagnostics Ireland Ltd was the designated manager and the person responsible for governance and management of the radiation protection of service users undergoing medial radiological procedures at Affidea Letterkenny. 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 who was the undertaking representative, the quality manager who was the designated manager, the clinical services manager, radiation protection officers, MPEs and operations manager. Other individuals were invited to attend as needed.

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 for the protection of patients needs to consistently and clearly define the professions considered practitioners by Affidea Letterkenny. Documentation should also reflect local practices at Affidea Letterkenny and clearly identify the allocation of the role of practitioners for the different aspects of clinical responsibility to ensure that day-to-day practices and local policy are aligned, unambiguous and consistent.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspector was satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner. The inspector was also satisfied that the optimisation process involved the practitioner and the medical physics expert, similarly, the inspector was assured that the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: 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 hospital, 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 DRLs, the definition of 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 Letterkenny 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 Letterkenny.

Judgment: Compliant

Safe Delivery of Medical Exposures

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

Following review of a sample of referrals for general X-ray and DXA the inspector was satisfied that Affidea Letterkenny had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded.

The inspector was satisfied that diagnostic reference levels (DRLs) were established, used and reviewed. The inspector reviewed examples of a range of clinical audits used to monitor and improve compliance with regulatory requirements including pregnancy protocol compliance, justification and patient dose audits. The undertaking had developed a bespoke method to ensure that information relating to patient exposure consistently formed part of the medical radiological procedure report and this system had inbuilt forcing functions to ensure that patient exposure information was included on all reports generated for medical imaging procedures.

The inspector reviewed documentation and records of accidental and unintended exposures and significant event near misses. Affidea Letterkenny demonstrated a comprehensive approach to the investigation and mitigation of risk from such events, particularly in the area of procedure justification, which was seen as a positive commitment to service improvement.

Records of acceptance and performance testing for all radiological equipment at the facility satisfied the inspector that the undertaking had implemented and maintained a quality assurance (QA) programme, however, improvements in the timely review of performance testing by the MPE need to be implemented by the undertaking to satisfy the requirements of Regulation 14.

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 Letterkenny.

Regulation 8: Justification of medical exposures

The inspector spoke with staff and reviewed a sample of referrals 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. 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.

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. Local facility DRLs were displayed in the clinical areas visited by the inspector on the day of inspection.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspector found that written protocols were established for standard medical radiological procedures. A sample of these were reviewed in the clinical areas visited by inspector.

The inspector spoke with staff and reviewed a sample of imaging reports from both clinical areas on the day of inspection and observed that information relating to patient exposure consistently formed part of the report for medical imaging procedures. The inspector was informed by staff that forcing functions built into the radiology information system ensured that radiography staff had to manually input this information which was subsequently transferred to the individual reports of the medical radiological procedures.

Documentation and records reviewed by the inspector demonstrated a systematic approach to the routine audit of radiation safety practice. The undertaking employed an audit schedule which documented the routine audits completed, including pregnancy status records, patient dose, patient identification and justification audits. Justification audits reviewed were a subset of records of events potentially involving accidental or unintended medical exposures as discussed under Regulation 17. The same record keeping system was used for systematic justification audits. This was seen as a good use of the system to record and analyse events involving accidental or unintended medical exposures to improve the regulatory requirements in relation to Regulation 8, 13 and 17 while simultaneously improving service user outcomes through the routine review and analysis of medical procedure justification.

Judgment: Compliant

Regulation 14: Equipment

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

After QA record review and communication with staff and management the inspector was satisfied that Affidea Letterkenny had implemented and maintained a QA programme and carried out acceptance and performance testing, however, MPE QA records indicated that QA was completed in May 2022 but was not signed off by the MPE until October 2022. This protracted delay in MPE sign off of performance testing should be addressed by the undertaking to ensure that all medical radiological equipment is kept under strict surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspector that Affidea Letterkenny 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 a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures and had taken all reasonable measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility.

At the time of inspection Affidea Letterkenny had not reported any incidents to HIQA. The inspector was satisfied that this did not represent a failure to identify, record or report such events.

Near miss event records were reviewed on site which demonstrated a strong overlap with the undertakings routine analysis of justification of medical procedures as

discussed under Regulation 13. These records included the relevant communication with referrers in relation to unjustified procedures and demonstrated good referrer practitioner interaction which improved communication pathways and strengthened the justification process.
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	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Affidea Letterkenny OSV-0005985

Inspection ID: MON-0036814

Date of inspection: 07/12/2022

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: Documentation has been updated by the Clinical Services Manager and the Quality Manager to fully comply with regulation 6(3). The description of radiographer as a practitioner had been updated accordingly with clear roles and responsibility of the radiographer as a practitioner. The latter had been implemented on the 31st of January 2023 effectively and communicated to all staff via company portal. The updated documentation is available on Affidea's shared drive. The updated document had been shared with the MPE. The documentation will be reviewed biannual as per company policy. Any changes to the document will be communicated to all relevant staff.	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: New SLA will ensure an agreed time frame for QA reports are submitted within two weeks of completion – this will ensure any action items are addressed in a timely manner. Any urgent action items will be flagged immediately to the QM and the CSM and the RSO	

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	31/01/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Substantially Compliant	Yellow	31/03/2023

	protection.			