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 Cork
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	The Elysian, Eglinton Street, Cork
Type of inspection:	Announced
Date of inspection:	08 January 2020
Medical Radiological Installation Service ID:	OSV-0005982
Fieldwork ID:	MON-0028342

About the medical radiological installation:

Affidea Diagnostics Ireland Limited is a private diagnostic imaging provider which operates a number of facilities nationwide. Affidea Cork is one of those medical radiological installations and provides computed tomography (CT), plain X-ray and Dual-energy X-ray absorptiometry (DXA) imaging under S.I. 256 of 2018. These services are provided to a variety of referrers which include specialist consultants in the Cork and greater Munster region, external general practitioners and internal referrals from the ExpressCare service on 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
Wednesday 8 January 2020	09:00hrs to 15:50hrs	Kay Sugrue	Lead
Wednesday 8 January 2020	09:00hrs to 15:50hrs	Maeve McGarry	Support

Governance and management arrangements for medical exposures

Overall, inspectors found that Affidea Diagnostics Ireland Ltd had effective leadership, governance and management arrangements in place at its Cork clinic with systems and processes detailing a clear allocation of responsibility for the protection of service users. The Radiation Safety Committee was a sub-committee of the Clinical Governance Committee with overall responsibility for the health and safety of service users attending its services for medical exposures. The Chief Medical Officer and Country Manager of Affidea Diagnostics Ireland Ltd. were members of both the Radiation Safety Committee and the Clinical Governance Committee.

Inspectors were assured from minutes reviewed from both these committees and from discussions with senior management that there were clear lines of communication on matters relating to radiation safety. These minutes also demonstrated that the undertaking was aware of its legal duties with respect of these regulations and was proactively addressing any areas of improvement identified to ensure compliance with the regulations. From discussions and records reviewed during the inspection, inspectors were satisfied that there were strong local management arrangements for the radiation protection of service users on site.

Inspectors found through the review of documentation and discussions with staff 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. Clinical responsibility was aligned with the person carrying out the practical aspects of each medical exposure. Delegation of the practical aspects was documented appropriately and clearly understood by staff in discussions with inspectors.

Affidea Diagnostics Ireland Ltd. had policies, procedures, guidelines and protocols in place to support staff however inspectors identified that the clinic's radiation safety procedures reviewed should be updated to better reflect current legislation and to ensure they are consistent with day-to-day practice as told to inspectors. Inspectors also found that while regular clinical auditing was undertaken at the clinic in line with regulations, there was room to expand auditing to provide better assurances around compliance with processes and procedures. Senior management had identified this as an area for improvement prior to the inspection.

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 the clinic and to meet the regulatory requirements. Inspectors found that the MPE role could be more clearly defined within local procedures to reflect specific MPE responsibilities and involvement required by current regulations. In addition, local procedures should differentiate the role of the

MPE from the role of the Radiation Protection Advisor which is required under different regulations.

Regulation 4: Referrers

On the day of inspection, referrals reviewed by inspectors were found to be compliant with regulations. An appropriate referrer was identifiable in all referrals reviewed by inspectors and included the medical council number. Referrals were accepted electronically and in hardcopy format, and were received from both external and internal sources. In discussions with inspectors, staff demonstrated a clear understanding of the referral process.

The local radiation safety procedures reviewed by inspectors stated referrals were accepted from medical practitioners and dentists. The policy stated that radiographers can act as referrers subject to training and in line with local protocol detailing scope of practice. Staff articulated that the scope of referral privileges for radiographers was limited and changes to referral privileges were under discussion locally. In practice, staff informed inspectors that radiographers modified or extended referrals in consultation with a radiologist.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors found that practices observed at Affidea Cork were compliant with the requirements of this regulation. In discussions with inspectors, staff were clear that the radiographer was the practitioner with responsibility for medical exposures undertaken at the clinic each day.

Inspectors identified some inconsistencies in the documentation provided on the role of the practitioner at the installation. For example, the clinical specialist radiographer was the identifiable practitioner with responsibility for justifying CT procedures on a day-to-day basis which was not consistent with local procedures. Gaps in documentation identified by inspectors during the inspection did not present a regulatory non compliance but should be addressed to ensure definitions and roles are clearly outlined and provide greater clarity for radiology staff working in the clinic.

Judgment: Compliant

Regulation 6: Undertaking

The organisation structures provided to the inspectors outlined a clear allocation of responsibilities for the radiation protection of service users. On the day of inspection, staff who spoke to inspectors could articulate the reporting structures and responsibilities in line with the organisational structures provided. The Country Manager was the undertaking representative for Affidea Diagnostics Ireland Ltd. and reported to Affidea Group Board located in Budapest.

The Country Medical Director and Country Manager were members of the Radiation Safety Committee, the Clinical Governance Committee and the Executive board which provided assurances to inspectors that there was appropriate membership at each forum to ensure communication of matters relating to radiation protection.

The Radiation Protection Committee met twice per year and reported into Clinical Governance, who held monthly meetings. To provide additional assurance and oversight, inspectors were informed by the undertaking representative that weekly and monthly local management meetings were held at the Cork clinic. The schedule for these meetings were viewed by inspectors.

Judgment: Compliant

Regulation 10: Responsibilities

The systems and processes in place reviewed by inspectors ensured that all medical exposures took place under the clinical responsibility of a practitioner.

The process of justification involved the practitioner and the referrer and this was evident through communication between the various professionals involved and was recorded in the local radiology information system.

Local radiation safety procedures indicated that the practical aspects of medical exposure were delegated to appropriately registered radiographers. An updated version of these procedures provided to inspectors outlined that the practical aspects of Dual-energy X-ray absorptiometry (DXA) procedures was delegated to a registered nurse with recognised training in radiation protection.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that the undertaking had arrangements in place to provide a medical physics expert (MPE) service by an off-site MPE. Inspectors were informed by the MPE that was contracted to the Affidea Cork clinic that continuity of the MPE

service was provided by another RPA/MPE in other sites within the undertaking's remit as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The Radiation Safety Procedures viewed by inspectors stated that a Radiation Protection Advisor (RPA) was appointed to fulfil the requirements under separate but parallel legislation, Statutory Instrument Number 30 of 2019 (S.I 30 of 2019), and would also act as the MPE to provide the medical physicist service requirements as relevant to S.I. 256 of 2018. From review of documentation and discussions with staff including the RPA/MPE, inspectors found that the focus of responsibilities for the RPA/MPE role was weighted towards the requirements of S.I. 30 of 2019.

Through discussion and review of records, inspectors were satisfied that the MPE had contributed to the review of diagnostic reference levels, analysis of radiation incidents, training of practitioners and staff and quality assurance and acceptance testing of medical radiological equipment in line with regulatory requirements. However, inspectors were not assured that the MPE took responsibility for dosimetry in line with regulations. Evidence provided indicated that the responsibility was shared between the contracted MPE service in Ireland and the medical physics department located elsewhere in Europe which is not recognised under this regulation.

Inspectors were informed that selection of equipment required to perform radiation protection measurements was undertaken centrally at Affidea head office without input from the MPE contracted service.

Overall, inspectors found that the responsibilities of MPEs as required under the regulations could be more clearly distinguished from the role of the RPA in the service. Furthermore, responsibility for dosimetric analysis of the service should be clearly traceable to an identifiable MPE in the Register of Medical Physics Experts.

Judgment: Substantially Compliant

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

Affidea Diagnostics Ireland Ltd. carried out a relatively high volume of CT exposures on site each year. Inspectors saw evidence of communication between staff at the clinic and the MPE which clearly showed that the MPE was available for consultation

and advice on matters relating to radiation protection of medical exposure as required.

Inspectors found that the involvement of the MPE in radiology practices such as CT exposures involving high doses could be more proactive in approach. Inspectors were informed that oversight of monthly CT dose monitoring audits was carried out remotely at the Budapest installation, reviewed monthly by the Radiation Safety Officer (RSO) in the clinic and twice a year by the MPE at the Radiation Safety Committee meetings. Following on from this inspection, involvement of the MPE should be reviewed by the undertaking to provide an assurance that level of MPE involvement is appropriate to the potential risks posed by the volume of high dose CT procedures carried out at the clinic.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors found overall that Affidea Diagnostic Ireland Ltd. had systems and processes in place to provide assurances on the radiation protection of patient undergoing medical radiological procedures at its Cork clinic.

Good examples of practice seen by inspectors was evident in the comprehensive justification process demonstrated by staff on the day of the inspection that was supported by a bespoke radiation information system. This system had inbuilt controls providing assurance to the undertaking that justification in advance had been completed for each requested medical exposure. The system provided clear identification of the practitioner carrying out justification and was also the repository for the records of justification.

Other areas of good practice related to monthly dose monitoring audits conducted for all CT procedures conducted at the clinic and reviewed locally by the RSO. The system for dose monitoring also provided alerts to radiographers and practitioners should DRLs be breached which was an additional assurance for the radiation protection of patients.

Inspectors found appropriate quality assurance programmes for all medical radiological equipment in use at the clinic with evidence that there was a medical radiological equipment replacement programme in place.

DRLs were established and reviewed annually for higher dose medical radiological procedures such as CT examinations and also for general radiography. There was a potential area for improvement in relation to assessment of reference dose or Dose Area Product verification for DXA scans.The review of such doses would provide additional assurance on optimisation for service users attending for DXA scans.

Inspectors identified areas for improvement relating to the tracking, trending and analysis of radiation safety incidents which was not routinely done up to the time of the inspection. Other areas for improvement related to local procedures which should be updated to align with the current Regulations and should be reflective of day-to-day practices particularly relating to the role of the practitioner involved the justification of CT procedures. Inspectors also found that information relating to patient exposure did not form part of the report of the medical radiological procedure in line with regulatory requirements which should be addressed to ensure compliance with Regulation 13(2).

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of referrals on the day of the inspection and found that Affidea Diagnostic Ireland Ltd. was compliant overall with the requirements of this regulation.

The radiology information system viewed by inspectors provided a comprehensive system for recording the referral and justification processes.

Individual referrals viewed by inspectors showed that medical information relevant to the patient and the reason for the request was included in each case. There was sufficient evidence demonstrated to inspectors to provide assurance that where practicable, previous diagnostic information was sought, reviewed and uploaded to the system if available.

Electronic communication between the justifying practitioner and the radiologist, the clinical specialist radiographer and referring practitioner was also reviewed which demonstrated that the benefits and risks of alternative modalities were considered and changes made appropriately during the justification process.

Information for patients on benefits and risks associated with radiation dose were available in each of the clinical areas visited by inspectors. Inspectors were informed that an electronic version of this information was due to be approved for access on the clinic's website in the near future.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors saw evidence of diagnostic reference levels (DRLs) established for all medical procedures carried out in the radiography room and and CT.

Established DRLs viewed by inspectors had been developed from 2018 data and were due to be updated using 2019 data.The DRLs were signed off at the Radiation

Protection Committee annually by the MPE. Locally established DRLs were displayed alongside national DRL values. In addition to DRLs, a dose monitoring system was in place. This system produced a monthly report from CT procedures carried out at the facility. These reports were reviewed by the RSO.

Inspectors were informed that the dose monitoring system benchmarked facility data against national DRLs and provided alerts should a breach of these levels occur. Inspectors reviewed the Standard Operating Procedure (SOP) for Radiology Dose Audit which had been revised in 2019 and provided guidance on the auditing of patient doses resulting from medical radiological procedures and the collection of data for the establishment of DRLs. Although, documentation provided to inspectors showed that DXA represented a significant number of the annual total radiodiagnostic procedures undertaken by the clinic, there was a potential area for improvement in relation to assessment of reference dose or Dose Area Product verification for DXA scans. This would provide additional assurances to management of the optimisation of all doses within the facility.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols were viewed by inspectors for each standard radiodiagnostic procedures provided by the clinic in line with Regulation 13(1). Inspectors identified an area of improvement relating to the approval and stakeholder involvement of protocols applied at the facility. Inspectors were informed that protocols and local procedures were circulated to key stakeholders such as the MPE and radiologists for approval. Inspectors were also informed by senior management that the Radiation Safety Committee was responsible for approving local procedures, however assurances on the approval of policies developed in 2019 was not seen in the minutes provided and consistent consultation and approval by key stakeholders was not strongly evident in documents viewed by inspectors.

Information relating to patient exposure was not seen on report of medical exposures viewed by inspectors. Senior management at the clinic acknowledged that this would be an area of focus following the inspection.

Referal guidelines were available internally in hardcopy format to referrers. Inspectors also found that clinical audits were conducted at the clinic which met the requirements of Regulation 13(4). Audits undertaken included Monthly Dose Audits, Pregnancy Checks and Identification Audits. In discussions with senior management, inspectors were informed that there were established plans to expand the audit practices to provide added assurance relating to radiation protection for service users. Inspectors saw a 2020 audit schedule which showed that radiation safety audits would take place in April and October 2020 in addition to audits routinely undertaken.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date equipment inventory was provided to inspectors in compliance with regulatory requirements. Inspectors was satisfied that there was appropriate surveillance and oversight of all medical radiological equipment in use within the clinic and an equipment replacement programme in place.

Inspectors viewed records of annual quality assurance programmes and performance testing for all medical radiological equipment for 2019 which was signed off by the MPE. Maintenance records for CT reviewed during the inspection were signed off by the RSO.

There was minuted evidence that annual quality assurance and regular quality control and assurance checks were discussed at the Radiation Safety Committee. On review of weekly and monthly quality control and assurance checks performed by radiographers, inspectors noted that not all checks were consistently documented in line with local policy. This was an area for improvement discussed at the Radiation Safety Committee in 2019 minutes viewed by inspectors which should be addressed following this inspection to provide assurances on compliance with local quality assurance processes.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Regulatory aspects of this regulation assessed by inspectors were found to be compliant. Multilingual pregnancy posters were displayed in procedure rooms and patient safety waiting areas. Monthly pregnancy status audits were undertaken. Inspectors saw evidence on the radiology information system that radiographers performed pregnancy status assessments during the justification of requested medical radiological procedures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The undertaking had a system in place for recording all incidents which included both ionising radiation incidents and non-ionising incidents. Radiation Safety Committee and Clinical Governance Committee minutes showed that radiation safety

incidents were discussed as a standard agenda item. Inspectors found that tracking and trending of radiation safety incidents was not routinely performed prior to the inspection. Inspectors were told that radiation safety incidents were recorded and included in all incidents occurring within the clinic. Senior management acknowledged this finding on the day of the inspection and informed inspectors that this issue had already been identified as an area of improvement for 2020.

Documentation provided and reviewed by inspectors following the inspection provided an assurance that the systems in place had the capacity to track and trend radiation safety incidents. Inspectors were satisfied that Affidea Diagnostics Ireland Ltd. had implemented measures to improve radiation safety incidents which included the introduction of an electronic system for recording all clinical incidents in January 2020.

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 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	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially 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 Cork OSV-0005982

Inspection ID: MON-0028342

Date of inspection: 08/01/2020

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 20: Responsibilities of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:

1. We have made significant efforts to distinguish between the roles of the RPA and the MPE through separating out staff and patient safety related controls in the radiation safety procedures.

2. We have also separated out these issues in the standing agenda of the Radiation Safety Committee.

3. We will undertake to list the separate roles and responsibilities of both the MPE and the RPA when next revising the radiation safety procedures.

4. We would further contend although the same medical physicist performs both the RPA and MPE role in this case, it does not undermine the level and value of the work performed.

5. We will ensure a greater role for the MPE in patient dosimetry going forward by forwarding regular dose excellence reports to the MPE for review prior to signing off on LDRLs.

6. The MPE will provide a written review, a comprehensive QA assessment in line with RP 162 is performed annually on all x-ray equipment. This QA assessment includes both radiation dose performance and image quality assessment.

7. Any issues that are noted in the dosimetry/image quality performance is noted in the report and followed up and closed out by Radiography staff on site.

All of the above actioned immediately but to be signed off at the next RPC May 2020. To be submitted 30th April 2020.

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

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
More MPE involvement regarding appropriate input to protocols.

1. Any new procedures will be revised to ensure that all decisions regarding equipment selection, where optimisation may be in question, are sent to the local MPE for an opinion. No new equipment planned at present.

2. Any significant changes to imaging protocols will also be sent to the local MPE for an opinion. These are reviewed yearly, next date for review October 2020.

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
1. The policy on dose audits and DRLs was updated and submitted.

2. While significant variation in DEXA dose is unlikely, DEXA can be included in the next dose audit, it must be noted no national levels were in existence at time of inspection. Dose Audit for 2019 completed for Xray and CT, Dexa to be completed by end of March 2020.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
1. Our protocols are not centrally approved by HQ Budapest but approved by our Consultant Radiologists and by Clinical Governance.

2. X-ray and CT were completed October 2019.

3. As an improvement measure the protocols will also be reviewed and approved by all relevant stakeholders including the MPEs in April 2020.

Patient exposure was not seen on report of medical exposures viewed by inspectors –

1. The issue of exposure data on reports is a problem everywhere. Perhaps note that we will engage with our RIS provider to plan an appropriate IT solution for this, Completion date Q4 2020.

2. This will be aided by the introduction of DR imaging in the Cork clinic. Which will be in place from the 23rd March 2020.

3. We do have a dose available should a referrer / shareholder require same.

4. Audit schedule is now in place.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
1. Reintroducing a training programme stressing the importance of the QA tests, monthly sign off by RPO has now been introduced for all QA and audits.

2. QA policy currently being reviewed and updated, MPE to review by end of March 2020.

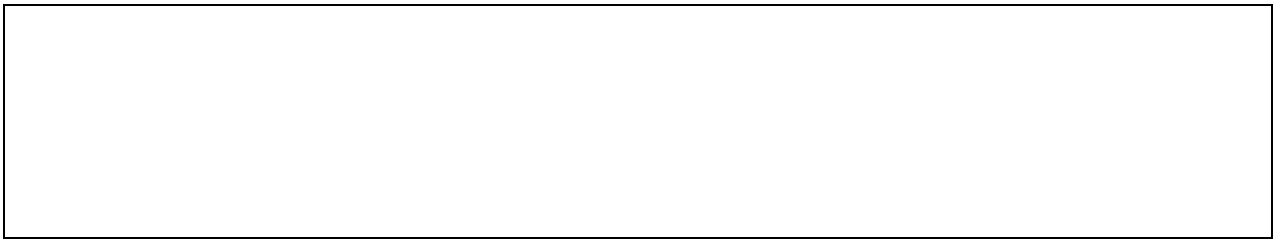
3. RSO to sign off on all QA monthly to ensure All checks are in place. This is done with immediate effect.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
1. New policy now in place which clearly defines near miss and significant events.

2. Training rolled out to all staff in Cork Clinic.

3. New tracker in place February 2020.



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 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	10/03/2020
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	10/03/2020
Regulation 13(2)	An undertaking shall ensure that	Not Compliant	Yellow	31/12/2020

	information relating to patient exposure forms part of the report of the medical radiological procedure.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	27/01/2020
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 events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	28/02/2020
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article	Substantially Compliant	Yellow	30/04/2020

	22(4) of the Directive.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Substantially Compliant	Yellow	10/03/2020
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological	Substantially Compliant	Yellow	10/03/2020

	equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate	Substantially Compliant	Yellow	10/03/2020

	with the radiological risk posed by the practice.			
Regulation 21(2)(b)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c), a medical physics expert shall be involved, and	Substantially Compliant	Yellow	10/03/2020