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 Dundrum
Undertaking Name:	Affidea Diagnostics Ireland Ltd
Address of Ionising Radiation Installation:	Rockfield Medical Campus, Dublin 16
Type of inspection:	Announced
Date of inspection:	29 September 2022
Medical Radiological Installation Service ID:	OSV-0005983
Fieldwork ID:	MON-0037331

About the medical radiological installation:

Affidea Diagnostics Ireland Ltd provides dual-energy x-ray absorptiometry (DXA), general radiography (X-ray) and computed tomography (CT) medical radiological imaging procedures at its facility in Affidea Dundrum. Affidea Dundrum accepts 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
Thursday 29 September 2022	10:00hrs to 16:30hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of Affidea Diagnostics Ireland Ltd at Affidea Dundrum was carried out on the 29 September 2022 to assess compliance against the regulations. As part of this inspection, the inspector visited the dual-energy x-ray absorptiometry (DXA), general radiography (X-ray) and computed tomography (CT) areas at this medical imaging facility.

On the day of inspection, Affidea Diagnostics Ireland Ltd's local governance and management arrangements to facilitate the safe delivery of medical exposure to ionising radiation at Affidea Dundrum were reviewed by the inspector. The quality manager for Affidea Diagnostics Ireland Ltd was the designated manager and the person responsible for the radiation protection of service users undergoing medial radiological procedures at the facility. Affidea Diagnostics Ireland Ltd had established a radiation safety committee (RSC) which the inspector found met twice a year. The RSC was found to be the main forum for providing oversight to senior management regarding the radiation protection of service users at Affidea Dundrum**.** The reporting and oversight structure for Affidea Dundrum and the undertaking, Affidea Diagnostics Ireland Ltd, was described to the inspector by management and a diagram of the radiation protection structure was also provided and reviewed as part of the inspection.

The inspector was satisfied that only referrals for medical exposures received from persons entitled to refer as per the regulations were carried out at the facility. Likewise, from reviewing a sample of records of medical radiological procedures on the day of inspection, the inspector found that these medical radiological procedures took place under the clinical responsibility of a practitioner, as defined in the regulations. However, on the day of inspection, the inspector found that documentation did not clearly allocate responsibility for different aspects of radiation protection. In particular, the role of radiographers as practitioners and the allocation of some elements of clinical responsibility, were not clearly documented. Additionally, the inspector found that documentation at the facility did not always fully align with the requirements of the regulations assessed as part of this inspection. Reviewing and updating of documentation was identified as an area for improvement to ensure the clear allocation of responsibility and roles for the radiation protection of service users at Affidea Dundrum.

Additionally, the involvement of a medical physics expert (MPE), in line with Regulations 19, 20 and 21, was also identified as an area for improvement. While an MPE contributed to the quality assurance (QA) programme for medical radiological equipment at the facility, the inspector was not satisfied that the contribution of an MPE met the requirements of the regulations, commensurate with the radiological risk of the medical radiological procedures being conducted at Affidea Dundrum. For example, the inspector found the MPE's involvement in the application and use of diagnostic reference levels (DRLs) as a non-compliance with the regulations on this

inspection.

Notwithstanding the non-compliances identified over the course of the inspection, the inspector was satisfied that governance and management arrangements were in place to ensure the radiation protection of service users undergoing medical radiological procedures at the facility.

Regulation 4: Referrers

The inspector reviewed a sample of referrals and spoke with staff and found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at Affidea Dundrum.

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 took clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at Affidea Dundrum were reviewed as part of this inspection. Documentation, including local policies, procedures, guidelines, records and an organisational chart, were also reviewed as part of the inspection.

On the day of inspection, the inspector spoke with staff and management at the imaging facility and found 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 Dundrum. 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.

While Affidea Dundrum had measures in place to ensure that only individuals as defined in the regulations could take clinical responsibility for medical radiological procedures, the inspector found that documentation reviewed did not clearly specify who could take clinical responsibility for the different aspects of medical exposure to ionising radiation at the facility. In particular, the role of radiographers as practitioners, and the elements of clinical responsibility allocated to them, was not clearly documented. It is important that policies, procedures and guidelines clearly indicate the allocation of responsibility for radiation protection at Affidea Dundrum. Similarly, documentation should reflect local practices at Affidea Dundrum 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 and meet the requirements of the regulations.

Additionally, the inspector found that documentation at the facility did not always fully align with the regulations being assessed as part of this inspection. For example, some documentation reviewed at the facility was found to be not complaint with the current Irish regulations as the allocation of responsibility to groups of individuals for different aspects of clinical responsibility, such as referral and justification, was aligned with previous Irish legislation and with legislation from other jurisdictions.

Overall, while the inspector was satisfied that governance and management arrangements are in place to ensure the safe delivery of medical radiological procedures at Affidea Dundrum, the facility could benefit from reviewing, consolidating and streamlining documentation to ensure the clear allocation of responsibility for the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take 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. The inspector was also satisfied 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 the hospital by individuals entitled to act as practitioners in the regulations.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, management and the MPE communicated the processes in place to ensure the continuity of medical physics expertise at the facility. However, written records evidencing these arrangements for Affidea Dundrum were not available on the day of inspection. While documentation outlining MPE arrangements for some of the other Affidea facilities was submitted following the inspection, documentation specific to the arrangements in place to ensure the continuity of medical physics expertise at the facility at Dundrum was not provided. As a result the inspector was not assured that Affidea Diagnostics Ireland Ltd had a formalised mechanism in place to ensure the ongoing provision of an appropriate MPE service at its imaging facility at Affidea Dundrum.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and spoke with staff, management and the MPE to assess the arrangements in place to ensure the appropriate involvement and contribution of an MPE at Affidea Dundrum, in line with the requirements of Regulation 20.

On the day of inspection the inspector found that an MPE gave advice on medical radiological equipment, including contributing to the QA of medical radiological equipment at Affidea Dundrum. The inspector was also informed that an MPE was involved in conducting training for members of staff across Affidea Diagnostics Ireland Ltd. However, over the course of the inspection, the contribution of an MPE to the application and use of DRLs was identified as an area of improvement for the facility in line with the inspector's findings of non compliance with Regulation 11.

Judgment: Substantially Compliant

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

On the day of inspection, the inspector spoke with staff, management and an MPE. The inspector also reviewed documentation and other records related to the involvement of an MPE, and their role in acting or giving specialist advice, as appropriate, on matters relating to radiation physics.

While the inspector was satisfied that, for the most part, an MPE was appropriately involved and acted or gave specialist advice on matters relating to medical physics for medical radiological practices, as outlined in Regulation 20, the contribution of an

MPE to the application and use of DRLs must be improved to ensure compliance with the regulations and fully demonstrate an appropriate level of involvement, in line with the requirements of this regulation.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Affidea Dundrum. Signage in the form of posters containing information about the benefits and risks associated with medical exposure to ionising radiation was observed in changing rooms. All referrals reviewed as part of the inspection were in writing and were accompanied by sufficient information. Staff informed the inspector that a practitioner justified all medical exposures in advance and justification in advance by a practitioner was found to be consistently recorded.

Information relating to patient exposure was included on all of the reports of medical radiological procedures reviewed on the day of inspection. The inspector found that clinical audit was carried out and referral guidelines for medical imaging were also available. However, while written protocols were available for standard medical radiological procedures, inconsistencies in the information contained in this documentation was identified as an area that Affidea Dundrum must address to come into full compliance with the regulations.

While DRLs where found to be established and used, an area for improvement was found with regards the methodology used to generate DRLs at the facility. The inspector communicated to staff on the day that DRLs should be generated in line with national and international guidance and best practice guidelines. Furthermore, increased contribution by an MPE to the use and application of DRLs at the facility could also assist Affidea Dundum in achieving full compliance with Regulation 11.

The inspector was satisfied that a practitioner carried out an inquiry as to the pregnancy status of service users, where appropriate, and this inquiry was recorded in writing and adherence regularly audited. The inspector also observed posters in changing areas to raise awareness of the importance of special protection during pregnancy. However, while staff communicated the processes carried out where pregnancy cannot be ruled out, this was not clearly documented in the facility's policies. To ensure the unambiguous and consistent application of the regulations for the special protection required during pregnancy, documentation should be reviewed and updated to ensure it is consistent and aligns with both day-to-day practice and the requirements of Regulation 16.

The facility had established a QA programme, including performance testing, for medical radiological equipment. An up-to-date inventory was provided in advance of the inspection. Affidea Dundrum also had a dose monitoring system in place which

was noted as an example of good practice in ensuring ongoing assessment of patient doses at the facility.The inspector was therefore assured that Affidea Dundrum's medical radiological equipment was kept under strict surveillance with regards to radiation protection.

In addition, arrangements were found to be in place regarding recording and analysing incidents involving, or potentially involving accidental and unintended exposures to ionising radiation. A good culture of reporting was also identified on the day of inspection.

Subject to addressing areas for improvement noted in this section, the inspector were satisfied that systems were in place to help ensure the safe delivery of medical exposures at Affidea Dundrum.

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. On the day of inspection, the inspector spoke with practitioners 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.

Staff at the facility communicated to the inspector the process by which a practitioner considered the information available to ensure that only medical exposures that were justified were carried out at the facility. As part of the inspection the inspector also reviewed records and relevant documentation relating to the justification of medical exposures at Affidea Dundrum. The facility had mechanisms in place to ensure that procedures that were not justification were not carried out. For example, staff had recorded and reviewed situations where referrals were not justified by a practitioner to identity trends and other learning opportunities and this was identified as a positive finding on the day. Additionally, information about the benefits and risks associated with the radiation dose from medical exposures in radiology was available to patients in the form of signs in changing areas at the facility.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation submitted to HIQA in advance of the inspection in addition to other records and data provided on the day of inspection.

The inspector also spoke with staff and management, including the MPE, to determine how DRLSs were established, used and reviewed at Affidea Dundum.

Affidea Dundrum had established DRLs for radiodiagnostic examinations in DXA, general X-ray and CT. The inspector observed DRLs displayed in all control rooms on the day of inspection. However, the inspector found that DRLs were not established and reviewed in line with national and international guidance and best practice methodology, such as described in HIQA's *Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation*. This was communicated by the inspector as an area of improvement that needs to be addressed at the imaging facility to come into full compliance with this regulation. Additionally, the increased contribution and involvement of an MPE in the establishment, use and review of DRLs, in line with the requirements of regulations, would further assist Affidea Dundrum in ensuring that local facility DRLs were appropriately established and reviewed.

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspector reviewed a sample of medical radiological procedures and found that information relating to patient exposure formed part of the report of these medical radiological procedures as required by Regulation 13(2). Management and staff at Affidea Dundrum communicated that the inclusion of information about patient exposure was now automated and included on all reports of medical exposures. A programme of clinical audit was established and the inspector reviewed a sample of clinical audits conducted at the facility. Referral guidelines for medical imaging were also available.

On the day of inspection, the inspector found that written protocols were established for standard medical radiological procedures and these protocols were available in each area where medical exposures were conducted. However, multiple versions of written protocols were found to be available for general X-ray procedures and following a review by the inspector were found to not fully align with each other. These written protocols also included information about who can carry out justification at the facility but this information did not align with the regulations and should therefore be reviewed and updated. Similarly, written protocols available for DXA procedures were also found to contain information about who can refer for a DXA procedure to Affidea Dundrum which was also found to be inconsistent with the regulations.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was satisfied that an appropriate QA programme was in place to ensure that medical radiological equipment at the Affidea Dundrum was kept under strict surveillance. An up-to-date inventory was provided in advance of the inspection.

Affidea Diagnostics Ireland Ltd had implemented a quality assurance programme which included a quality assurance assessment annually by an MPE. Documentation reviewed on the day of inspection demonstrated that regular quality control, including regular preventative maintenance and servicing by equipment vendors was also routinely performed. This provided an assurance to the inspector that the medical radiological equipment at the facility is maintained in good working condition.

Affidea Dundrum had also integrated a dose monitoring system into their service which was noted as an example of good practice in ensuring ongoing assessment of patient doses at the facility.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the changing rooms at the facility. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations. Inspectors reviewed a sample of referrals and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing. Adherence to the *LMP policy* was found to be regularly audited.

However, a review of some of the policies in place at Affidea Dundrum, which were reviewed on the day of inspection, identified an inconsistency in the policies regarding the age at which staff at Affidea Diagnostics Ireland Ltd carried out the inquiry regarding patents' pregnancy status. Furthermore, while staff communicated the processes that they carried out where pregnancy cannot be ruled out, these processes were not clearly or consistently documented in the facility's *LMP policy* and other Affidea Dundrum policies and procedures, including overarching Affidea Diagnostics Ireland Ltd policies and standard operating procedures. To ensure the unambiguous and consistent application of the regulations for the special protection required during pregnancy, documentation should be reviewed and updated to ensure it is consistent and aligns with both day-to-day practice and the requirements of Regulation 16.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Affidea Diagnostics Ireland Ltd had an electronic incident reporting system in place to record incidents and ensure relevant management are informed of all events involving or potential involving accidental or unintended medical exposure to ionising radiation. Affidea Dundrum records reviewed showed that no significant events had taken place to date and that no events involving an accidental or unintended exposure to ionising radiation had occurred in 2022. However, the inspector saw evidence that a positive reporting culture was in place at the facility. For example, documentation and records of potential accidental and unintended medical exposures were available for review on the day of inspection.

All events potentially involving an unintended or accidental medical exposure at Affidea Dundrum were discussed at management meetings and the RSC which assured the inspector that senior management had sufficient oversight of issues relating to accidental and unintended exposures. A feedback mechanism to inform staff of any issues or corrective actions was also in place. An information sheet was available in the staff room where all staff had to sign that they had taken note of any feedback or learning arising from a review of events. This was noted as a positive action by Affidea Dundrum to increase staff awareness of any lessons learned and ensure that mitigating actions are implemented to reduce the risk of occurrence of any incidents.

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	Substantially 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	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 Dundrum OSV-0005983

Inspection ID: MON-0037331

Date of inspection: 29/09/2022

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: Sections 1.2.6 and 3.1.6 of the procedures 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 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: A formal SLA outlining MPE arrangements specific to Dundrum is now in place to ensure the ongoing provision of an appropriate MPE service.	
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: The MPE, as part of their SLA agreement, has increased involvement in the use and review of DRLs, in line with the national and international guidance and best practice.

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: Mechanism are now in place, including an SLA, ensuring the MPE is involved in medical radiological procedures in line with the level of radiological risk, including involvement in the application and use of DRLs.	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Full review of the DRLs with the involvement of both the MPE and the Clinical Services Manager has now been completed, in line with the requirements of regulations. Local facility DRLs will continue to be reviewed as required.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: A full review and update of the written protocols is being undertaken for both X-Ray and DEXA and on completion will be in line with the regulations.	

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 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	05/12/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Substantially Compliant	Yellow	17/11/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	05/12/2022
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	05/12/2022
Regulation 16(2)	If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the	Substantially Compliant	Yellow	05/12/2022

	medical 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.			
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	12/11/2022
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	Substantially Compliant	Yellow	12/11/2022

	to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological 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	Substantially	Yellow	12/11/2022

	shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Compliant		
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	12/11/2022
Regulation 21(2)(c)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved,	Substantially Compliant	Yellow	12/11/2022

	as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.			