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:	Bon Secours Diagnostic
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Bon Secours Health System, Barringtons, George's Quay, Limerick
Type of inspection:	Announced
Date of inspection:	25 February 2020
Medical Radiological Installation Service ID:	OSV-0005992
Fieldwork ID:	MON-0028556

About the medical radiological installation:

Bon Secours Diagnostic Imaging (BSDI) is contracted for the provision of all Radiology Services within the Radiology Department of the Bon Secours Hospital Limerick at Barringtons including MRI, CT, General X-ray, Ultrasound, and DEXA. Additionally, BSDI provide a radiographer to undertake Theatre Screening and the provision of a radiographer for Pain Service. This is a wholly private service for inpatients of the Bon Secours Hospital, Limerick at Barringtons with the addition of privately insured individuals and a self-paying outpatient service as required.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 25 February 2020	09:20hrs to 15:40hrs	Kay Sugrue	Lead
Tuesday 25 February 2020	09:20hrs to 15:40hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors were satisfied that governance arrangements in place for the radiation protection of service users subject to medical radiological procedures were appropriate. The allocation of responsibility for the referral and conduct of medical exposures at Bon Secours Diagnostic was clearly defined and documented. Documented governance structures reviewed by inspectors showed that overall responsibility for the radiation protection of service users was held by the undertaking Alliance Medical Diagnostic Imaging Ltd. Bon Secours Diagnostic was co-located within a hospital and Alliance Medical Diagnostic Imaging Ltd had formal arrangements in place to provide a diagnostic imaging service for this hospital. To ensure dual governance and oversight for the radiation protection of service users, inspectors saw evidence of established communication pathways between these two entities in documentation provided.

Inspectors reviewed Radiation Safety Committee (RSC) meeting minutes demonstrating that there was effective oversight of matters relating to radiation protection. In addition, regular facility management meetings also took place to ensure continuity of oversight in the interim between RSC meetings which were held twice a year. Inspectors found that attendance by clinicians involved in the conduct of medical exposures at the facility could be improved. This would help ensure there was appropriate representation of clinicians at future RSC meetings in line with the committee terms of reference.

Inspectors found that referrals accepted at the facility were from those entitled to refer in line with Regulation 4. The facility had processes in place ensuring a radiographer was present for the conduct of all medical exposures. Inspectors were satisfied through the review of documentation and discussions with staff that all medical exposures took place under the clinical responsibility of a practitioner.

However, inspectors identified an area for improvement relating to the recognition of radiographer practitioner privileges at the facility. Local radiation safety procedures reviewed only identified radiologists as practitioners which did not reflect everyday practices . These local procedures should be updated to reflect practitioner roles performed by radiographers each day as described to and seen by inspectors to ensure alignment with regulations.

Medical Physics Expert (MPE) involvement in medical radiological practices was evident, with the level of involvement commensurate with the radiological risk posed by the practice. Inspectors were informed that continuity of medical physics expertise was provided through this contracted service.

Overall, inspectors were assured that Bon Secours Diagnostic had strong governance arrangements in place for the radiation protection of its service users. Some improvement in the facility's radiation safety procedures

was required but once updated should provide full clarity on practitioner roles at Bons Secours Diagnostic.

Regulation 4: Referrers

Inspectors saw both hardcopy and electronic versions of referrals which were both accepted by the radiology service. From discussions with staff and referrals viewed, inspectors found that referrals were only accepted from recognised referrers in line with regulatory requirements. Referrers were clearly identifiable in each of the referrals viewed by inspectors. Referrer professional registration numbers could be checked and verified by staff if needed using the radiology information system. This process was demonstrated to inspectors.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed a number of professional registration records, professional qualifications and records of radiation safety training. These records and discussions with staff provided evidence that medical exposures only took place under the clinical responsibility of a practitioner. Radiation Safety Procedures reviewed by inspectors identified practitioners as radiologists however the scope of practice for radiographer in the role of practitioner was not outlined and this should be addressed following this inspection.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that Bon Secours Diagnostic had clearly defined the allocation of responsibility for the radiation protection of services users subject to medical exposures at its facility. Documentation provided showed clear lines of communication within corporate and clinical governance structures. Governance structures of Alliance Medical Diagnostic Imaging Ltd viewed showed local oversight for radiation protection was provided by the Radiation Safety Committee which in turn had established lines of communication upwards to the undertaking representative and undertaking. Minutes of senior management team meetings were viewed by inspectors. These meetings were held on a monthly basis and provided a regular forum to discuss and address radiation safety issues arising at the facility on a day-to-day basis. Discussions with staff demonstrated that the

allocation of responsibility for the radiation protection of service users was clearly understood and reflected governance structures outlined in documentation reviewed by inspectors.

Bons Secours Diagnostic was co-located within the grounds of a private hospital and provided a diagnostic imaging service for this hospital. A good example of radiation protection governance arrangements described to inspectors and seen in documents reviewed was the established links between the host hospital and the undertaking. For example, dual governance of radiation protection was facilitated through senior management representation on relevant committees from both co-located facilities. Inspectors were informed that these links helped to provide oversight and greater assurances to both organisations on the radiation protection of patients referred from the host hospital to Bon Secours Diagnostic.

On review of RSC minutes for 2019, inspectors identified scope to improve clinician representation at the RSC meetings in line with its documented terms of reference.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors found that there were systems and processes in place to ensure that all medical exposures took place under the clinical responsibility of a practitioner. The practical aspects of medical exposures were not delegated which meant that radiographers were required to be present for all medical exposures conducted at the facility. Documentation reviewed by inspectors showed that there was a practitioner-in-charge at the facility and the roles and responsibilities of each profession were outlined. However, inspectors found that the justification of general radiology procedures and the determination of pregnancy status was described as a delegated responsibility for radiographers. Practitioner privileges such as these were not recognised in the radiation safety procedures viewed by inspectors. Documentation relating to these practitioner privileges should be updated to reflect day-to-day practices as described and observed by inspectors during the inspection.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that Bon Secours Diagnostic had access to off-site MPE services which also provided continued access to MPE service should the contracted MPE be unavailable. From discussions with management and staff, it was clear to inspectors that staff had appropriate access to the MPE if and when required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors saw evidence that the MPE registration on the register of MPE's was up-to-date. From discussions with staff and review of documentation, inspectors were satisfied that the MPE met the requirements of this regulations. Examples of evidence seen included MPE involvement in quality assurance of medical radiological equipment, patient dosimetry, review and sign off of facility diagnostic reference levels, advice and dose calculation for radiation incidents and staff training.

Judgment: Compliant

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

From the documentation reviewed and discussions with the MPE and staff, inspectors were satisfied that MPE involvement in medical exposures was commensurate with the radiological risk posed by the practice provided by this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the that service users subject to medical exposures delivered by Bon Secours Diagnostic were safe. Overall, Bon Secours Diagnostic demonstrated a good level of compliance with some improvements relating to documentation and process required to meet full compliance with the Regulations.

Inspectors found through discussions with staff that there was strong local ownership and awareness shown on matters relating to the radiation protection of service users attending for medical exposures at the facility. Inspectors saw evidence of processes in place to optimise each medical exposure. Quality assurance programmes for medical radiological equipment were reviewed and found to be compliant with regulations. There were established processes in place for the reporting and communication of radiation incidents and near misses with evidence of oversight by the RSC.

Inspectors saw evidence of good practice such as the promotion of referral guidelines through printed cards detailing electronic access to approved referral guidelines. This was a good initiative tailored for the attention of external referrers. Other positive areas seen by inspectors related to the comprehensive audit schedule and records reviewed. The facility informed inspectors that a monthly external peer review for image quality and reporting was also in place in line with best practice guidance.

While inspectors were satisfied that justification for each medical exposures conducted at the facility was undertaken, the record of justification for medical exposures other than computed tomography procedures was not evident on procedures reviewed during the inspection. Improvements in documentation of justification for all medical radiological procedures once implemented should provide evidence of compliance with Regulations 8(8) and 8(15). Inspectors also identified scope to improve adherence to local protocols during the process of justification to ensure that alternative modalities involving less or no exposure to ionising radiation are considered. The involvement of the referrer in the process of justification specifically relating to pregnancy enquiry also needed to be reviewed. Gaps in documentation were observed by inspectors on information related to the pregnancy status provided on relevant referrals viewed. Sufficient medical data should be included on the referral to aid the practitioner in justifying the requested procedure and to ensure compliance with Regulations 8(10)(c) and 8(11).

There was a co-ordinated process in place for the establishment, oversight and application of diagnostic reference levels (DRLs) for most but not all medical radiological procedures conducted at the facility. Inspectors found that DRLs were not established for dual-energy X-ray absorptiometry (DXA) procedures. This was identified as a potential area for improvement in relation to assessment of reference dose or Dose Area Product verification for DXA scans and would provide additional assurances to management of the optimisation of all doses delivered.

Inspectors also found potential to improve the formal approval process on written protocols for new procedures. Governance oversight would provide greater assurance that these supporting documents are in place before new medical radiological procedures are implemented as a standard practice.

Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. To ensure compliance with Regulation 13(2), information relating to service user exposure should form part of the report of the medical radiological procedure.

Inspectors found that while there were many good practices observed at the time of the inspection. Bon Secours Diagnostic however must implement a number of improvements if regulatory compliance is to be achieved. Specifically, improvements are required to meet compliance with Regulations 8, 11 and 13.

Regulation 8: Justification of medical exposures

Information outlining the benefits and risks associated with radiation for standard medical radiological procedures were observed by inspectors in patient waiting areas. Information was provided in different formats including posters and patient information leaflets.

Referrals reviewed by inspectors were in writing, included a rationale for the request and the referrer was identifiable in line with regulatory requirements. Clinical history was also included in all referrals viewed.

However inspectors noted that the pregnancy status of the service user (where relevant) was not documented by the referrer on internal referrals examined. Despite this gap, inspectors were assured that determination of pregnancy status was undertaken by a practitioner during the process of justifying each requested examination. This was evident in the number of completed pregnancy status assessments viewed by inspectors which were uploaded onto the radiology information system. Overall, the dual role of the referrer and the practitioner in the process of justification should be enhanced. This should assure the Alliance Medical Diagnostic Imaging Ltd. that all relevant information is provided by the referrer to the practitioner to facilitate justification and ensure the radiation protection of women of child bearing years undergoing medical exposure.

Discussions with staff demonstrated to inspectors that requested procedures were justified in advance by either a radiologist or a radiographer. The procedure for justifying medical exposures was consistently articulated by all practitioners who spoke with inspectors. However, inspectors found that the process for justification was not documented in all cases. For example, radiologists routinely justified CT procedures at the facility. Justification was recorded on the referral and uploaded onto the radiological information system. A similar system for recording justification of general radiography procedures justified by radiographers was not evident. This meant that compliance with regulations 8(8) and 8(15) was not evident in all referrals reviewed by inspectors. This was acknowledged by staff during the inspection.

An area of improvement identified by inspectors related to the assessment of adherence with local protocols when justifying medical radiological procedures. In one referral reviewed by inspectors, the modality for the examination requested was not in line with recommendations outlined in local protocols. There was no documented evidence to demonstrate that the efficacy, benefits and risks of available alternative modalities was taken into account during the justification process. This was not in line with local protocol viewed for the specific procedure and had the potential to result in unnecessary exposures to ionising radiation. Inspectors saw evidence that this issue was addressed immediately following this inspection.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that facility DRLs for all procedures had been established for all standard medical radiological procedures with the exception of DXA scans. The assessment of reference dose or Dose Area Product verification for DXA scans was acknowledged as an area for improvement. Facility DRLs for other imaging modalities were benchmarked against national DRLs and observed by inspectors displayed on walls in clinical areas.

Inspectors were informed that there was multidisciplinary input for the development and approval of DRLs which were reviewed annually. The most recent review had been completed in December 2019. Staff told inspectors that the service was performing below national levels and within established facility DRLs.

Judgment: Substantially Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical radiological procedures provided at Bons Secours Diagnostic. These protocols were available to staff in each procedure room inspected.

Inspectors found that there was a need to improve the management and oversight on the formal approval of new protocols and procedures through appropriate governance arrangements. Inspectors found technical parameters for CT procedures introduced in June 2019 and more recently in January 2020 were in place. However written protocols supporting these new medical radiological procedures had not been established prior to implementing these practices. This finding must be addressed without delay to ensure compliance with Regulation 13(1). Inspectors also identified scope to involve the MPE in the development of new protocols in the future. This in turn would provide greater assurances on optimising medical exposures for the benefit of service users.

Information relating to the patient procedure was not recorded on reports viewed by inspectors. This finding was acknowledged by staff at the time of the inspection.

Referral guidelines (iRefer) were available to referrers and staff on desktop computers. A good initiative was seen by inspectors to promote the use of approved referral guidelines by referrers referring to the facility. Access cards developed by the Bon Secours Diagnostic were provided to external referrers. These cards provided access details enabling electronic access to iRefer guidelines.

Inspectors found that Bon Secours Diagnostic had a system of audit in place. A comprehensive schedule of audit for 2020 was viewed demonstrating that regular

audit was undertaken at the facility. Inspectors reviewed reports of clinical audit undertaken in 2019. Audits carried out included clinical justification audit, a radiation dose audit, a pregnancy procedures audit.

Inspectors were informed that the facility was participating in a peer review audit for image quality and report writing which was ongoing at the time of inspection. Inspectors considered this a example of good practice and oversight.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors reviewed documentation and were satisfied that there was an appropriate quality assurance programme in place for all medical radiological equipment. Records for acceptance testing for new equipment installed in 2019 were viewed. An up-to-date inventory of medical radiological equipment was provided to inspectors. Equipment on the inventory had passed annual quality assurance tests and were signed off by an MPE. Internal quality control checks were regularly undertaken and documented in line with internal processes. These records were overseen by the Radiation Protection Officer and were accessible to staff on computer desktops. Fault logs reviewed by inspectors demonstrated that issues arising were resolved in a timely way.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were satisfied that there was an established process to determine the pregnancy status of services users subject to medical exposures. Records viewed demonstrated that radiographers had responsibility for making enquiries on pregnancy status. These records were uploaded on the radiology information system.

Inspectors observed posters in service user waiting area with the aim of increasing the awareness of women to whom this regulation applies. Pregnancy procedures were included in Local Radiation Safety Procedures approved in May 2019.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation and discussions with staff demonstrated that Bon Secours Diagnostic had comprehensive systems and processes in place in to record, analyse and trend radiation incidents. Radiation safety incidents arising during the conduct of medical exposures of patients referred from the co-located hospital were communicated through established communication links to their Quality and Patient Safety Department.These links helped to facilitate the appropriate follow-up of such incidents ensuring each one was fully addressed.

Inspectors found while the necessary processes were in place, overall reporting rates were relatively low when compared with activity levels within the service. It was acknowledged by senior management during discussion that there was potential to improve staff awareness on reporting near misses with a potential to increase overall reporting.

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	Compliant
Regulation 10: Responsibilities	Substantially 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	Substantially 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	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Bon Secours Diagnostic OSV-0005992

Inspection ID: MON-0028556

Date of inspection: 25/02/2020

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 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: Since the inspection by HIQA the Radiation Safety Procedures version 5.2 have been updated to reflect the role of a Radiographer as a practitioner in the practical aspects of Medical exposures in line with the IIRRT guidance. Completed 31/03/2020	
Regulation 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: Since the inspection by HIQA the documentation of the justification procedure as practiced in CT has been rolled out to the other modalities so that a record may be obtained if required at a future date. New process implemented 02/03/2020	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:	

Since the HIQA inspection Diagnostic Reference levels have been established in DEXA. This means that Diagnostic Reference Levels are now in place for all modalities. Completed 11/03/2020

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: Since the HIQA inspection written protocols have been established for the protocols for the two new procedures which were being developed in conjunction with the Radiologist specialising in Cardiology and the Applications specialist. Protocols completed and approved by the Radiologist specialising in Cardiology 02/03/2020. These protocols will be reviewed at the next RPC. Final sign off from lead Radiologist expected by the 30/04/2020. IT is working on a solution to ensure that dose records are contained on the patients Radiological report. To be in place by 31/12/2020

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 8(1)(b)	A person shall not carry out a medical exposure unless it takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.	Substantially Compliant	Yellow	02/03/2020
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	02/03/2020
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless	Substantially Compliant	Yellow	02/03/2020

	the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).			
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.	Substantially Compliant	Yellow	02/03/2020
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	02/03/2020
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	31/03/2020

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	02/03/2020
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	30/04/2020
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Yellow	31/12/2020