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:	Department of Radiology, Beaumont Private Clinic
Undertaking Name:	Department of Radiology, Beaumont Private Clinic
Address of Ionising Radiation Installation:	Beaumont Hospital Campus, Dublin 9
Type of inspection:	Announced
Date of inspection:	19 May 2021
Medical Radiological Installation Service ID:	OSV-0006059
Fieldwork ID:	MON-0031225

About the medical radiological installation:

The Department of Radiology, Beaumont Private Clinic is an outpatient diagnostic facility providing a range of diagnostic studies including computed tomography (CT), ultrasound (US), dual-energy X-ray absorptiometry (DXA), general radiography and mammography. The referral sources for these patients are general practitioners (GPs) and consultants within the private clinic and the associated public hospital. The majority of GP referrals are referred electronically through Healthlink, the national web-based messaging service. The department also has a diagnostic imaging workstation with access to the national integrated medical imaging system (NIMIS) radiology information systems (RIS) in addition to local picture archiving and communication systems (PACS).

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 19 May 2021	11:00hrs to 16:00hrs	Lee O'Hora	Lead
Wednesday 19 May 2021	11:00hrs to 16:00hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

Inspectors conducted an on-site inspection of the Department of Radiology, Beaumont Private Clinic on 19 May 2021. The Department of Radiology, Beaumont Private Clinic operates as a partnership with 12 consultant radiologist partners. The communication pathways between partners were well established and articulated on the day of inspection. Inspectors were informed that the managing partner was the undertaking representative and had a pivotal role in the governance and management arrangements for medical exposures within the undertaking. The Department of Radiology, Beaumont Private Clinic incorporated a radiation safety committee (RSC) into its governance system which reported directly to the undertaking through one of the partners who acted as chair of the committee. The radiography services manager (RSM) also acted as the radiation safety officer (RSO), attended the RSC meetings and had a key role in the operational oversight of day-to-day radiation safety practice and continuity of service within the department.

Inspectors were satisfied that, at the time of inspection, the Department of Radiology, Beaumont Private Clinic had systems in place to ensure that only appropriately registered professionals referred service users for medical radiological procedures and acted as practitioners and that all medical exposures took place under the clinical responsibility of a practitioner.

On the day of inspection, inspectors were informed the RSM role in the service had recently been in a state of transition. Breaks in the continuity of this role, essential for the day-to-day operational oversight of radiation safety issues, had subsequent effects on regulatory compliance including the allocation of responsibility for governance, oversight of radiological equipment and establishment and maintenance of diagnostic reference levels (DRLs). Despite this, inspectors were satisfied that the existing governance arrangements provided an assurance of the safe delivery of medical radiological procedures, although interim measures should be taken to ensure any further staff turnover does not further affect regulatory compliance and that recommendations made in this report are put into place.

Inspectors reviewed documentation and spoke with staff regarding the role of the medical physics expert (MPE) in the safe delivery of medical exposures. Although inspectors were assured that the Department of Radiology, Beaumont Private Clinic had continuity of MPE expertise, it was noted that the undertaking should involve the MPE to a greater extent in areas such as CT, as required in the regulations. Inspectors noted that there was an absence of documentation from the undertaking highlighting the responsibilities, advice and contributions of the MPE. The existing arrangement between the Department of Radiology, Beaumont Private Clinic and the MPE, while not presenting a current safety risk, should be formalised and documented to ensure regulatory compliance.

Regulation 4: Referrers

Following review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that the Department of Radiology, Beaumont Private Clinic only accepted referrals from appropriately recognised referrers.

Inspectors were informed that referrals via digital referral pathways such as Healthlink and the radiology information system (RIS) could only be placed from registered professionals who could refer patients for medical radiological procedures. Inspectors were informed that internal written referrals were only accepted from Beaumont Private Clinic consultants and written GP referrals reviewed routinely contained medical council registration numbers.

Judgment: Compliant

Regulation 5: Practitioners

Documentation reviewed by inspectors identified registered radiographers and medical practitioners as practitioners within the service. Staff informed inspectors that only radiographers and consultant radiologists specifically acted as practitioners at the facility. On-site review of professional registration satisfied inspectors that only the appropriately qualified staff acted as practitioners at the Department of Radiology, Beaumont Private Clinic.

Judgment: Compliant

Regulation 6: Undertaking

The Department of Radiology, Beaumont Private Clinic operated as a partnership with 12 consultant radiologists as partners. The managing partner played a pivotal role in the day-to-day radiation safety governance of the radiology department as the undertaking representative. Inspectors were informed that multiple communication pathways, including email and monthly meetings, ensured regular partner communication of relevant issues. The undertaking also used a Radiation Safety Committee (RSC) as part of the governance structure for the safe delivery of medical exposure to ionising radiation. The RSC members consisted of a partner consultant radiologist, the radiation safety officer (RSO) and the medical physics expert (MPE). Inspectors were supplied with terms of reference and minutes from the last three RSC meetings.

Following review of documentation and speaking with staff, inspectors found that the Radiography Services Manager (RSM) also performed the role of the RSO. Inspectors were informed that the RSM played a fundamental role in the day-to-day radiation safety operations of the department including taking responsibility for implementation of the majority of actions arising from the RSC. These actions included the review of diagnostic reference levels (DRLs) and communication of radiation safety updates to staff. The RSM also played an essential role in linking with both the MPE and equipment manufacturers to facilitate access to medical radiological equipment as well as oversight and close off of any outstanding equipment issues.

Document review highlighted the need for the undertaking to clearly allocate the roles and responsibilities of the MPE in the protection of service users from medical exposure to ionising radiation.

Furthermore on the day of inspection, inspectors were informed that the RSM role had been recently filled by a new member of staff. As training was still ongoing, the undertaking representative was fulfilling the role of the RSO as an interim arrangement. Gaps in continuity of this key role, essential for the operational oversight of radiation safety issues, was noted by inspectors as having an effect on the subsequent regulatory compliance with Regulation 6 and other regulations. Interim measures need to be strengthened to ensure any further staff turnover does not affect the undertakings ability to ensure the safe delivery of medical exposures to ionising radiation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors were assured that all medical radiological exposures took place under the clinical responsibility of a practitioner. Inspectors were informed that the Department of Radiology, Beaumont Private Clinic had a consultant radiologist present at all times for advice if required by other practitioners.

Inspectors were assured that both the practitioner and the MPE were involved in the optimisation process. The MPE's input into in-house quality assurance (QA) testing and continued involvement in the RSC was articulated to inspectors on the day. However it was also noted by staff that the undertaking could further enhance the involvement of the MPE in optimisation through routine inclusion in the development and review of departmental procedure protocols, particularly in the CT department.

Document review, staff communication and referral review satisfied inspectors that both the referrer and practitioner were involved in the justification process.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that, despite recent COVID-19 related restrictions, the MPE was available via phone, email and video conferencing for contribution and advice as necessary. Inspectors were satisfied that arrangements were in place to ensure continuity of expertise albeit at the time of inspection this arrangement was not formalised in documentation.

Formal arrangements such as service level agreements (SLA) or contracts detailing the role and responsibilities of the MPE were not available on the day of inspection. Inspectors were subsequently informed that the engagement of the MPE, while long established, had yet to be formally documented. This lack of formal evidence of involvement of the MPE should be addressed by the undertaking to ensure regulatory compliance.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

After meeting with staff and reviewing QA records, inspectors were assured that the MPE was responsible for dosimetry and gave advice on equipment in the form of risk analysis although documentary records, maintained by the undertaking, was limited on the day of inspection. Furthermore, in house radiation safety training of practitioners, previously supplied by the MPE, had not been delivered since the commencement of the Regulations in February 2019. Staff informed inspectors that the MPE contributed to the undertaking's QA program, reviews of DRLs and initial notifications of accidental or unintended medical exposure. However, inspectors found that that the undertaking should involve the MPE to a greater degree in contributing to the analysis of accidental or unintended medical exposures.

Overall, noting the effect that previous breaks in the continuity of the RSM role within the service, inspectors found that the undertaking should formalise the role and responsibilities of the MPE and involve the MPE to a greater extent in areas required by the regulations to provide continuity in radiation protection support.

Judgment: Substantially Compliant

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

Inspectors found that the input of the MPE could be developed and formalised to ensure that involvement is commensurate with the radiological risk posed by

practices potentially involving high doses, for example CT. The undertaking should avail of the support of the MPE, and the opportunities afforded by the MPE, to address areas for improvement relating specifically to the areas outlined in Regulation 20.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors were satisfied that the undertaking had processes in place to ensure the safe conduct of medical radiological procedures at the Department of Radiology, Beaumont Private Clinic, although some improvements could be made. Inspectors were satisfied that processes were in place to ensure that all medical procedure referrals were accompanied by the relevant information and justified in advance by a practitioner, however the record of individual justification, by a practitioner, was not consistently recorded and needs to be addressed to ensure regulatory compliance. The Department of Radiology, Beaumont Private Clinic ensured that a consultant radiologist was available at all times for advice if required, on all aspects of justification and this was seen as a positive arrangement.

Information on the risks associated with medical exposure to ionising radiation was available throughout the radiology department in the form of 'practitioner to patient' explanation posters. Information relating to the benefits and risks associated with medical exposure to radiation was well articulated by staff in the clinical area to inspectors. Patient radiation risk information handouts were available on the day of inspection but there was a lack of awareness of this information by clinical staff met with on the day. This was seen as an area for improvement and practitioners must be made aware of relevant radiation safety information and resources available to them.

There was also an inconsistent approach to the establishment, review and use of DRLs at the Department of Radiology, Beaumont Private Clinic. While inspectors were satisfied that CT DRLs had been established, reviewed and used in the CT department, DRLs for mammography and general radiography required updating. Furthermore, any individual DRLs that are found to exceed national DRLs should be investigated and corrective actions taken where necessary. For example, there were an absence of records of investigation or corrective actions taken with general radiography. DRL documentation also needs to be updated to reflect systems, processes and key personnel involved in the establishment review and use of DRLs.

Written protocols were available for every type of standard medical radiological procedure and these were readily available in the clinical areas. Inspectors noted that some protocols required update and the undertaking should consider a systematic multi-disciplinary approach to the review of imaging protocols, to ensure imaging protocols are optimised, up to date and reflect best practice. Inspectors

were informed, and subsequently observed, that information relating to exposure did not form part of the report of the medical radiological procedure. This was acknowledged by management as an area for improvement to ensure regulatory compliance.

RSC minutes detailed clinical audit as a standing agenda point. Inspectors reviewed reject analysis audit records and were satisfied that the audit results were fed back to staff. However justification and pregnancy audits detailed in the RSC minutes as being completed in December 2020 were not available for review. The undertaking must ensure that systems are in place to ensure documented audits are undertaken, recorded and used to improve radiation safety practice.

Inspectors reviewed in-house, manufacturer and MPE quality assurance (QA) records. Inspectors were informed that MPE QA testing of the DXA equipment was outstanding and dates had yet to be established to address the outstanding performance testing. Communication with staff and management informed inspectors that breaks in continuity of key radiation safety personnel delayed some actions being taken in a timely manner. The undertaking should have oversight of the management and coordination of all QA testing including the follow up and recording of all issues highlighted by QA tests and this noted as an area for improvement requiring attention.

Finally, following review of accidental and unintended exposure notifications submitted to HIQA and recorded locally and discussion with staff, inspectors were satisfied that all reasonable measures were taken to minimise the probability and magnitude of accidental or unintended exposures and that the undertaking had appropriate systems in place to record and analyse all such events.

Overall, noting there were issues requiring immediate attention and areas noted for improvement on inspection, inspectors were assured that these would be addressed by management at the Department of Radiology, Beaumont Private Clinic.

Regulation 8: Justification of medical exposures

Inspectors were informed that all CT and Mammography referrals are justified by consultant radiologists and DXA and general radiography referrals are justified by radiographers in conjunction with radiologists if needed. This process was well defined in documentation reviewed by inspectors.

For written referrals, practitioners signed the referral forms having satisfied themselves that the medical radiological procedure was justified in advance of the procedure being performed. However, records of individual justification were not available for all referrals reviewed by inspectors on the day of inspection. Inspectors were informed that the RIS system did have a facility to assign the practitioner justifying the procedure but staff articulated that this was generally done after the procedure was complete. A consistent approach to ensure that a record of individual

justification in advance of the procedure taking place must to be adopted to ensure regulatory compliance.

Inspectors were satisfied after meeting with staff and reviewing documentation that the practitioner routinely sought previous diagnostic information. Information on practitioner to patient radiation risk was also displayed in the clinical area. Staff clearly articulated radiation risk information in simple language to inspectors and demonstrated confidence in providing patients with adequate information relating to the benefits and risks associated with the radiation dose. Inspectors were supplied with patient information handouts, however staff met with in the clinical area did not seem aware of the availability or location of these handouts. This is seen as an area for potential improvement through effective communication with staff regarding the availability of this resource.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The DRL policy document reviewed by inspectors allocated responsibility for the establishment, review and use of DRLs to a managing partner. However, over the course of the inspection inspectors were informed that the RSM and the MPE had significant involvement in the process to establish and review DRLs locally. Documentation should be updated to reflect the operational processes and relevant staff used by the undertaking to establish, review and use DRLs.

Records reviewed by inspectors evidenced that CT DRLs were established in June 2020. These were displayed in the CT control room and were readily available to staff in the CT department. General radiography and mammography DRLs were displayed in the respective clinical areas. Inspectors were informed that these were outdated and needed to be updated to align with DRLs supplied to HIQA in December 2020 as part of the national general radiography and mammography DRL review.

The updated local facility DRLs supplied to HIQA were not documented locally on the day of inspection and there was no evidence on site that these local facility DRLs had been made available to staff. Three local facility DRLs supplied, as part of the national general radiography and mammography DRL review, were marginally above the national DRL. On the day of inspection, inspectors were informed that the appropriate investigations and reviews had not yet taken place and there was an absence of associated records of investigations or records of corrective actions taken. These areas noted for improvement should be addressed by management at the Department of Radiology, Beaumont Private Clinic.

Judgment: Not Compliant

Regulation 13: Procedures

Written protocols for mammography, CT, general radiography and DXA scanning were provided to inspectors. These were available to staff in the clinical area and staff articulated a good knowledge of the location of relevant protocols. General radiography protocols reviewed by inspectors were dated July 2016 and there wasn't evidence of systematic review or updates available. CT protocols reviewed on site had references to CT procedures only being done when certain staff members were present however upon speaking with staff it was revealed that these members of staff were no longer working at the facility. While protocols were available, the systematic review and update of protocols, involving the appropriate staff, would provide the undertaking with assurances that all medical radiological procedures are optimised.

Inspectors were informed and subsequently observed through image report review that information relating to patient exposure did not form part of the report.

RSC minutes for 8 December 2020 reviewed by inspectors detailed justification audits, pregnancy policy compliance audits and reject analysis audits noted as being complete. On the day of inspection inspectors saw evidence of reject analysis audits for 2020 and observed that the results of these audits were displayed in the clinical area. Inspectors also reviewed records of the sharing of audit results with individual staff members. However, records of justification and pregnancy compliance audits were not available on the day of inspection and were subsequently requested as follow up documentation. Subsequent communications with the undertaking revealed that these audits were not completed in 2020 and the minutes of the RSC were incorrect. A comprehensive programme of audit and follow up as required would provide greater assurance to the undertaking of compliance with regulations.

Judgment: Not Compliant

Regulation 14: Equipment

A full inventory was supplied in advance to inspectors and confirmed on site. CT and general radiography equipment annual QA records were supplied to inspectors and were up to date and confirmed that equipment was operating within tolerances. Inspectors were also supplied with routine manufacturer preventative maintenance service reports for DXA and general radiography.

DXA quality assurance records for 9 September 2019 were reviewed by inspectors. RSC minutes from 8 December 2020 noted that DXA testing was outstanding due to COVID-19 restrictions. The medical radiological inventory request supplied to inspectors detailed that the MPE testing was scheduled for 15 May 2021. At the time of inspection, inspectors were informed that the scheduled quality assurance had

not been complete and there wasn't formal plans or arrangements to address the overdue testing required.

Mammography MPE testing records from 19 June 2020 highlighted three specific issues that required the attention of the service engineer. Service engineer records from the 7 July 2020 and 20 July recorded the resolution of two of these issues but that a remaining issue had not been addressed at the time. On the day of inspection, there wasn't evidence available to inspectors that this issue had been addressed and resolved. Subsequent service reports and emails supplied satisfied inspectors that this issue had indeed been resolved by a service engineer on the 9 July 2020.

Although inspectors were satisfied that issues had been addressed, updated arrangements are required to ensure all medical radiological equipment is quality assured and outstanding testing is prioritised. Furthermore, any issues that are highlighted, addressed or outstanding should be recorded in a manner that is readily available to both the undertaking the the Authority.

Judgment: Not Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that the Department of Radiology, Beaumont Private Clinic had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection.

Multilingual posters were observed throughout the department and inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Documentation reviewed satisfied inspectors that the Department of Radiology, Beaumont Private Clinic had systems in place for the record keeping and analysis of accidental and unintended exposures and significant events. Documentation reviewed by inspectors listed a individual member of staff as a key role in the reporting of incidents however this staff member no longer worked at the department at the time of inspection. Documentation must be updated to accurately reflect the individuals or job titles of relevant staff integral to the incident reporting pathway for clarity.

Staff spoken to on the day of inspection consistently articulated the process for dealing with accident and unintended exposures and near misses. Inspectors observed that information on reporting and investigation process, incident trending reviews and individual incident reports were available to all staff in the clinical area.
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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Department of Radiology, Beaumont Private Clinic OSV-0006059

Inspection ID: MON-0031225

Date of inspection: 19/05/2021

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: So it is true that there certainly is a gap in the RSO coverage since our previous RSM/RSO left. In an effort to resolve this we have taken on a new radiographer, thus allowing the current RSO dedicated time per week to complete RSO duties. This radiographer will have a whole time position and have responsibility for CT and General. The proposed start date is 1/11/21 as he has to give 3 months notice at the current job. The aim would be to have him trained arrive at the time of the applications training portion of the new CT. The current RSO will take the British based course online to improve his knowledge but in the interim the managing partner will document a list for him of his duties per week/month as an RSO	
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: We have the role of the MPE documented in our Local Radiation Guidelines. The undertaking has signed a Service Level Agreement (SLA) with the local MPE for the provision of physics services dated 7/7/21 reflecting this role and in accordance with Regulation 20 of SI 256 of 2018.	

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:
As part of the documentation of responsibilities to the MPE we are going to ask that the internal Radiation safety program training is part of that. The SLA agreement with the undertaking states the requirement for 'organising, as required, courses of radiation safety for staff'. The SLA with the MPE also specifies that the MPE is involved in the 'investigation, reporting of all incidents, accidents or other abnormal situations involving ionising radiation".
Although the events will be documented and assessed at the time of the inadvertent exposure events are discussed also at the radiation safety meeting so that we can met in person to discuss any recommendations with the MPE

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:
The undertaking will involve the MPE in higher dose procedures such as CT as discussed. The service scope as outlined in the undertaking's SLA with the MPE is commensurate with the dose and inadvertent exposure risk of CT. This would include inadvertent exposure and DRL acquisition as stated above. In addition risk assessment for the new CT equipment with recommendations regarding shielding.

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
All studies justified by radiologist (CT and mammography) will have a signed approval scanned into the RIS system in order to have a scanned record of the justification of the study that is searchable.
In order to improve the robustness of this record keeping of the justification we will conduct an audit on the process this year.

Staff will be made aware of the patient information leaflet which requires updating and it will stored in its current location in the reporting room.

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
The undertaking have an existing policy document regarding DRLs. This will be updated to reflect the workflow with the practical acquisition and retrieving of DRLs to be performed by the RSM but to be initiated and overseen by the MPE. Outliers will be investigated by MPE who will recommend corrective action.
In order to come into line the Managing partner met with the MPE on 7/7/21.
The specific areas to be assessed for each relevant modality were listed. The mechanism as to how to acquire the dose data was discussed and it will be up to the Managing partner, RSM to assimilate and tabulate the data which is then passed to the MPE.
So the process of acquiring the up to date DRL has begun. This will be repeated every year.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
It is correct that the CT protocols are quite heterogeneous. The reason being that there have now been 3 different CT operators since 2016. We have tried to change protocols to improve image quality whilst keeping us with the appropriate DRL's for such an old 6 slice machine. Our new CT will arrive in November which will give us the opportunity to create an entirely new set of more succinct protocols. In addition a new tomography mammography machine will also be placed late this year 2022. This means that there will be 2 completely new protocols required for both machines which should address any existing heterogeneity of existing protocols. As regards general radiography the equipment and therefore the protocol has not changed since 2016 but we will review the protocols after we reassess the DRL's to ensure that the appropriate changes are made. Protocol review will be carried out by the Managing Partner, RSM for General and CT but will be carried out with the individual specialist practitioner radiographer in both mammography and DEXA. Therefore the clean-up and renewal of the General protocols will be by end 31/12/21. In all cases the new protocols when created or changed will be submitted to the MPE for approval.

Given that our RIS provider is one of the largest in the UK and soon to be the national RIS associated we work with them to ensure that all DRL are recorded automatically on the patients report. This will likely take some time and also likely a visit from the software provider but we would aim to have it done by 31/3/22

The rejection analysis will continue monthly and we will redo the pregnancy audit and justification audit by 31/12/21 and document that in our forthcoming radiation safety meeting

Regulation 14: Equipment	Not Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
DEXA Q/A and testing has been performed as of Friday 9/7/21.
The Q/A schedule is documented on the calendar both written and electronically on the RIS diary so that everybody is aware of when the Q/A days will happen. The dates are given to the Managing Partner of the undertaking generally or the RSM and the clerical staff then asked to block off the relevant days electronically.

Specific issues related to equipment raised by either MPE or the service engineer will need to have a closed loop system in order to ensure their resolution. Issues raised at the time of testing will be documented in writing and the RSM is to be notified. In the absence of the RSM the managing Partner of the undertaking will assume that role. The RSM will ensure that the appropriate action is taken and the resolution of the said issues are documented on any further service testing

In addition the issues raised during testing will be discussed locally at radiation safety committee meeting which will document the issues raised and require documented evidence from the service engineer that they are resolved.

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	01/11/2021
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	Substantially Compliant	Yellow	01/09/2021

	exposure, and shall provide such records to the Authority on request.			
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	01/09/2021
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Orange	01/09/2021
Regulation 11(7)	An undertaking shall retain a	Not Compliant	Orange	01/09/2021

	record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.			
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	31/12/2021
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	Orange	31/12/2021
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	01/09/2021
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	01/09/2021
Regulation 14(3)(b)	An undertaking shall carry out the	Not Compliant	Orange	01/09/2021

	following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
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	07/07/2021
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;	Substantially Compliant	Yellow	07/07/2021

	(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 shall ensure that, in medical radiological practices, a medical physics	Substantially Compliant	Yellow	07/07/2021

	expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.			