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:	Blackrock Clinic
Undertaking Name:	Blackrock Clinic
Address of Ionising Radiation Installation:	Rock Road, Blackrock, Co. Dublin
Type of inspection:	Announced
Date of inspection:	16 March 2023
Medical Radiological Installation Service ID:	OSV-0007390
Fieldwork ID:	MON-0039121

About the medical radiological installation:

The Radiology Department in Blackrock Clinic provides advanced medical imaging to a large range of specialities including cardiology, orthopaedics, oncology, respiratory, gynaecology and many more. We also offer a service to general practitioners and other hospitals across Ireland. In order to provide this service to our users we offer a wide range of imaging equipment. The Radiology service is led by highly qualified radiologists and supported by a multidisciplinary team consisting of radiographers, physicists, nurses, support staff and the administration team. The Radiology Department consists of five modalities located in nine rooms and images approximately 65,000 patients per year. We provide weekend and out of hours imaging in general radiology, CT and MRI to support the needs of the hospital and Emergency Department. We also provide imaging on the wards, ICU, Theatre and the Angiography Department. The Angiography Department consists of three cardiac catheterisation labs attached to a 16-bed day unit which provides structural, interventional cardiology, radiology and electrophysiology services to patients referred to Blackrock Clinic. Our cardiac catherisation labs run five days per week Monday – Friday, with an on-call service at night and over the weekends. Currently there are six theatres on the lower ground floor and a further two theatres and two minor procedure rooms on the fifth floor that require support from the Radiology Department during their lists. The hybrid theatre on the lower ground floor has a fixed C-arm unit to assist with vascular cases. We have four mobile C-arms that move between theatres 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
Thursday 16 March 2023	08:55hrs to 15:10hrs	Kay Sugrue	Lead
Thursday 16 March 2023	08:55hrs to 15:10hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations was conducted at the Blackrock Clinic, on the 16 March 2023. Inspectors reviewed documentation outlining the governance structures in place for the radiation protection of service users and spoke with several staff members during the course of this inspection.

Oversight for radiation protection was provided by the Radiation Safety Committee (RSC) which reported upwards to the Medical Advisory Committee (MAC) and from there to the undertaking. From the arrangements reviewed and discussions with staff and management, it was evident to inspectors that staff were aware of, and familiar with the established reporting lines from the clinical setting up to the undertaking.

Hospital policy viewed by inspectors clearly defined who could act as a referrer at Blackrock Clinic which was as per Regulation 4(1). However, from a number of referrals viewed and following discussions with staff, inspectors found that this policy was not consistently followed across the radiology service**.** While inspectors were satisfied that this discrepancy between policy and practice did not represent a radiation safety risk to service users, the undertaking must make improvements to ensure that local practice is consistently aligned with local policy.

Following review of documents and records, and speaking with staff, inspectors were satisfied that clinical responsibility for medical exposures was only taken by persons entitled to act as practitioners as per Regulation 5. Inspectors found that the undertaking had ensured there was appropriate involvement of a practitioner and MPE in the optimisation of medical exposures at this facility. As an additional assurance mechanism, a radiographer was present for all medical exposures conducted at this facility. Inspectors were satisfied from evidence viewed that a referrer and practitioner were involved in the justification process within the radiology department. However, further assurance was required in relation to the referral process for medical exposures carried out in the theatre fluoroscopy service. The need for greater delineation of the practitioner role in this setting was also an area of improvement identified by inspectors. There was some ambiguity demonstrated in discussions with staff and management on who the practitioner was for medical exposures carried out in this service. Consequently, further action must be taken by the undertaking to ensure that the allocation of responsibilities for the radiation protection of service users as per Regulation 6(3) is clear and understood by all staff. Staff and management at the hospital informed inspectors that these gaps in compliance had already been identified in this service and would act immediately to address any deficiencies identified during this inspection.

From the records reviewed and discussions with staff, inspectors were satisfied that staff in Blackrock Clinic had ensured contingency arrangements for the continuity of Medical Physics Expert (MPE) expertise in the facility. Inspectors saw strong evidence of MPE involvement in all areas of MPE responsibilities as per regulations

and were therefore satisfied that the level of MPE involvement was proportionate to the radiological risk posed by the service.

While inspectors were satisfied overall, that the right professionals were involved in the conduct of medical exposures delivered by the hospital, some areas for improvement were identified to improve regulatory compliance.

Regulation 4: Referrers

Inspectors viewed the hospital's *Radiation Safety Procedures* which detailed who could act as referrer for medial radiological procedures in this hospital as defined in Regulation 4(1). The role and scope of practice for a nurse and a radiographer to act as referrers within the hospital was further delineated in the document *Delegation of Duties for Medical Exposures* viewed by inspectors. Inspectors spoke with staff who explained their understanding of the referral process.

Inspectors viewed a sample of written referrals in each service visited and found that in general, the referrer was identifiable. However, in a small sample viewed, the professional registration number of the referrer was not evident. Staff informed the inspectors that the registration number for referrers was not routinely checked to verify each referrer. This does not align with the referral process outlined in the *Justification Procedure for all Radiology Referrals* document which stated that the referrer must include their professional registration number on all referrals.

While inspectors were satisfied that this gap did not represent a radiation safety risk to the service user, the processes need to be improved to ensure that referrals are available for all procedures and that local practice is aligned with the local policies and the regulations.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, inspectors reviewed a sample of records in relation to medical exposures and found that only those entitled to act as practitioners, as per the regulations, had taken clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation and spoke to a number of staff and found that governance arrangements at the hospital were understood and effective. The hospital had an RSC which had multidisciplinary membership. The hospital CEO who was also the undertaking representative was a member of this committee providing assurance of direct communication upwards to the MAC, the undertaking and the overarching governance of Blackrock Health Board of Directors. There were also direct reporting lines from Radiation Protection Advisers (RPAs), Medical Physics Experts (MPEs) and the Designated Manager to the CEO of Blackrock Clinic which were confirmed in discussions with staff and consistent with documented arrangements viewed.

The RSC was responsible for radiation safety and protection of service users undergoing medical exposures involving ionising radiation at the hospital. Inspectors reviewed minutes from the RSC and found evidence that this forum met the established terms of reference. The Radiology Compliance Working Group and the Radiological Clinical Audit Committee reported to the RSC, the latter produced a 2022 annual report which was submitted to the RSC and this report was reviewed by inspectors.

Inspectors viewed a number of hospital policies applied in the radiology service and found that the allocation of responsibility for the protection of service users undergoing medical exposures was, for the most part, clearly outlined within the hospital. The policy on the *Delegation of duties for medical exposures* viewed by inspectors outlined the role of nurses and radiographers as referrers in each speciality and the delegation of the practical aspects to other professions such as MPEs and non-radiology medical consultants. Practitioner responsibilities were also outlined in this policy. Justification for medical exposures was the responsibility of radiologists and radiographers in all services with the exception of theatre and angiography imaging services. In these specialities, non-radiology medical consultants were allocated responsibility for justifying medical exposures undertaken there, and although this is permitted by the regulations, they were not identified as practitioners by the undertaking. Additionally, discussions with staff demonstrated a lack of clarity relating to who the practitioner was in these services. Inspectors were provided with differing accounts on who staff understood to be the practitioner in the theatre service. Although not seen as a safety risk at the time of the inspection, the undertaking must address any uncertainty to ensure that the allocation of responsibilities is clear to all staff as per Regulation 6(3) and is consistent with hospital policy and aligned to practice and the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors were assured by the systems and processes in place in the hospital that all medical exposures took place under the clinical responsibility of a practitioner. Delegation of the practical aspects of a medial radiological procedure was

documented in local policy and met regulatory requirements. There was evidence provided to show that a practitioner and MPE were involved in the optimisation process. As an additional assurance on the optimisation process, medical exposures delivered outside the radiology department such as in the cardiology interventional suites and fluoroscopy examinations performed in theatre were conducted in the presence of a radiographer. From records viewed in which the referrer was not clearly identified or the referral evident, more assurance was required to ensure that the referrer was consistently involved in the justification process as per Regulation 10(3)(b).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

From the records reviewed and discussions with staff, inspectors were satisfied that Blackrock Clinic had ensured contingency arrangements for the continuity of MPE expertise in the facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration certificates were reviewed by inspectors on the day of inspection and found to be up-to-date and met regulatory requirements. Inspectors spoke to an MPE who outlined that staff had access to an MPE onsite during core working hours. In addition, staff informed inspectors that an MPE was readily contactable via the phone if needed and also included in instant messaging groups used within the radiology department.

Inspectors saw evidence in documentation viewed demonstrating involvement of an MPE in quality assurance of medical radiological equipment, dosimetry, review and sign off of facility DRLs and advice and dose calculation for radiation incidents. Additionally, records viewed demonstrated that an MPE contributed to the development of protocols and delivered training on radiation protection to staff.

From documentation reviewed and discussion with management and staff, inspectors were satisfied that the hospital had appropriate arrangements in place to ensure the fulfilment of MPE responsibilities as per Regulation 20.

Judgment: Compliant

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

Inspectors reviewed documentation and spoke to staff and were satisfied that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was proportional to the level of risk posed at this facility providing numerous imaging services with different levels of complexity. While MPE involvement was evident and met regulatory requirements, inspectors were informed that medical physics resources were not formally prioritised towards higher radiological risk services which was an area under review for implementation in the future.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at Blackrock Clinic. Inspectors found examples of good practice evident in clinical audits conducted at this facility which were focused on improving the radiation protection of service users attending for medical radiological procedures.

Good practices were also evident in the strict surveillance of medical radiological equipment that showed there was an appropriate quality assurance (QA) programme in place, regular performance testing and strong oversight by the undertaking in relation to the programme of replacement of medical radiological equipment. Another example of good practice was found in the management of incidents involving medical exposure where corrective actions implemented resulted in a reduction in the number of radiation incidents related to scheduling issues.

A review of renal protocols applied for procedures carried out in the computed tomography (CT) service provided a good example of optimisation as per Regulation 9. Inspectors were satisfied that special attention was given for high dose procedures such as those delivered in the interventional cardiology service, as per Regulation 15. However, day-to-day practices described by staff to inspectors regarding the follow up of service users who had been subject to radiation doses exceeding established thresholds should be reviewed to ensure consistency with hospital policy.

Inspectors found that while there were many good areas of practice identified during this inspection, improvements in compliance was needed with respect of Regulations 8, 11, 13 and 16. Following a review of the justification process of medical radiological procedures across the various services provided at Blackrock Clinic, greater assurance was required regarding Regulation 8(10). The undertaking needs to ensure that sufficient information is provided by a referrer to inform the

justification process and improve compliance with this regulation for all procedures within each speciality. Additionally, information on the risks and benefits associated with medical exposure to ionising radiation provided to service users was observed by inspectors to be relatively limited. Staff informed inspectors that this was an area already identified that required action to improve compliance and that work had already commenced to address any deficiencies found.

Diagnostic reference levels (DRLs) for adult procedures had been established by staff at the hospital and were displayed in the control rooms of the areas inspected. Inspectors were informed that very low levels of paediatric procedures were conducted at this installation, however, the undertaking had established local DRLs for general X-ray procedures and was taking steps to establish paediatric DRLs in all other relevant areas. The process described by staff for the review of DRLs found to be above national DRLs did not provide assurance that appropriate reviews were conducted and corrective actions implemented in a timely way as per Regulations 11(6) and 11(7). Therefore, further action needs to be taken by the undertaking to improve compliance with this regulation.

Written protocols were established for each type of standard adult medical radiological procedure as per Regulation 13(1). However, there was scope to define and document the process for ratifying protocols to ensure a standardised approach is maintained across the radiology service. A non-compliance was identified regarding Regulation 13(2) which was evident in a sample of reports of medical radiological procedures viewed by inspectors. Management at the hospital informed inspectors that a solution to ensure that information relating to service user exposure is included in all reports of medical exposures was underway which was expected to be implemented by mid-2023.

A non-compliance was identified on the day of the inspection regarding the process for determining pregnancy status of patients undergoing fluoroscopy imaging in theatre which differed from what was followed in the majority of cases in other radiology services provided at the hospital. In this service, and as outlined in hospital policy, pregnancy determination was made by a radiographer based on secondary information provided during peri-operative assessment by persons not recognised as a practitioner under these regulations. Additionally, inspectors identified a gap in the information provided to service users, who may be breastfeeding, on the special protections to be considered when undergoing nuclear medicine procedures. These findings relating to Regulation 16 were discussed with staff and management and an assurance was provided to inspectors that measures would be implemented to come into compliance with the requirements of this regulation.

Notwithstanding the findings above and detailed under regulations in this section, inspectors were satisfied that non-compliances identified did not represent a radiological risk to service users.

Regulation 8: Justification of medical exposures

Inspectors viewed records relating to medical radiological procedures conducted at the hospital and spoke with staff and management in relation to the process of justification. The justification process detailed in the document *Justification Procedure for all Radiology Referrals* outlined how justification was recorded in each modality. For example, for justification of procedures carried out in general X-ray, the radiographer's signature was recorded on the referral form. In the majority of cases the record of justification was evident to inspectors either on the radiology information system or documented on referral forms. However, the process for justification in theatre was less clear.

Inspectors were informed that in the theatre setting, the surgeon was responsible for justifying theatre imaging procedures which was undertaken during the consent process. The radiographer then confirmed that the procedure was justified with their initials prior to the procedure. However, from a review of a sample of medical radiological procedure records conducted in the theatre fluoroscopy service, the referral was not identifiable in the patients record and the reason for the procedure and relevant clinical information was also not evident. From the evidence gathered, inspectors concluded that the process for referring and justifying medical radiological procedures in theatre fluoroscopy services required action by the undertaking to meet the requirements of Regulation 8 (10) and 8 (11).

While awareness posters about pregnancy were evident in clinical areas, there was little evidence of information provided to service users on the risks and benefits associated with ionising radiation doses as per Regulation 8(13). Inspectors were informed that information on risks and benefits was not routinely provided to service users unless requested. Staff and management at Blackrock Clinic informed inspectors that they were aware of this gap in compliance and work was underway to address the deficit.

Judgment: Not Compliant

Regulation 9: Optimisation

Inspectors were assured, from documentation viewed and discussions with staff, that doses due to medical exposures were kept as low as reasonably achievable at Blackrock Clinic. In the CT service, staff informed inspectors that the protocol for service users with renal impairment had been reviewed. Subsequently, the CT protocol for these service users was optimised to ensure optimum diagnostic information was obtained. This was seen as a good example of optimisation through the consideration of the appropriate protocol and equipment selection, the consistent production of adequate diagnostic information, the practical aspects of medical radiological procedures and the assessment and evaluation of service user doses.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors found from documentation viewed and discussion with staff that hospital DRLs for all adult radiological practices provided at the hospital were established and these were reviewed, used and compared to national DRLs as per Regulation 11(5). Inspectors were informed that low levels of paediatric medical radiological procedures were performed in this facility, however, paediatric DRLs had been established for most general X-ray procedures. Inspectors viewed local and national DRLs displayed in the control rooms of each service assessed. The process for establishing DRLs was outlined in local policy. However, in situations where local DRLs consistently exceeded national DRLs, the process for carrying out appropriate reviews to determine whether the optimisation of protection and safety for service users is adequate was not defined in documentation viewed or clearly articulated by staff.

Staff at the hospital compared local DRLs established in 2021 with 2022 DRLs and had identified an upward drift in 2022 local DRLs across some types of examinations. Inspectors noted from the comprehensive 2022 DRL Audit Report viewed, that the majority of 2022 facility DRLs were within national DRL values. However, a small number of facility DRLs in the modalities of fluoroscopy, interventional cardiology and nuclear medicine were found to be consistently above the national DRLs. The outcome of this audit detailed seven recommendations including a review of procedures where the local DRLs were above national DRLs, ongoing review of procedures associated with increasing local DRLs and to establish paediatric DRLs for relevant procedures. Inspectors were informed that this report was circulated to relevant stakeholders and discussed at the RSC. However, a formal review to determine the reason for these increases had not been conducted and corrective actions, if any, had not been recorded as per Regulation 11(6) and 11(7). Staff informed inspectors that provisional data for 2023 DRLs indicated that in general, local DRLs had returned to normal values without any corrective actions, however, one local DRL continued to remain above the national DRL. The process described did not satisfy inspectors that a proactive approach or sufficient action had been taken to address the higher than normal DRLs seen in the 2022 data. Therefore, the process to review DRLs found to be above national DRLs should be strengthened to ensure that timely corrective actions are taken to reduce the dose as relevant and to improve compliance with this regulation.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors reviewed a sample of protocols for standard radiological procedures

undertaken in the modalities inspected. These protocols were accessible to staff in the clinical areas. Staff informed inspectors that access to protocols were limited to specific staff and were password protected to prevent unauthorised editing of protocols. Inspectors saw evidence of tracking of recent revisions in the CT protocols. Staff described the processes for updating protocols which involved multidisciplinary input when required, however, formal ratification by radiology governance was not evident in the protocols or documents viewed by inspectors. Therefore, while meeting the requirement of Regulation 13(1), there was scope to formalise the approval process for the revision and update of protocols following this inspection.

Inspectors reviewed a sample of reports of medical radiological procedures and found that information relating to service user exposure was included in reports viewed in nuclear medicine procedures but was not routinely contained in reports of medical exposures from other radiological services as required by Regulation 13(2). Management at the hospital were aware of this gap in compliance and work was in progress since 2020 to procure a system that would facilitate the inclusion of patient dose into the record of the report. The solution was described as imminent, however, inspectors were not provided with an expected date of implementation.

Evidence based referral guidelines were observed by inspectors in electronic format on computer desktops in the clinical areas inspected.

The hospital had a radiological clinical audit committee and produced an annual report to the RSC. Inspectors viewed the 2022 report and found that there was a multitude of clinical audits conducted for each quarter of the year. Audits undertaken included audits in relation to pregnancy status, high skin dose, reject analysis, turnaround time, patient identification, DRLs and image quality of portable chest X-rays. The hospital also monitored its compliance with the regulations in an audit carried out in 2022.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in advance of the inspection. There was evidence viewed in documentation and discussion with staff to demonstrate that medical radiological equipment was kept under strict surveillance regarding radiation protection. Inspectors were satisfied that a quality assurance programme was defined, implemented and maintained and records verified that QA by an MPE and regular performance testing were carried out as per the frequency outlined in the QA programme. The undertaking had a process in place to ensure that ageing medical radiological equipment was prioritised for replacement. Inspectors saw evidence to demonstrate that there was an annual formal review of medical radiological equipment by the undertaking to ensure that equipment which was past the nominal

date for replacement was either approved for continued clinical use with a revised replacement date or taken out of clinical use.

Overall, the evidence gathered satisfied inspectors that the processes and arrangements in place ensured that medical radiological equipment was kept under strict surveillance which provided assurance that equipment was safe for clinical use; thereby meeting the requirements of this regulation.

Judgment: Compliant

Regulation 15: Special practices

Inspectors were provided with a document *Management of High Skin Doses in Interventional Fluoroscopy Procedures* which detailed the procedure for radiation dose optimisation during interventional procedures. Defined threshold doses with the potential to result in skin damage were also outlined with the associated time the radiation effects would be expected to manifest. The undertaking ensured that a radiographer was present and acted as the practitioner for all interventional cardiology procedures conducted in this service and monitored radiation doses throughout the procedures.

Inspectors visited one of the cardiology interventional suites and spoke with staff performing procedures there. Staff described the mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the service user. For example, a high dose alert system was utilised in the interventional cardiology departments to prompt practitioners if a procedure was reaching a pre-defined radiation dose threshold. Once reached, these pre-defined radiation dose thresholds were used in conjunction with dose monitoring software to determine potential areas of high skin dose, and guide appropriate service user follow up.

Inspectors were informed that the radiographer followed up with these service users two weeks after the procedure to determine if there was any evidence of skin damage. While this was seen by inspectors as an example of good practice, the process described to inspectors differed from what was outlined in hospital policy in which the responsibility rested with the service user to contact the consultant two weeks following the procedure if they were experiencing any symptoms of tissue damage. Therefore the undertaking should review the policy and procedure in place to ensure consistency with day-to-day practices.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The hospital had a "*Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures in Blackrock Clinic*" which was approved in October 2020. A review of this policy due in January 2023 was not evident on the day of the inspection. This policy was applied to females between the ages of 12 and 55 years inclusively, however, inspectors viewed a record in the fluoroscopy theatre service where a pregnancy declaration form had not been undertaken in line with local policy.

The process for inquiring about pregnancy for service users undergoing a surgical procedure involving sedation or anaesthetic with the possibility of medical exposure X-ray was outlined in this policy. This process detailed that the nurse admitting a patient was responsible for making the pregnancy enquiry and documenting the service user's menstrual and pregnancy status in the patient record. Staff told inspectors that this was the process followed in the theatre fluorscopy service. Based on what was described and viewed in documentation provided, inspectors found that the determination of pregnancy by a practitioner was based on a secondary source of information and therefore were not satisfied that a referrer and or practitioner was responsible for making the pregnancy enquiry in all cases in the Theatre Department as per Regulation 16(1).

In the nuclear medicine service, inspectors identified scope to improve information provided to service users in advance of the procedure to increase awareness of the need for special protection during medical exposures when breastfeeding.

In addition, inspectors viewed quarterly pregnancy status audits conducted across all radiology services within the hospital in 2022 and noted that while compliance levels had improved by the end of the year, radiology services provided in theatre and the cardiology interventional performed less favourably than those services provided in the main Radiology Department. Inspectors also identified the audit templates used did not assess if the person determining the pregnancy status was a recognised referrer or practitioner as per Regulation 16(1). Hospital management informed the inspectors that they were aware that there were deficits in compliance with respect of this regulation and corrective measures would be implemented following this inspection to bridge the gaps identified by inspectors.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied that the Blackrock Clinic had implemented an appropriate system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures. Minutes of the RSC were reviewed by inspectors and detailed that radiation incidents were a standing agenda item.

In advance of this inspection inspectors reviewed quarterly radiation incident reports

from 2022 and the *Annual Radiation Incident Summary Report for 2022*. These reports demonstrated the trending of incident data and showed that the number of radiation incidents involving service user medical exposures decreased significantly in 2022, while the number of near misses reported over this period increased. The identification of near misses offers the potential to identify a hazard or risk and implement corrective action to help prevent a more serious incident from occurring.

Inspectors were assured from the evidence gathered that staff at the Blackrock Clinic had implemented a comprehensive approach to the analysis and subsequent implementation of corrective actions to reduce the possibility of recurrence of incidents. For example, Blackrock Clinic had implemented a range of corrective actions after a comprehensive and multidisciplinary analysis of events where scheduling errors occurred in the CT department. Corrective actions included the implementation of a radiographer checklist referred to as the 'PAUSED' process which was undertaken as part of the vetting procedure on the day prior to the scheduled examination. This process contained a review of referral forms to incorporate specific service user details, justification in advance, system settings, user checks and exposure factors for the planned procedure and also included a field for 'date of the scan' in the department. Staff informed inspectors that the use of incident data and subsequent implementation of these corrective actions had reduced the recurrence of similar scheduling incidents which had previously resulted in unintended exposures of individuals subject to medical exposure. This was seen as an example of good practice in the effective and proactive use of incident data to reduce the risk of recurrence of accidental and unintended exposures and significant events.

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	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	Not Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Blackrock Clinic OSV-0007390

Inspection ID: MON-0039121

Date of inspection: 16/03/2023

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: Policy on the delegation of duties for medical exposures has been updated to clarify who acts as practitioner in each modality including the Angiography and Theatre imaging services. Training sessions to be held with staff in these areas based on this updated policy so that all are aware of who is acting as practitioner. These sessions will be held in June 2023.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: Referrals for the Angiography and Theatre imaging services will be provided in writing in advance of each procedure. Theatre: Referrer providing completed request form prior to examination. Angiography: Request form completed by referrer to be signed with professional registration details (e.g. Irish Medical Council number) and uploaded to patient's record on the hospital's Computerised Radiology Information System (CRIS). The justification procedure for radiology referrals has been updated to reflect these changes in practice and enable clinical audit of same. The Medical Director and Clinical Director of Cardiology have been informed of these changes. The Clinical Director of Radiology will communicate this to the Medical Advisory Committee (next meeting scheduled for 31 May 2023). Compliance audits will be performed starting July 2023.	

Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Referrals for the Theatre imaging service will be provided in writing in advance of each procedure.
The justification procedure for Radiology referrals has been updated to reflect these changes to allow justification to be completed in advance.
The Medical Director and Clinical Director of Cardiology have been informed of these changes.
The Clinical Director of Radiology will communicate this to the Medical Advisory Committee (next meeting scheduled for 31 May 2023).
Compliance audits will be performed starting July 2023.
Hospital website is being updated with information for service users on the risks and benefits associated with ionising radiation doses. Service users will be directed to this information in the correspondence confirming their appointment. Scheduled to be published June 2023.
Information posters will be placed in all clinical areas and be visible to service users, scheduled for July 2023.

Regulation 11: Diagnostic reference levels	Substantially Compliant

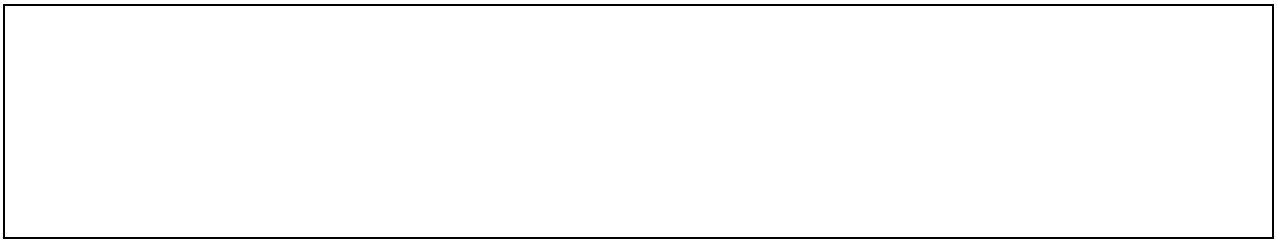
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
Audit report of diagnostic reference levels (DRLs) for 2023 has been completed and presented to the Radiological Clinical Audit Committee and Radiation Safety Committee. This report including details of procedure types where the local DRL has increased over the previous year and some local DRLs which exceed established national or international DRLs.
Radiological protocol review group to be established whose membership will include Clinical Specialist Radiographers, Medical Physics Experts, Consultant Radiologists, and Radiology management.
This group will be the mechanism for the periodic review of imaging protocols including those where the local DRL is either significantly higher/lower than previous years or which exceeds the relevant national/international DRL.
Proposed changes to imaging protocols will be discussed in this group before submission to the Radiation Safety Committee for review and approval.
This group will meet at least quarterly with the first meeting to be held in June 2023 to review the actions required from the recent DRL audit report.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Proposed solution to enable the automatic inclusion of information relating to service user exposure in radiological reports conceptualised in September 2021.
This information will be communicated from our DoseWatch dose management system to the corresponding radiological report in our computerised radiology information system.
Project approved by Blackrock Clinic Information and Communication Technology (ICT) Project Review Group in March 2022, and Blackrock Clinic ICT requested systems of work and formal quotations from providers in May 2022.
Approved by ICT Steering Committee in April 2023.
Anticipated delivery of solution is Q4 2023.

Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:
Pregnancy policy for medical exposures has been updated to make clearer and reinforce that it is the responsibility of the Referrer and Practitioner to determine a service users' pregnancy status in advance of medical exposures and references to other personnel (nursing/anaesthetic staff) have been removed.
The pregnancy status form has been updated and the section on re-justification has been amended to reflect the updated policy.
This updated policy was approved by the Radiation Safety Committee (22 May 2023).
Monthly pregnancy status audit has been updated to include role of the Practitioner.
Training sessions to be held with Radiology and Theatre staff based on this updated policy. These sessions will be held in June 2023.
Appointment letter for service users attending the Nuclear Medicine department has been updated to request that service users who may be breastfeeding inform the clinical team so that information can be provided to them in advance.
Hospital website is being updated with information for service users on the risks and benefits associated with ionising radiation doses including information specific to Nuclear Medicine examinations and associated precautions for service users who may be breastfeeding. Service users will be directed to this information in the correspondence confirming their appointment. Scheduled to be published June 2023.
Information posters will be placed in all clinical areas and be visible to service users, scheduled for July 2023.



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	01/07/2023
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Substantially Compliant	Yellow	01/07/2023

Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Substantially Compliant	Yellow	01/07/2023
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Substantially Compliant	Yellow	01/07/2023
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	01/07/2023
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer	Not Compliant	Orange	01/08/2023

	or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.			
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Substantially Compliant	Yellow	01/07/2023
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	01/07/2023
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out	Not Compliant	Orange	01/07/2023

	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(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	31/12/2023
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	Not Compliant	Orange	01/07/2023
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such	Substantially Compliant	Yellow	01/07/2023

	records to the Authority on request.			
Regulation 16(4)	Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to increase the awareness of individuals to whom this Regulation applies, through measures such as public notices in appropriate places.	Substantially Compliant	Yellow	01/08/2023