



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Blackrock Health Blackrock Clinic
Undertaking Name:	Blackrock Clinic
Address of Ionising Radiation Installation:	Rock Road, Blackrock, Co. Dublin
Type of inspection:	Announced
Date of inspection:	31 July 2025
Medical Radiological Installation Service ID:	OSV-0007390
Fieldwork ID:	MON-0044593

## About the medical radiological installation (the following information was provided by the undertaking):

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 GPs and other hospitals across Ireland. To provide this service to our users we offer a wide range of imaging with state-of-the-art 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 7 modalities located in 11 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 3 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 cath labs run five days per week Monday – Friday, with an on-call service at night and over the weekends. Currently there are 6 theatres on the lower ground floor and a further 2 theatres and 2 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, as amended. 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

## **1. Governance and management arrangements for medical exposures:**

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 31 July 2025	09:00hrs to 15:10hrs	Margaret Keaveney	Lead
Thursday 31 July 2025	09:00hrs to 15:10hrs	Kay Sugrue	Support

## Governance and management arrangements for medical exposures

On 31 July 2025, inspectors completed an inspection of the medical radiological services at the Blackrock Health Blackrock Clinic to follow up on the compliance plan actions from the previous inspection of 16 March 2023, and to assess the undertaking's ongoing compliance with the regulations. It was evident that since the previous inspection the undertaking of this service had implemented effective measures to achieve compliance with Regulations 8, 10 and 16. However, during this inspection, inspectors identified ongoing gaps in compliance with Regulations 6, 11 and 13 which the undertaking must address to strengthen the radiation protection of service users.

As part of this inspection, inspectors reviewed documentation relevant to medical exposures completed in the general radiography, computed tomography (CT), nuclear medicine, interventional radiology, theatre and angiography and Positron Emission Tomography (PET) /CT areas of the radiology department and also spoke with staff and management in these areas.

Overall responsibility for the radiation protection of service users lies with Blackrock Clinic as the undertaking for this facility and inspectors were assured that the undertaking had implemented appropriate radiation protection governance structures to oversee the safe delivery of medical exposures in the radiology service. Radiology governance and management arrangements consisted of multiple forums including a radiation compliance group (RCG), a radiation protocol review group, a radiological clinical audit committee and a radiation safety committee (RSC). These forums had appropriate multidisciplinary representation from within the radiology service, hospital management and those individuals involved in the delivery of medical exposures in areas outside the radiology department. The Chief Executive Officer (CEO) of Blackrock Health Blackrock Clinic was the undertaking representative of the service, and attended the RSC meetings, thereby ensuring that all relevant radiation protection matters in the service were communicated up to the undertaking.

Following a review of documents and records, and from speaking with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Inspectors also noted that the undertaking had implemented a clearly documented pathway, with appropriately allocated roles and responsibilities, for the justification of new practices in the service. However, despite these allocations, inspectors noted that action was required by the undertaking to ensure that all roles and responsibilities on radiation protection were clearly allocated in the service. This is further discussed under Regulation 6: Undertaking in this report.

Inspectors reviewed documentation and spoke with management staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures in the service. Evidence of professional registration and arrangements to ensure continuity of MPE expertise was provided to inspectors. From the documentation reviewed, inspectors were assured that the level of involvement of MPEs was proportionate to the level of radiological risk at the hospital.

Overall, despite the improvements required in some areas, inspectors found that the undertaking's management team had made good efforts since the previous inspection to comply with the regulations and that service users were receiving safe medical exposures at Blackrock Health Blackrock Clinic.

#### Regulation 4: Referrers

At Blackrock Health Blackrock Clinic, the role of referrer had been allocated to medical practitioners and dentists, and also to radiographers who could make adapted and secondary referrals for medical exposures.

From discussions with staff and the review of a sample of medical exposures records, inspectors were satisfied that only referrals for medical radiological procedures from persons as defined in Regulation 4, were carried out at this service.

Judgment: Compliant

#### Regulation 5: Practitioners

Inspectors noted that only those entitled to act as practitioners were found to take clinical responsibility for medical exposures completed in Blackrock Health Blackrock Clinic. In this facility, radiographers and medical practitioners had been allocated the role of practitioner, which is in line with the requirements of Regulation 5.

Judgment: Compliant

#### Regulation 6: Undertaking

Inspectors reviewed documentation including governance structure organograms and spoke with staff and management in relation to governance arrangements in place at Blackrock Health Blackrock Clinic. The undertaking, Blackrock Clinic, had established a radiation compliance group (RCG) which met monthly to discuss radiation protection matters such as the equipment quality assurance (QA) programme, any incidents that had occurred in the radiology service, risk

assessments relevant to the radiology service and clinical audit results and actions. The RCG membership comprised of radiology service managers (RSMs), radiation protection officer (RPO), a medical physics expert (MPE) and the Head of the Cardiology Services. The undertaking had also established a radiation protocol review group, with similar membership to the RCG, which was responsible for the monitoring, review and approval of written and imaging protocols in the radiology department. A radiological clinical audit committee (RCAC) had also been established by the undertaking and met four times annually to co-ordinate and review radiological clinical audits completed in the service, and to recommend changes based on audit results. Membership of this committee included representatives from all radiology disciplines and the hospital's quality department.

Each of these committees reported into the undertaking's radiation safety committee (RSC), which met four times per year to further discuss items raised at these sub-committee meetings. The RSC meetings were chaired by the Clinical Director of Radiology, and attended by the Chief Executive Officer (CEO) of the service, MPEs, RSMs, the RPO, nurse managers and representatives from each imaging modality area. The CEO is also the undertaking representative of Blackrock Health Blackrock Clinic, and through their attendance at the RSC meetings, were informed of all radiation protection matters in the service. Inspectors were informed that matters discussed at the RSC were subsequently reported to the Clinical Governance Committee, and that every three months a report was submitted by this committee to the board of the undertaking, Blackrock Clinic.

However despite these oversight arrangements, inspectors noted that action was required to ensure that all roles and responsibilities on radiation protection were clearly allocated and documented in the relevant documentation, and that they aligned with the regulations. For example;

- In the policy *Delegation of Duties for Medical Exposures Blackrock Health, Blackrock Clinic*, nurses had been allocated the role of referrer for a particular set of medical exposures. However, inspectors were informed by staff that currently such referrals were not accepted from nurses and therefore this allocation did not align with practices in the service. A clear allocation of roles and responsibilities is a key part of the overall radiation protection of services users in a high dose service.
- Under the regulations, responsibility for the clinical evaluation of the outcome of medical exposures must be allocated to practitioners. On review of the *Radiation Safety Procedures for Blackrock Clinic*, inspectors noted that the undertaking had only allocated the role of practitioner to radiologists and radiographers in the service. However, in the policy *Delegation of Duties for Medical Exposures Blackrock Health, Blackrock Clinic* non-radiology medical practitioners had been allocated some responsibilities for a particular sub-set of medical exposures. Therefore, action is required by the undertaking to ensure that allocation of the practitioner role aligns with current practice in the service and is consistently documented in hospital policies and procedures.
- Inspectors also noted that in the policy *Delegation of Duties for Medical Exposures Blackrock Health, Blackrock Clinic*, the practical aspects of specific

sets of medical exposures had been allocated to non-radiology medical consultants. While, the undertaking had ensured that a radiographer, as practitioner for radiation protection, was also present during these medical exposures, the undertaking should review the allocation of responsibilities to ensure that all practical aspects are only allocated to those who have completed training as set out in Regulation 22.

Notwithstanding these gaps in compliance with Regulation 6, inspectors were satisfied that service users were receiving a safe medical exposures to ionising radiation at Blackrock Health Blackrock Clinic.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

Inspectors observed that only persons entitled to act as a practitioner, as defined in Regulation 5, took clinical responsibility for the medical radiological procedures at Blackrock Health Blackrock Clinic. It was also noted that practitioners and the MPE were involved in the optimisation process for medical exposures to ionising radiation. From discussions with staff and a review of medical records, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures conducted in the service.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure continuity of medical physics expertise at Blackrock Health Blackrock Clinic.

Inspectors were also informed that a member of the physics team was in training to become a MPE. This was noted as a good example of proactively strengthening the radiation protection of service users and MPE continuity arrangements in the service.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

From a review of documentation and discussions with staff, inspectors noted that the MPE team were involved in and contributed to radiological practices and the

radiation protection of services users at Blackrock Health Blackrock Clinic. The current professional certification records for the team were available to inspectors on the day of inspection.

There was good evidence that the MPE team took responsibility for dosimetry and contributed to a range of responsibilities relating to medical radiological practices in the service, as per Regulation 20(2). A review of documentation and various records showed that they were involved in the optimisation of medical exposures, and contributed to the quality assurance (QA) and acceptance testing of medical radiological equipment. The team had also contributed to the review and approval of local diagnostic reference levels (DRLs) for each piece of equipment, and provided advice and dose calculation for radiation incidents. Inspectors were also informed that the MPE had recently advised on the procurement of a replacement piece of equipment, and ensured that it met the needs of the service.

Inspectors noted that an MPE attended and contributed to the RSC, Radiology Clinical Audit Committee, Radiology Compliance Group and Radiology Protocol Review Group meetings. Inspectors were also informed that they had developed the local radiation protection training policy which guided on the radiation protection training to be delivered to staff involved in the radiology service.

Judgment: Compliant

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

From discussions with staff and a review of documentation review, inspectors were satisfied that MPE's involvement in medical radiological practices at Blackrock Health Blackrock Clinic was proportionate to the level of radiological risk associated with practices in the service.

Judgment: Compliant

### Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors saw that the undertaking's management team was committed to improving the radiation protection of service user with many good examples identified under Regulations 9 and 15. This was achieved through the proactive clinical audit of imaging protocols and DRLs by the radiology staff, and by implementing process improvements as a result of incident analysis and learning. However, inspectors noted that further action was required by the undertaking to achieve full compliance with Regulations 11 and 13.

As outlined in *Justification Procedure for Radiology Referrals*, the justification process differed for the various imaging modalities in the service. Staff, in the various modalities who spoke with inspectors, were aware of their specific responsibilities in the justification process and a review of a sample of service user records demonstrated that these processes were correctly followed. Inspectors observed that since the previous inspection, the undertaking had come into compliance with Regulation 8 with information posters now displayed in service user waiting areas. Following the previous inspection, the team had also stated that the hospital website would be updated with information on the risks and benefits associated with ionising radiation and that service users would be directed to this information in correspondence confirming their appointment. However, on the day of the inspection, this information was only available on the website for medical exposures completed in CT. The undertaking should consider providing information on the risks and benefits of medical exposures to all service users which would further enhance the radiation protection of service users and ensure that the compliance plan for Regulation 8 from the previous inspection is fully implemented.

Inspectors noted that there was a clinical audit programme for radiological practices in place in the service, and that management arrangements had been established which provided the undertaking with oversight of this clinical audit programme. Examples of good clinical audit practices were seen by inspectors, such as a supplementary clinical audit which had recently been completed on one set of DRLs following the introduction of a new piece of equipment. However, inspectors were not satisfied that the undertaking's current approach to clinical audit was fully aligned to HIQA's national procedures on clinical audit, which were published in November 2023. This is further discussed under Regulation 13: Procedures below.

Inspectors also noted that, since the previous inspection, the undertakings' management team had made good efforts to ensure that information relating to service users exposures was included in reports of medical exposures, as required in the regulations. However, for a sub-set of procedures completed in theatre, inspectors were informed that a medical exposure report was not generated and therefore information relating to the medical exposure was not available for this group of service users. This is also further discussed under Regulation 13 below.

From a review of an up-to-date inventory of equipment and QA reports, inspectors were satisfied that there was an appropriate QA programme in place in the service, which included the QA of calibration equipment used by the MPEs. Inspectors saw from a review of RSC meeting minutes that quality assurance and equipment replacement programmes were routinely discussed at these meetings.

Since the previous inspection, the undertaking had implemented appropriate processes to determine the pregnancy status of service users, where relevant, in all imaging modalities. From a review of service user records and clinical audits, inspectors were assured that this process was safe and effective. Inspectors also reviewed records that evidenced that there were good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Overall, inspectors were satisfied that the hospital had many good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

## Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of referrals for medical exposures on the day of the inspection and noted that each was in writing, stated the reason for requesting the particular procedure and was accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment. A sample of records were viewed by inspectors, and evidenced that this justification process had been completed. Inspectors also noted that since the previous inspection, the document *Justification Procedure for Radiology Referrals* had been appropriately updated to ensure that the process for justifying medical exposure procedures was now clearly outlined to guide all staff involved in justifying medical exposures completed in the service. In order to monitor compliance with the justification process, the management team in Blackrock Health Blackrock Clinic had included the process of justification in the local audit programme, and this was noted as an example of good practice in the service.

Since the previous inspection, the undertaking's management team had made efforts to improve service users' access to information on the benefits and risks associated with ionising radiation, with information posters now on display in service user waiting areas. Following the previous inspection, the team had added information on the risk and benefits associated with ionising radiation doses received in CT to the service's website.

Judgment: Compliant

## Regulation 9: Optimisation

A review of documentation and discussions with staff informed inspectors of the many good optimisation measures in place for medical radiological procedures completed in Blackrock Health Blackrock Clinic. For example, inspectors were informed that an imaging template was used during a particular X-ray exposure, which removed the need for an additional X-ray image and thereby reduced the overall radiation dose received by this particular cohort of service users.

Inspectors were also informed that an imaging protocol for a particular nuclear medicine procedure had recently been refined which resulted in a reduced amount of radiopharmaceutical dose being administered to service users and also reduced scanning time. Additionally, in the CT service, the team had completed a quality improvement project which involved the review of a particular imaging protocol and had resulted in the optimising of imaging parameters for CT service users in

accordance to their body mass index. Inspectors noted that a colour coded chart on imaging parameters had been developed and was on display in the CT console area to guide and support staff when completing such exposures.

The use of audit to monitor the radiation protection of service users was also identified as an area of good practice in the service. For example, inspectors noted from a review of RSC meeting minutes that DRL reviews for particular procedures were requested and completed to identify if such procedures could be further optimised. Inspectors were informed that one recently completed audit on breathing artefacts had resulted in improved image quality.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs had been established for common radiological procedures completed in Blackrock Health Blackrock Clinic. During a tour of the department, inspectors observed that this information was displayed in all console areas, and staff who spoke with inspectors demonstrated an awareness of how to use the data when completing medical exposures of ionising radiation.

The Radiological Protocol Review Group was responsible for the initial review and, where relevant, the investigation of DRL data. Inspectors saw that the group had developed a *2025 Audit Report on 2024 DRL data* which was presented to members of the radiology team at a recent RSC meeting. From a review of the report, inspectors noted that the undertaking had committed to investigating any DRL data that exceeded national levels or any data that exceeded the previous years' local DRLs. In line with this local approach to DRL investigations, the report evidenced that for some procedures, where the 2024 DRL data was above national levels or significantly above the 2023 DRLs, the physics' audit team had investigated the data to determine what had contributed to the changes and that, where applicable, measures such as additional training had been agreed on and implemented to reduce exposure doses. Inspectors were informed that the doses associated with these procedures were to be reviewed again in the short-term to ensure that the measures introduced continued to be effective, which was identified as an area of good practice in the service.

However, inspectors noted that this same approach to reviewing DRL data had not been applied to all cases where the local DRLs exceeded the national levels or significantly exceeded the previous years' levels. In some cases, there was no evidence that investigations had been completed or audit recommendations actioned. In order to fully comply with Regulation 11(6), the undertaking must ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for all service users is adequate and ensure that appropriate corrective action is taken without undue delay. The undertaking

must also ensure that records of these reviews and corrective actions are retained and available to the Authority, in order to fully comply with Regulation 11(7).

Judgment: Substantially Compliant

### Regulation 13: Procedures

Written protocols were in place and available to staff at Blackrock Health Blackrock Clinic for standard radiological procedures as required by Regulation 13(1). From a review of the *Radiology Protocol Review policy*, inspectors saw that the Radiological Protocol Review Group were responsible for the ratification of periodic reviews of these written protocols. Inspectors also noted that the radiology management team had recently updated a number of written protocols in order to provide further optimisation guidance to practitioners, which was identified as an area of good practice in the service. Inspectors also noted that referral guidelines were available to staff on desktops in each clinical area.

Inspectors were informed that since the previous inspection, the undertaking had implemented measures to comply with Regulation 13(2), which requires that patient exposure information formed part of all reports on medical exposures. On the day of the inspection, inspectors reviewed a sample of service user records and found that information relating to the patient exposure formed part of most of the reports that were available for review by inspectors. However, for a sub-set of procedures completed in theatre, inspectors were informed that a report was not generated. While for other medical exposures completed in theatre, a report was generated but information relating to the patient exposure did not form part of the report. Inspectors were informed that although the measures introduced to address the gap in compliance with Regulation 13(2) had been implemented in this area, these measures had since ceased in practice. Due to this ongoing gap in compliance with Regulation 13(2), the undertaking must provide greater assurance that corrective measures taken to comply with the Regulation 13(2) are consistently applied and monitored by the undertaking for all medical exposures completed in the service.

The undertaking had formed a multi-disciplinary Radiological Clinical Audit Committee (RCAC), which according to its terms of reference, was responsible for co-ordinating and reviewing radiological clinical audits in the service, recommending changes to local practice based on audit findings and reporting significant change to the RSC. The committee was also tasked with producing an annual report on completed and proposed clinical audits, which was reviewed by the RSC and the radiologist group meeting. Inspectors noted from a recent audit progress report and from RCAC meeting minutes that a number of audits were routinely completed in the service, such as on referrals and justification, checks for pregnancy status, reject analysis, and high skin dose procedures. Inspectors also noted that a supplementary clinical audit had recently been completed on one set of DRLs following the introduction of a new piece of equipment. This was noted as an area of good practice in the service. However, inspectors were not satisfied that the undertaking's

current approach to clinical audit was fully aligned to HIQA's national procedures on clinical audit, which were published in November 2023. For example, from a review of documentation and discussions with the management team, a clinical audit strategy had not been fully developed, which set out the principles and essential criteria, as outlined in the national procedures, that the local clinical audit programme was to be developed against. Inspectors also noted that from the clinical audits completed in the service, that it was not clear if any actions and recommendations had been identified from these audits and assigned to individuals with responsibility for implementing these actions within defined time lines. The management team informed inspectors that this gap in compliance had been identified and work was underway to ensure clinical audit practices at this service aligned with the national procedures as required under Regulation 13(4).

Judgment: Substantially Compliant

### Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at Blackrock Health Blackrock Clinic was provided to inspectors in advance of the inspection. Inspectors saw that radiographers and MPEs were responsible for carrying out on-going performance testing, and that testing requirements were clearly outlined in documents such as *Physics QA/QC Programme for Ionising Equipment* and *User QA programme*. The MPE team were assigned responsibility for developing and implementing the QA programme, which comprised weekly, monthly and annual testing of the equipment.

Records of completed tests were reviewed by inspectors and demonstrated that all QA testing was up-to-date, and that acceptance and commissioning testing had been completed for equipment in use in the department. Additionally, inspectors reviewed a risk assessment developed by the management team that monitored radiological equipment reaching its replacement date. Inspectors noted that a multidisciplinary team regularly reviewed and updated this risk assessment, with equipment added as necessary and also reflected equipment that was removed or replaced. This proactive monitoring of equipment was noted as an area of good practice in the service.

From a review of records and from discussions with staff, inspectors were satisfied that the undertaking had appropriate measures in place to ensure that all medical radiological equipment in the service was kept under strict surveillance regarding radiation protection.

Judgment: Compliant

### Regulation 15: Special practices

During a discussion with the radiology management team, inspectors were informed of the measures in place to ensure that service users who could potentially receive a high skin dose during a procedure were identified and, where necessary, appropriately followed up. Inspectors reviewed a *High Skin Dose Policy*, which supported and guided staff in their roles and responsibilities in this area.

Inspectors were also informed that a practitioner was present to optimise and monitor radiation doses throughout each procedure which provided assurance that potential high dose procedures were optimised. Overall, inspectors were satisfied from reviewing the systems in place, and discussions with staff, that special attention was given to optimising medical exposures involving high doses to the patient as per Regulation 15.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

On the day of the inspection, inspectors saw that since the previous inspection in March 2023, the undertaking had implemented a number of effective measures to achieve compliance with Regulation 16. A document titled *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures in Blackrock Clinic* had been updated to clarify the role and responsibilities of the referrer and practitioners in the service in determining service users' pregnancy status in advance of medical exposures for all imaging modalities in the service. As per the compliance plan from the previous inspection, this policy now aligned with the current regulations and compliance with this policy was regularly audited.

Inspectors also noted that, since the previous inspection, the undertaking's management team had placed multiple notices in the waiting areas of the service to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures. Inspectors also noted that the undertaking had since updated the service's website with information for service users specific to nuclear medicine examinations and associated precautions for service users who may be breastfeeding.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

From discussions with staff and a review of documents, inspectors were satisfied that the undertaking's management team had an appropriate system in place for

recording and analysing events involving or potentially involving accidental or unintended medical exposures that occurred in the service. The incident management process and structures were outlined in the *Group Incident Management Policy & Framework, including Sentinel Event Management* and in the *Radiation Safety Procedures* for Blackrock Clinic and included information on the requirement to notify HIQA of certain reportable incidents.

Inspectors were informed that when an actual or potential radiation incident occurred, it was recorded by staff on an online system, which subsequently notified relevant members of the radiology management team who investigated and managed the event. All incidents were discussed at the Radiology Compliance Group meetings and subsequently at the RSC meetings, which provided the undertaking representative with oversight of incident investigations and the actions agreed and implemented where necessary.

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, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	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	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Blackrock Health Blackrock Clinic OSV-0007390

Inspection ID: MON-0044593

Date of inspection: 31/07/2025

## 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, as amended.

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Radiation Safety Procedures for Blackrock Clinic will be updated to provide clear allocation of all responsibilities for medical exposures. Relevant information from the Delegation of Duties for Medical Exposures policy will be incorporated into the radiation safety procedures. The Delegation of Duties for Medical Exposures policy will be retired. This will ensure information is consistent and in a single document. The roles and responsibilities for medical exposures, including training records, will be audited and the results presented at the Radiological Clinical Audit Committee.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:</p> <p>Regulation 11(6) The Diagnostic Reference Levels policy will be updated to include that any significant trends or outliers that consistently exceed relevant diagnostic reference levels that are identified will be brought to the relevant Clinical Specialist Radiographers for review. These findings will be presented at the Radiological Protocol Review Group where corrective actions will be agreed and tracked.</p> <p>Regulation 11(7) The Diagnostic Reference Levels policy will be updated to include that all reviews will be submitted to the Radiological Protocol Review Group. The Radiological Protocol Review Group will retain and manage the records of these reviews.</p>	

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>Regulation 13(2)  The existing process for ensuring patient exposure information forms part of the report for medical radiological procedures will be applied to all modalities. This will be routinely audited and the results presented at the Radiological Clinical Audit Committee to ensure ongoing compliance.</p> <p>Regulation 13(4)  A clinical audit strategy has been drafted and tabled for approval at the next meeting of the Radiological Clinical Audit Committee.</p>	

## 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	31/03/2026
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and	Substantially Compliant	Yellow	31/03/2026

	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.			
Regulation 11(7)	An undertaking shall retain a 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.	Substantially Compliant	Yellow	31/03/2026
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	31/03/2026
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	31/12/2025