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 Health Hermitage Clinic
Undertaking Name:	Blackrock Health Hermitage Clinic
Address of Ionising Radiation Installation:	Old Lucan Road, Lucan, Dublin 20
Type of inspection:	Announced
Date of inspection:	03 July 2024
Medical Radiological Installation Service ID:	OSV-0007033
Fieldwork ID:	MON-0042766

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

Blackrock Health Hermitage Clinic is part of the Blackrock Healthcare Group which also includes Blackrock Clinic and Galway Clinic. The hospital has 112 inpatient beds, oncology, day-care, operating theatres, emergency, radiotherapy, cardiology and diagnostic imaging facilities. Consulting and dental suites are also located on the campus.

Radiology perform approximately 70,000 imaging examinations per year with 25% performed on inpatients and 75% performed on outpatients. Radiology operates a seven day service with an on-call facility for general X-ray and computed tomography. Services provided by the radiology department include:

- General radiography, dental X-rays (orthopantography) and fluoroscopy
- Mobile radiography, theatre, wards and day surgery
- Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound
- Mammography
- Interventional Radiology
- Nuclear Medicine (SPECT/CT)
- Radiography support for the interventional cardiology department.

The radiotherapy services provide CT simulation, treatment planning and treatment delivery, for patients undergoing external beam radiotherapy. CyberKnife services are also provided by the radiotherapy department.

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[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] 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.

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
Wednesday 3 July 2024	09:00hrs to 15:55hrs	Margaret Keaveney	Lead
Wednesday 3 July 2024	09:00hrs to 15:55hrs	Lee O'Hora	Support
Wednesday 3 July 2024	09:00hrs to 15:55hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the medical radiological services at the Blackrock Health Hermitage Clinic (BHHC) on 03 July 2024, to follow up on the compliance plan actions from the previous inspection of 21 July 2021, and to also assess the undertaking's ongoing compliance with the regulations. It was evident that the BHHC, as the undertaking, had implemented measures to address the gaps in compliance identified in the previous inspection, under Regulations 6 and 17. However, during this inspection, inspectors identified gaps in compliance with Regulations 8, 13, 14 and 19, and further gaps under Regulation 6.

On the day of the inspection, inspectors visited the radiotherapy department and the nuclear medicine, interventional radiology and CT modalities within the radiology department. While inspectors did not visit all imaging modalities in the radiology department, they reviewed documents and records applicable to all imaging modalities and met with the management team and staff, allocated responsibility for the radiation protection of all service users.

Inspectors observed that the undertaking, Blackrock Health Hermitage Clinic, had established governance and management arrangements, to provide oversight of the radiation protection measures in the service. At departmental level, the Radiation Services Governance Group (RSGG) met every three months, and was attended by the Clinical Services Director, the Clinical Directors from the Radiotherapy and Radiology departments, the radiation therapy services manager (RTSM) and the radiology services manager (RSM) and members of the medical physics expert (MPE) teams. Items such as incidents and equipment testing were among the issues considered by the RSGG. The RSGG subsequently reported into the Radiation Safety Committee (RSC). Inspectors were also informed that a Radiotherapy Services Quality meeting was held monthly in the radiotherapy department, and attended by the Clinical Director of Radiotherapy, RTSM and MPE, to provide day-to-day operational oversight of the service, such as incidents, equipment surveillance and clinical audit.

The RSC meetings were held quarterly, and were attended by, among others, the BHHC's chief executive officer (CEO), Quality/Risk department representative, Head of Clinical Service, Clinical Directors of each department, RSM, RTSM, MPE team members. The meeting minutes evidenced that representatives from interventional cardiology and theatre, where radiological procedures were completed, also attended which was in line with the actions identified in the compliance plan from the previous inspection. The meeting minutes also showed that items such as incidents, clinical audit and diagnostic reference levels (DRLs) were discussed, and that the committee also approved new or revised policies and procedures. Inspectors also reviewed other documentation that evidenced well established lines of communication from the RSC upwards, via the Quality Improvement and Risk

Management Committee, to the undertaking's executive management team, of which the CEO is also a member.

While it was evident that the undertaking's governance and management groups and committees met regularly and discussed a range of radiation protection measures, action was required to ensure that these forums adequately monitored the measures implemented. For example, the undertaking had not ensured that there was adequate arrangements in place to ensure the continuity of medical physicist expertise in the radiology service, as outlined in Regulation 19. Also gaps in the clear allocation of roles and responsibilities on matters relating to DRL approval and the strict surveillance of equipment had not been identified by the management team.

During the course of the inspection, inspectors met with the undertaking's management team to discuss local arrangements for the justification of new practices in the BHHC, and were informed that a draft policy on the process for this was being developed. Inspectors reviewed the *Blackrock Health Group Guidelines-Principles for the introduction of a new device, new procedure or new technique policy*, and observed that it outlined a number of good principles and pathways to ensure that before any new device, procedure or technique was introduced in the service, an application in advance must be submitted to key radiation protection personnel in the service. However, inspectors noted that this draft policy did not include details on contacting HIQA on or applying to HIQA for generic justification where appropriate. It also did not include details of how the undertaking would ensure that any new device, procedure or technique, introduced since 15 January 2019, was considered for and or required generic justification. In order to comply with its regulatory responsibilities under Regulation 7. The undertaking must ensure that this draft policy is further developed to include all such details.

A sample of electronic records for patients, undergoing radiotherapy medical exposures, were reviewed by inspectors during the inspection which showed that appropriate persons as per the regulations were involved in referring for medical exposures completed at the service. Inspectors were also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

Notwithstanding the areas for improvement identified over the course of the inspection, inspectors were assured that the undertaking had systems in place for the governance and management of the service in the radiology and radiotherapy departments at the Blackrock Health Hermitage Clinic.

Regulation 4: Referrers

On the day of inspection, inspectors were assured that the medical exposures, carried out in the BHHC, were referred only by individuals entitled to refer as per the regulations.

In the radiotherapy department, referrals were only accepted from appropriately registered medical practitioners, and from radiation therapists for adapted and modified referrals. While in the radiology department, referrals were only accepted from appropriately registered medical practitioners, dentists and from radiographers for adapted and modified referrals.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors found that only those defined in the regulations as practitioners took clinical responsibility for individual medical exposures carried out in the BHHC.

In the radiotherapy department, radiation oncologists and radiation therapists acted as practitioners, while in the radiology department this role was allocated to radiologists and radiographers.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors observed that the undertaking had good governance and management arrangements in place, to provide oversight of radiation protection measures in the radiology and radiotherapy departments at BHHC. The undertaking's management team had strong document management systems in place in both departments, which alerted appropriate personnel when routine document reviews were required. Inspectors reviewed a sample of documents, and noted that each had been reviewed as scheduled and any changes approved.

However, inspectors noted that although the documents aligned with the regulations, further updates were required to ensure that they aligned with local practices and that all roles and responsibilities are clearly allocated. For example;

- the *Optimisation and Management of Local Diagnostic Reference Levels* procedure did not allocate the role of approving reviewed DRLs in all areas of the radiology department. Inspectors noted that this had resulted in delays in approving reviewed DRLs in one imaging modality
- inspectors also noted that action was required to further allocate roles and responsibilities in the equipment quality assurance programme, which would ensure that all medical radiological equipment in use in the service was kept under strict surveillance. The gaps identified by inspectors in this area are further discussed under Regulation 14 in this report

- although the undertaking's *Radiation Safety Procedures for the Use and Application of Ionising Radiation at the BHHC* had been recently updated, further review was required to ensure that all allocated roles and responsibilities aligned with the current regulations.

During the inspection, inspectors also identified that the undertaking's management team had not informed the Authority of changes in the undertaking's details, which had occurred in September 2021. Such updates are required to ensure that the Authority is kept up-to-date of the undertaking who is responsible for the radiation protection of service users and for the safe delivery of medical exposures in the service.

While some improvements were required in documentation and allocation of responsibilities, inspectors were satisfied that overall there were effective arrangements in place to ensure the radiation protection of service users in the radiology and radiotherapy departments at the Blackrock Health Hermitage Clinic.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, inspectors found that clinical responsibility for medical exposures was allocated and completed only by radiation oncologists and radiation therapists in the radiotherapy department and only by medical practitioners, dentists and radiographers in the radiology department of the BHHC.

From discussions with staff and a review of a sample of patient records and other documents, inspectors were also satisfied that both referrers and practitioners were involved in the justification of individual medical exposures in the service.

Similarly, inspectors found evidence that practitioners and MPEs were appropriately involved in the optimisation of all aspects of all medical exposures carried out in the service.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

In the radiotherapy department, inspectors were satisfied that the undertaking had arrangements in place to ensure access to, and continuity of, medical physicist expertise as required by Regulation 19(9). This was provided by a team of MPE's dedicated to the department.

However, inspectors were informed of a recent gap in the continuity of medical physicist expertise in the diagnostic radiology department. While inspectors were assured that, on the day of the inspection, this gap had been adequately addressed by the undertaking, with revised continuity arrangements in place, the undertaking was found to be not compliant with Regulation 19(9).

Inspectors were also informed that physics staff, employed in the service, were being provided with training to become MPE's. This was noted as a good example of proactively strengthening radiation protection of service users and MPE continuity arrangements in the service.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of the medical physicists engaged by the undertaking to provide specialist advice, as appropriate, on matters relating to radiation physics which met the requirements of Regulation 20(1).

Evidence viewed in documentation, and discussions with the undertaking's management team and the medical physicists, demonstrated that the MPE's fulfilled a range of responsibilities as per Regulation 20(2) relevant to the practice. Inspectors noted that the teams were responsible for dosimetry and in advising on the dose calculation for radiation incidents in both departments. They were also involved in the quality assurance and acceptance testing of medical radiological equipment, and in dose optimisation, for example through the review of the specifications of new equipment to ensure that they produce quality images using the lowest doses achievable.

Inspectors also noted that the undertaking had arrangements in place for the MPE and Radiation Protection Advisor in the service to liaise when required.

While inspectors were assured that the MPE's provided training for radiographers and radiation therapists in relevant aspects of radiation protection, improvements should be made to include all practitioners in the radiology service in the BHHC in these training programmes.

Judgment: Compliant

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

Inspectors were satisfied that the level of MPE involvement was commensurate with the radiological risk posed by the medical radiological practices, in both the

radiology and radiotherapy departments, at the BHHC. From documentation viewed and discussions with the MPE and management staff, inspectors were assured that the recent short-term gap in the MPE service in the radiology department, as discussed under Regulation 19, had not impacted the measures in place to manage radiological risks in the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

During the course of the inspection, inspectors observed that the undertaking had implemented many effective processes and procedures in both the radiology and the radiotherapy departments that ensured the radiation protection of patients and the safe delivery of medical exposures.

From speaking with staff and a review of a sample of referrals in the radiotherapy service, inspectors were assured that all referrals for medical exposures were in writing, contained the reason for the requests and were accompanied by sufficient additional data. From this review, inspectors were also satisfied that radiotherapy procedures were justified in advance, by a person entitled, as per the regulations, to take clinical responsibility for justification. While in the radiology department, inspectors were assured that the processes for the justification in advance were adequate for most imaging areas, the information available to justify theatre interventional radiology exposures was not sufficient to allow practitioners to consider the benefits and the risk of the medical exposure. This is further discussed under Regulation 8 below.

Inspectors noted a strong multidisciplinary approach to the optimisation of medical radiological procedures at the BHHC. Inspectors also noted that the management teams had developed written protocols for the standard examinations carried out in both the radiotherapy and radiology departments, and that referral guidelines were available to referrers. Inspectors observed good processes in place regarding the inquiring and recording of patients' pregnancy and breastfeeding status at the hospital. There were also effective systems in place for recording and reviewing incidents involving, or potentially involving, accidental or unintended exposures to ionising radiation.

In the radiology department, inspectors observed gaps in the system that ensured information related to patient exposure formed part of the report. Inspectors also noted that while the undertaking had made good efforts to implement a clinical audit programme in the medical radiological services that was in line with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, further action was required to ensure it was integrated into the service's overall audit programme.

A QA programme for ionising radiation equipment was reviewed by inspectors in both the radiotherapy and radiology departments. This programme included a range of comprehensive tests that were performed before the equipment entered clinical use, and thereafter performed daily, monthly and annually by staff. However, inspectors observed that action was required to strengthen measures to ensure that all medical radiological equipment are kept under strict surveillance. This is further discussed under Regulation 14 below.

Notwithstanding the gaps identified under regulations 8, 13 and 14, inspectors were satisfied that systems were in place to support the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors reviewed a sample of referrals in both the radiotherapy and radiology departments. Inspectors observed that information leaflets were available to inform patients of the benefits and risks associated with their particular radiotherapy treatment course. In the radiology department inspectors observed posters were on display, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

In the radiotherapy department, inspectors noted that radiation oncologists referred patients for radiotherapy exposures by completing a treatment request form (TRF). The sample of referrals reviewed were in writing and stated the reason for the request, with each referral accompanied by sufficient medical data, such as diagnostic imaging and pathology reports. In signing the TRF, inspectors were informed that the radiation oncologist was justifying in advance the patients CT planning scan. Inspectors noted that this form also contained a section for the referral and justification of any repeat CT scan, if required. Inspectors were also informed that, by approving and signing the final treatment plan, the radiation oncologist justified in advance the radiotherapy treatment course, and any associated verification imaging, for the particular site being treated. Daily treatment records were also signed by two radiation therapists which served as an additional record of justifying radiotherapy treatment and associated imaging on that particular day. A review of a sample of patients radiotherapy records demonstrated that these practices were followed in each record.

In the radiotherapy department, inspectors were informed that a multidisciplinary team, of radiation oncologists, radiation therapists and medical physics experts, met weekly to discuss and justify radiotherapy treatment plans, for a particular cohort of patients receiving high dose treatment. This multi-disciplinary approach and discussion of justification in advance was acknowledged as an area of good practice in the radiotherapy department of BHHC.

In the diagnostic radiology department, inspectors spoke with radiographer practitioners who detailed the local process of justifying medical exposures in

advance of them being conducted. Inspectors reviewed a sample of referrals for medical exposures, and noted that each was from an appropriate referrer, and was in writing. Inspectors also noted that the referrals, other than those for theatre fluoroscopic radiology exposures, stated the reason for the request and were accompanied by sufficient medical data to allow practitioners to consider the benefits and the risk of the medical exposure. During a review of referrals for theatre fluoroscopic radiology exposures, inspectors noted that the indicated reason for the request was not sufficient to allow practitioners to consider the benefits and the risk of the medical exposure, and thereby adequately justify completing the exposure. This gap needs to be addressed to achieve full compliance with Regulation 8.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors noted that there was a multidisciplinary approach to optimisation processes and procedures for medical exposures to ionising radiation in both the radiology and radiotherapy departments in the BHHC. This approach to optimisation was identified as good practice in the service.

In the radiology department, the management team had developed a procedure *Optimisation and Management of Local Diagnostic Reference Levels*, which outlined how the use of DRLs contributed to the optimisation of doses delivered in the department. Inspectors also noted that a multidisciplinary team had completed a number of dose optimisation projects in CT and general X-ray imaging, to further optimise the dose delivered during medical radiological procedures. This commitment to continuous dose optimisation was identified as an area of good practice in the department.

In the radiotherapy department, inspectors were assured that there appropriate processes in place to ensure that all medical radiological procedure doses were kept as low as reasonably achievable. Prior to the inspection, inspectors reviewed the *Radiation Safety Procedures for the Use and Application of Ionising Radiation at the BHHC*, *Limitations for Concomitant Exposures during the Radiotherapy Treatment Pathway* and *Localisation Procedure-RT* which guided staff in the department in how to implement good optimisation practices. These practices were outlined for all medical exposures along the patients' radiotherapy pathway, and the staff responsible for these practices. Other policies and procedures were also reviewed which outlined how optimisation was best achieved during treatment planning and delivery, and through discussions with staff, inspectors were assured that staff were familiar with these optimisation practices.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors reviewed a policy titled *Optimisation and Management of Local Diagnostic Reference Levels* which had been updated in May 2024. Notwithstanding that this policy required some action on the allocation of responsibilities as discussed under Regulation 6, the policy clearly outlined the DRL dose audit process, the application of DRLs in clinical practice and the reporting and optimisation structure for reported high doses.

Inspectors found that local DRLs for radiodiagnostic examinations and interventional radiology procedures were established, regularly reviewed and used, having regard to the national diagnostic levels as required by Regulation 11(5). DRL charts were displayed in each clinical area and staff who spoke with inspectors demonstrated an awareness of how to use DRLs when carrying out medical exposures to ionising radiation. In the radiotherapy department, inspectors were informed that local DRLs had been established for CT treatment planning scans by staff to monitor scan doses to ensure that any high dose scans were identified and investigated. This was identified as an area of good practice in the service.

Judgment: Compliant

Regulation 13: Procedures

A sample of written protocols for radiology and radiotherapy exposures were reviewed by inspectors, and were easily accessible by staff through the undertaking's document management system. Inspectors also noted that these protocols were reviewed as and when required, and that the review team were clearly identifiable. Referral guidelines for medical imaging were also available to referrers in both departments.

In the radiotherapy department, a review of patient records showed that the radiation dose received by the patient was included in a discharge letter, which was generated for each patient after they finished their treatment course. Inspectors were also informed that a system had been implemented that ensured that the dose from the CT planning scan was recorded and available for patients. This was identified as an area of good practice in the service.

However, during a review of patient records in the radiology department, inspectors found that information relating to patient exposure did not form part of the report for all medical radiological procedures reviewed. The undertaking's management team informed inspectors that they were aware of this gap but were unable to address it with the supplier of the picture archiving and communication system (PACS) as they had temporarily paused service updates due to a recent operational issue. While inspectors acknowledged that the management team had made efforts to address the gap with the PACS supplier, the undertaking did not provide evidence

that alternative measures were in place, or were being considered, to provide information relating to patient exposure on individual reports. The undertaking was therefore found to be not compliant with Regulation 13(2).

Inspectors reviewed a document titled *Blackrock Health Hermitage Clinic Clinical Audit Strategy*, which had been developed by the undertaking's management team as part of the clinical audit programme in the service. Inspectors noted that good efforts had been made by the management team to ensure that the clinical audit strategy and programme aligned with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, published by HIQA in November 2023, however, they were not provided with evidence that this strategy and programme were integrated into the service's overall audit programme.

Inspectors noted that the programme included a 2024 audit schedule for both the radiology and radiotherapy departments. In addition, inspectors noted that a number of clinical audits had been completed in the service, such as audits on the assessment of dose, adherence to checking pregnancy status, and that the clinical justification of medical exposures was completed by staff. When gaps were identified, they were subsequently addressed through recommendations, which were actioned through a quality improvement plan. However, inspectors also noted that where audit results showed repeat non-compliance gaps, the management team had not re-evaluated the actions implemented and revised the recommendations to address these repeat gaps. For clinical audit to be meaningful, sustainable and achievable, it should be integrated into the service's overall audit programme and any implemented actions should be re-evaluated to complete the audit cycle, with the ultimate aim of continual improvements in the quality of the service provided.

Judgment: Substantially Compliant

Regulation 14: Equipment

Prior to the inspection, inspectors were provided with an up-to-date inventory of medical radiological equipment in the service, which was maintained by the undertaking's management team.

During the course of the inspection, inspectors reviewed the procedure *Quality Assurance Programme for Radiology and Diagnostic Imaging servi*ces, which provided guidance and support to staff in the radiology department, in implementing the equipment quality assurance (QA) and management programme. Through discussions with staff and a review of documentation, inspectors were also assured that there were appropriate processes and procedures to support the implementation and maintenance of a quality assurance programme for equipment in the radiotherapy department. Records reviewed demonstrated that the annual testing of medical radiological equipment had been completed by the MPE teams,

and that routine performance testing had been completed by radiographers, radiation therapists and the MPE teams in both the radiology and radiotherapy departments, as allocated.

Records also showed that acceptance testing for all radiological equipment had been completed before the first clinical use. However, inspectors noted that for one unit, there was no evidence that the test results had been reviewed and approved by appropriate personnel. Inspectors also noted that specific recommendations on the use of the equipment had been made during the acceptance testing, however, there was no evidence that these recommendations were appropriately actioned. Therefore, action was required by the undertaking's management team to ensure that all medical radiological equipment in use in the service was kept under strict surveillance regarding radiation protection, which would meet the requirements of Regulation 14 (1).

Judgment: Substantially Compliant

Regulation 15: Special practices

Throughout the day of the inspection, inspectors observed that the undertaking's management team had implemented a number of measures to ensure that high dose medical exposures were completed safely, and that service users receiving such doses were adequately protected.

In the radiotherapy department of the BHHC, inspectors observed that the management team had implemented a dual electronic and paper- based patient record system that ensured key tasks along the patients radiotherapy pathway were completed before the next task could be completed. This system was designed to ensure that appropriate safety checks were completed by appropriate personnel before any medical exposures were delivered. Inspectors were also informed that a fully electronic system was being implemented, which would further strengthen assurances that patients were receiving safe courses of radiotherapy treatment.

A multidisciplinary team had also developed a range of treatment site-specific clinical guidelines, which optimised treatment planning, treatment verification (measures to ensure that the correct area is being treated) and treatment delivery for patients having medical exposures in the radiotherapy department. Inspectors were informed that these guidelines were evidence-based and guided staff along the patients radiotherapy pathway in ensuring all high doses medical exposures were safely completed.

Inspectors also noted that particular attention had been given to dose optimisation for patients. For example, during CT planning for treatment, specific measures were taken, for relevant patients, prior to the scan to reduce organ motion, and that individualised immobilisation devices and scanning margins were carefully considered to ensure that the area scanned was limited to relevant areas only.

These individualised, specific measures also applied during daily treatment exposures, enhanced the accurate delivery of the treatment. Inspectors also noted that the CT scan dose delivered to patients was recorded and monitored to ensure that it was optimal.

In the radiotherapy treatment planning area, inspectors were informed by physics staff that specific planning protocols were used for each individualised treatment plan to ensure the doses to normal tissue is kept as low as possible while delivering the optimal treatment dose to the target area. Inspectors were also informed of a new treatment planning system that allowed staff to accurately combine previous treatment plans with proposed treatment plans, and thereby provide information which guided them to make optimal treatment decisions.

Inspectors were also informed of a specialist technique that delivered high doses of radiotherapy to a small target area, and that the multidisciplinary team had developed a range of policies and procedures, based on up-to-date international best practice, to guide and support staff in CT scanning, planning and treating this cohort of patients.

Inspectors were satisfied that the undertaking's team, in the BHHC, had multiple systems and processes in place to ensure patients undergoing high dose medical exposures were appropriately protected.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors noted that the undertaking's management team had developed and implemented separate, comprehensive policies to ascertain pregnancy status of women undergoing medical exposures, in both the radiology and radiotherapy departments. Each policy guided and supported practitioners and referrers on the process for enquiring about and recording pregnancy status for relevant patients undergoing medical exposures, and staff who spoke with inspectors in both departments demonstrated good knowledge of the policies and processes. Inspectors also observed that the management team had used clinical audit to monitor and assess adherence to these policies and procedures.

In the radiotherapy department, inspectors reviewed a number of patient records and found that this enquiry had been documented at the referral stage, and prior to the planning CT scan and on the first day of treatment by the treating radiation therapists. This process of repeatedly enquiring on and raising patient awareness was noted as an area of good radiation protection for this group of patients in the service. Similarly, the sample of records reviewed in the radiology department satisfied the inspectors that the undertaking's systems, for ensuring that all relevant service users were asked about pregnancy status by a practitioner and the answer recorded, were adhered to by staff.

Multilingual posters were observed throughout the radiotherapy and diagnostic imaging departments, which further assured inspectors that the undertaking's management team had taken appropriate measures to increase the awareness of service users, who may be pregnant or breastfeeding, of the need for special protection during medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident summary reports, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility.

Inspectors reviewed a document titled *Reporting of Radiation Incidents* which had been appropriately updated since the previous inspection, to ensure that it clearly represented all categories of notifiable incidents so that staff are aware of all categories relevant to their area. The document also outlined the overarching radiation incident reporting pathway in the BHHC and also included information on the requirement to notify HIQA of certain reportable incidents. Inspectors also spoke with a number of staff who clearly described the incident reporting process as outlined in this document. Staff also commented that they regularly received feedback on emerging trends and the outcome of incident investigations. Inspectors were satisfied that the hospital had a good culture of reporting for both incidents and near misses and that arrangements were in place to ensure that HIQA is notified of the occurrence of a significant event within the time frame if required. Inspectors also noted that quality improvement plans were implemented as a result of incident learning and management. For example, in the radiotherapy department, the CT planning process for one cohort of patients had been refined, and a new CT planning protocol developed and implemented.

Inspectors noted that both the radiotherapy and diagnostic radiology departments at BHHC had systems for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, which were appropriate in meeting the requirements of Regulation 17(1)(c).

From a review of documentation inspectors observed that incidents were a standing agenda item and had been discussed at recent RSGG and RSC meetings, thereby providing assurance that the undertaking has comprehensive oversight of radiation incidents in this facility.

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially 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 Hermitage Clinic OSV-0007033

Inspection ID: MON-0042766

Date of inspection: 03/07/2024

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: - The "Optimisation and Management of Local Diagnostic Reference Levels" policy has been updated to allocate the role of approving reviewed DRLs in all areas of the radiology department to the Clinical Director or their designee – attached. - The equipment quality assurance programme/policy was revised to ensure roles and responsibilities are clearly allocated. QA gaps will be monitored by the RPU audits on monthly bases. The most recent QA record audit is completed for July, showing a 100% compliance in the records. The RPU will continue to monitor the QA records to ensure there are no gaps in the future. Any non-compliance will be promptly escalated as appropriate by the relevant line manager – attached most recent audit. - The Undertaking details have been updated following the HIQA inspection i.e. change of legal entity and undertaking representative. - The Radiation Safety Procedures for the Use and Application of Ionising Radiation at the BHHC had been reviewed to ensure that all allocated roles and responsibilities align with the current regulations.	
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: - A training plan for the diagnostic senior physicist is ongoing in line with guidance of RP 174, working towards ICPM pre-registration in the coming 12 months, with full	

registration anticipated two years following this. The training plan is supported by the Head of Physics department and the Diagnostic MPE.

- To ensure adequate diagnostic MPE contingency, the hospital will maintain an SLA with the interim diagnostic MPE (in addition to the long standing diagnostic MPE) until the senior diagnostic physicist is fully registered. This will ensure there is no gap in continuity of medical physicist expertise in the diagnostic radiology department going forward.

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
• A paper referral process was introduced in order to improve compliance with SI 256/18 which states that the referral must be

".. accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment".

• Each morning, during theatre set up, the radiographer supplies the surgeon with paper referrals to complete for each case requiring x-ray screening. This allows the surgeon add the necessary clinical information to the referral in order for the practitioner to consider the benefits and risks of the medical exposure.

• The paper referral is scanned by the radiographer in conjunction with an electronic order placed for the procedure.

• An audit was carried out one month after the introduction of this paper referral process. The audit specifically focused on clinical indications relating to theatre screening exposures and showed 100% compliance for this new process with additional clinical information.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
The Quality Department has incorporated the Clinical Audit Strategy from DI and RT into the organisation's Clinical Audit Strategy. Medical exposure audit outcomes will now be included in the ongoing radiation safety updates to Quality Improvement and Risk Management (QIRM) meeting.

• The RSGG meeting has a standing agenda item on audits of medical exposures, any non-compliances will be discussed at this meeting and actions agreed. Repeated non-compliances will prompt the re-evaluation of actions implemented and revision of recommendations to ensure the repeated gaps are promptly addressed. The recommendations will be communicated to the line manager / relevant stakeholder to discuss with the relevant staff and will be re-evaluated in future audits.

• Where possible all modalities that can export patient dose information to the report has been checked and verified in collaboration with the vendors and the PACS team. Modalities that are unable to send the dose information due to limitations e.g. age and compatibility of software, will have dose information entered manually by the practitioner in the patient record on PACS. The dose information will be dictated by the reporting radiologist in Powerscribe and displayed on the patient's report.

• Dose information relating to patient exposure is now included in the report for all medical radiological procedures, ensuring the hospital is fully compliant with Regulation 13(2).

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
• An audit is completed to confirm that the acceptance test reports for all radiological equipment have been signed and any recommended action is completed and closed out. – attached specific recommendations from the general X-ray equipment acceptance testing has now been documented in the relevant SOP. – attached

• Recommendations or actions following any QA testing will be tracked with a date for rectification to ensure the recommendation/action is completed and closed out.

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	09/08/2024
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	Substantially Compliant	Yellow	15/07/2024

	requesting the particular procedure, and			
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	19/08/2024
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	12/08/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	09/08/2024
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Substantially Compliant	Yellow	16/08/2024