



**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:	Global Diagnostics (Blackrock Hall)
Undertaking Name:	Global Diagnostics Ireland
Address of Ionising Radiation Installation:	Blackrock, Cork
Type of inspection:	Announced
Date of inspection:	27 June 2025
Medical Radiological Installation Service ID:	OSV-0006649
Fieldwork ID:	MON-0044114

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

Global Diagnostics Ireland (trading as Medica) provides a DXA (Dual Energy X-ray Absorptiometry) service at Blackrock Hall from 08:30 to 18:00, three days a week. The DXA service is managed by a team of professionals, including a Regional Clinical Lead Radiographer and three Senior DXA Radiographers, all of whom work part-time. They are supported by a Radiology Services Manager, a Radiation Protection Officer, and a Head of Operations. Global Diagnostics Ireland conducts approximately 2000 DXA procedures annually at Blackrock Hall, serving both privately referred patients and those utilising the GP Direct scheme in the area.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Friday 27 June 2025	10:00hrs to 13:25hrs	Margaret Keaveney	Lead

Governance and management arrangements for medical exposures

The radiological service at Global Diagnostics (Blackrock Hall) comprises of one dual-energy X-ray absorptiometry (DXA) unit and provides medical exposures to ionising radiation to out-patients referred from general practitioners and hospital medical practitioners. During an inspection of this service, the inspector visited the DXA room, spoke with staff and reviewed a sample of documents to monitor the undertaking's compliance with the regulations. Overall, the inspector was assured that the undertaking's management team had made good efforts to comply with the regulations and provide a safe radiological service to service users. However, action was required under Regulations 6 and 13 to improve compliance with these regulations.

Global Diagnostics Ireland is the undertaking for Global Diagnostics (Blackrock Hall). The undertaking's management team had established a radiation protection unit (RPU) which, in accordance with its terms of reference, met yearly and was attended by the designated manager, the medical physics expert (MPE), a senior radiographer and the undertaking's radiation protection officer (RPO). The inspector was informed that a senior radiographer was responsible for overseeing the day-to-day aspects of radiation protection in the DXA unit, and was appropriately supported by the designated manager and RPO.

The inspector was also informed that the designated manager chairs the undertaking's Clinical Governance Committee, which meets quarterly to discuss radiation protection matters such as clinical audit, incidents involving ionising radiation and the radiological equipment monitoring programme. The undertaking's representative is also a member of this committee, which provides them with oversight of the radiological service at Global Diagnostics (Blackrock Hall).

A sample of service user records for medical exposures were reviewed by the inspector and showed that appropriate persons, as per the regulations, were involved in referring and justifying medical exposures completed in the service. The inspector was 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.

The inspector noted that MPE involvement in the service was proportionate to the radiological risk posed by the service, and that the undertaking's management team had good arrangements in place to ensure the continuity of this service.

Overall, the inspector was assured that service users were receiving a safe radiological service at Global Diagnostics (Blackrock Hall).

Regulation 4: Referrers

The inspector was satisfied that referrals for DXA ionising radiation examinations in Global Diagnostics (Blackrock Hall) were made only from persons as defined in Regulation 4, more specifically this role had been allocated to medical practitioners only in this facility.

Judgment: Compliant

Regulation 5: Practitioners

From discussions with staff, the inspector was informed that radiographers were allocated the role of practitioner in the service.

A review of a sample of medical exposure records verified that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures at Global Diagnostics (Blackrock Hall).

Judgment: Compliant

Regulation 6: Undertaking

The inspector was satisfied that the undertaking had implemented governance and management arrangements that provided oversight of radiology service at Global Diagnostics (Blackrock Hall). These arrangements were outlined in an organogram submitted in advance of the inspection, and were further evidenced by meeting minutes.

Although the undertaking's management team had developed a range of policies and procedures that supported and guided staff in their roles in completing medical exposures of ionising radiation, some action was required to ensure that all roles and responsibilities on radiation protection of service users were clearly allocated and documented in the relevant documentation. For example,

- from a review of documentation it was not clear to the inspector which professional groups had been allocated the role of practitioner at Global Diagnostics (Blackrock Hall). Although the inspector was satisfied that appropriate personnel were carrying out this role in the service, a clear allocation of key radiation protection roles is essential in a radiological service.
- the documented procedure for recording justification in advance did not align with the day-to-day practice in the service. The practice of justification of a

medical exposure determines if the net benefits of the exposure outweigh the possible risks and a clear allocation of responsibilities around this practice must be in place, as a key radiation protection measure to ensure that the exposure is necessary and useful.

While some improvements were required in the documented allocation of roles and responsibilities, the inspector was satisfied that the appropriate personnel were carrying out radiation protection measures and that service users in the radiology department received safe exposures of ionising radiation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From a review of documents and discussions with staff, the inspector was satisfied that practitioners, as defined in the regulations, took clinical responsibility for the medical radiological procedures in Global Diagnostics (Blackrock Hall).

Practitioners and the MPE were also noted to be involved in a number of optimisation processes for medical exposures to ionising radiation completed in the service. The inspector was also satisfied that the justification process for individual medical exposures involved the referrer and practitioner.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector spoke with the MPE engaged by the undertaking to provide medical physics expertise in Global Diagnostics (Blackrock Hall). They detailed the arrangements in place to ensure the continuity of medical physics expertise, which included cover by other MPEs, where and when necessary. Staff also reported that they had good access to medical physics expertise and advice when necessary.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE at Global Diagnostics (Blackrock Hall). and was satisfied that the MPE was involved in aspects of medical exposures as required by Regulation 20(2). For example, the MPE was a member of the radiation protection unit in the service and gave advice on medical

radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. They were also involved in optimisation practices, including the application and use of diagnostic reference levels (DRLs). They were available to carry out dose calculations for any incidents relating to ionising radiation and had contributed to the training programme for staff in radiation protection.

Judgment: Compliant

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

From discussions with staff and a review of documents, the inspector was satisfied that the level of involvement of the MPE at Global Diagnostics (Blackrock Hall). was commensurate with the radiological risk posed by the facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, the inspector saw that the management team at Global Diagnostics (Blackrock Hall) were committed to the radiation protection of service users, for example, through the implementation of a quality assurance programme for the DXA unit and the use of DRLs. However, the inspector also noted that action was required by the undertaking to ensure that the service's clinical audit strategy fully aligned with HIQA's *National Procedures for Clinical Audit of Medical Radiological Procedures*. This is further discussed under Regulation 13 below.

During the inspection, the inspector reviewed a number of referrals, received from external medical practitioners, and saw that each was in writing, stated the reason for the request and was accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff explained the process for the justification of each medical exposure, in advance of the exposure happening as required by Regulation 8, and recording of this was evident for all medical radiological procedures reviewed by the inspector. A review of these records also showed that information relating to the exposure formed part of the report as required by Regulation 13(2). The inspector also noted that local DRLs had been established and reviewed by a senior radiographer and the MPE, and were readily available to staff in the clinical areas.

The inspector reviewed records and spoke with staff which provided assurances that the undertaking had implemented a quality assurance programme for the DXA unit

in use in the service. The MPE stated that they were promptly contacted to provide guidance on any quality control test results if required, and the inspector also saw evidence that equipment manufacturers were involved in ensuring that all equipment was fit for use and provided a safe and reliable service to service users.

In relation to Regulation 13(4), the inspector noted that a number of clinical audits had been completed in the service. This included a review of a particular examination type to determine if all images taken as part of this procedure were required to provide the desired clinical outcome. The risks and benefits of each image was evaluated by the undertaking's team, and although the review determined that the existing examination protocol should not be changed, this audit was viewed as an example of good audit practice in the service. Despite this good use of clinical audit, the inspector noted that further work was required on the undertaking's clinical audit strategy to ensure that it fully aligned with the national procedures as required by the regulations.

The management team in Global Diagnostics (Blackrock Hall) had arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. This included ensuring that the undertaking had oversight of incidents and near misses that occurred in the service and that HIQA was notified of any reportable events.

Overall, the inspector was satisfied that systems and processes were in place at Global Diagnostics (Blackrock Hall) to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

All referrals reviewed by the inspector were in writing, stated the reason for the request and were accompanied by sufficient medical data which allowed the practitioner to consider the benefits and risks of the medical exposure. The inspector also observed that information about the benefits and risks associated with the radiation dose from medical exposures was available to service users in leaflet format.

On the day of inspection, the inspector spoke with a practitioner who outlined how medical exposures are justified in advance of the medical exposure being completed, which included staff recording in service user records that justification in advance had been completed. However, as stated in Regulation 6 above, the process described to the inspector did not align with that documented in the procedure.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The undertaking's management team had developed a document titled *Diagnostics Reference Levels (DRLs) for Medical Radiological Procedures Policy - Cork DXA*, which was last reviewed in June 2025. This document set out the roles and responsibilities in establishing, reviewing and using local diagnostic reference levels (DRLs). From a review of records, the inspector noted that local DRLs had been regularly reviewed and that national DRL data had been considered in these reviews. The latest DRL review was prominently displayed in the clinical area for use by staff.

The inspector was informed that, in the last 12 months, an additional review of DRL data had been completed to further assure the undertaking that the data in use fully enhanced the optimisation of radiological procedures. This review was identified as a good example of the undertaking's commitment to the radiation protection of service users.

Judgment: Compliant

Regulation 13: Procedures

The inspector reviewed written protocols available for standard DXA procedures for both adult and paediatric service users, and noted that they were accessible to staff in the clinical area and guided them on the optimised patient positioning, and exposure parameters for different medical exposures. The inspector also noted that appropriate referral guidelines were available to staff, for reference. Both measures ensured that the undertaking was meeting the requirements of Regulation 13(1) and (3).

A review of a sample of reports on medical exposures carried out in the service demonstrated that information relating to patient exposure formed part of the medical exposure report, as required by Regulation 13(2).

From a review of documentation, the inspector saw that although the undertaking's management team had developed a strategy document as part of their clinical audit programme for the service, it did not fully align with the national procedures published by HIQA in November 2023. In addition, the inspector noted that although a number of clinical audits on radiation protection processes and outcomes had been completed in the service; such as audits on the assessment of dose, the clinical justification of medical exposures and image quality; audits on the radiation protection structures in place in the service had not been completed which may have highlighted the gaps in compliance identified by the inspector during this inspection.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of the medical radiological equipment in use in the service was provided to the inspector in advance of this inspection.

The undertaking's *Equipment Maintenance and Quality Assurance Policy* stated that daily and monthly performance testing by radiography staff and annual testing by the MPE and the equipment manufacturer was to be completed on the medical radiological equipment in the service. The inspector reviewed a sample of records which showed that this testing was performed as planned, and that where further action was required, it was promptly completed. The inspector also noted that the QA programme was an agenda item in the RPU meetings.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The undertaking had an electronic system in place for the recording and review of any incidents and near misses, involving accidental or unintended exposures to ionising radiation, in the service. The inspector was informed that as an incident or near miss occurred, staff recorded the details on the system and also informed the RPO and Designated manager.

From a review of documentation, the inspector noted that recorded incidents or near misses were discussed at the yearly RPU meetings, and any learning and actions agreed to prevent future occurrences to other service users. For example, following a number of similar near misses where inappropriate referrals were received, the undertaking's staff team had contacted referrers and reiterated best practice with regard to DXA referral criteria. This was identified as an area of good practice by the undertaking's incident management team.

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	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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Global Diagnostics (Blackrock Hall) OSV-0006649

Inspection ID: MON-0044114

Date of inspection: 27/06/2025

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: Global Diagnostics (Blackrock Hall) have created a site-specific document: Cork DXA Referral Policy. This document clearly outlines the justification process Radiographers follow for DXA scans in Blackrock Hall Cork DXA. An amendment was made to the document: Cork DXA Radiation Safety Procedures to identify the Radiographer as the practitioner in Blackrock Hall Cork DXA. Both these documents will be brought to the Cork DXA Radiation Protection Unit in October 2025 for approval.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Global Diagnostics Blackrock Hall DXA will amend the clinical audit strategy to align with HIQA National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation. The existing Clinical Audit Strategy document will be amended, and changes will be discussed with staff at the next Medica Clinical Audit Workshop. Changes will be approved at the next Radiation Protection Unit meeting after the Clinical Audit Workshop in November 2025. These amendments will comprise of the inclusion of Structural Audits in line with HIQA Guidelines.	

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	31/10/2025
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures	Substantially Compliant	Yellow	31/12/2025

	established by the Authority.			
--	-------------------------------	--	--	--