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 (Cork)
Undertaking Name:	Global Diagnostics Ireland
Address of Ionising Radiation Installation:	Mahon, Cork
Type of inspection:	Announced
Date of inspection:	26 July 2022
Medical Radiological Installation Service ID:	OSV-0006468
Fieldwork ID:	MON-0036815

About the medical radiological installation:

Global Diagnostics Ireland Ltd trading as Medica is a managed radiology services company which provides diagnostic imaging and radiologist reporting services throughout Ireland.

Global Diagnostics Ireland Ltd are contracted by the VHI (VHI Health and Wellbeing Designated Activity Company) to provide a managed X-ray service in VHI Swiftcare Clinic, Mahon Point, Cork from 08:00 to 22:00 Monday to Sunday, 365 days of the year.

Global Diagnostics Ireland Ltd's X-ray service in VHI Swiftcare Cork is staffed by Global Diagnostics Ireland Ltd staff which includes an X-ray Clinical Specialist Radiographer and a Senior X-Ray Radiographer who are supported by a Radiology Services Manager, a Radiation Protection Officer and a Head of Operations.

Global Diagnostics Ireland Ltd conducts approximately 8200 medical radiological procedures (X-Ray) annually in VHI Swiftcare Cork from the in-house referring Physicians and Consultants.

A full range of X-ray examinations can be performed in Global Diagnostics Ireland Ltd.'s service in Cork as per our published clinical protocols.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 26 July 2022	09:55hrs to 13:35hrs	Kay Sugrue	Lead

Governance and management arrangements for medical exposures

An on-site inspection of Global Diagnostics (Cork) was carried out by an inspector on 26 July 2022. On the day of the inspection, the inspector spoke with members of the management team, the medical physics expert (MPE) contracted for the service, and radiology staff. From these discussions and review of the processes and systems in place, the inspector was satisfied there was a strong commitment demonstrated to the radiation protection of service users at this facility.

Global Diagnostics Ireland is the undertaking for this facility and is a subsidiary of Medica Diagnostics Ireland. Governance arrangements described to the inspector aligned with documentation reviewed in advance of the inspection. These arrangements demonstrated that there were clear lines of communication up to Medica Group Medical Advisory Board via the undertaking representative who was also the Managing Director of Global Diagnostics Ireland. A radiation safety committee (RSC) was in place and met twice a year. The inspector was assured that the governance arrangements in place on the day of the inspection were effective, however management stated that the undertaking and therefore the existing arrangements for this facility were due to change in the near future.

A sample of radiological procedures records were viewed during the inspection and showed that appropriate persons as per regulations were involved in referring and justifying medical exposures conducted at the facility. The processes outlined to the inspector aligned with local procedures viewed in advance of the inspection. Similarly, the undertaking had ensured that an MPE was engaged to provide specialist advice, as appropriate with MPE involvement proportionate to the radiological risk posed by the service.

Overall, the inspector was assured that there was a clear allocation of responsibility for the radiation protection of service users.

Regulation 4: Referrers

The inspector was satisfied that referrals reviewed were from referrers as defined in the regulations. Referrals were received from referrers working within the facility and were clearly identifiable in each of the referrals reviewed. Referral practices at the facility were underpinned by local policy that also outlined radiographer scope to adapt and request secondary referrals. A policy outlining nurse referral rights was viewed and nurse referrals were audited to ensure that scope to refer as outlined in policy was complied with.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied from the records of medical exposures reviewed on the day of inspection and from speaking with staff that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The inspector was satisfied that the facility had clearly defined the allocation of responsibility for the radiation protection of services users. Documentation reviewed by the inspector prior to and during the inspection demonstrated that there were clear lines of communication within corporate and clinical governance structures. Documented radiation protection governance arrangements aligned with those that staff consistently described to the inspector during discussions. Oversight for radiation protection was provided by a RSC that reported up to the overarching governance group, the Medica Group Medical Advisory Board. The undertaking representative for Global Diagnostics (Cork) who was also the managing director sat on both these forums. A sample of minutes from the Medica Group Medical Advisory Board was viewed on the day of the inspection and showed that actions and minutes from the RSC was an agenda item on this committee. The inspector was informed by management that the current undertaking for this facility was due to change in the near future with plans in place for a new undertaking to assume responsibility for the service.

Overall, the inspector was assured that there were appropriate governance and management arrangements in place at Global Diagnostics (Cork) to oversee radiation protection for service users.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that there were systems and processes in place to ensure that all medical exposures took place under the clinical responsibility of a practitioner. Clinical oversight was facilitated by a practitioner in charge who regularly attended on site and was available to radiology staff by phone when needed.

Documentation viewed and discussions with staff during the inspection

demonstrated that Global Diagnostics (Cork) had processes and procedures in place to ensure that the referrer and the practitioner were appropriately involved in the justification of individual medical radiological procedures. Similarly, a practitioner and MPE were involved in optimisation of medical exposures as per this regulation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The MPE's up-to-date professional registration certificate was reviewed by the inspector on the day of inspection and therefore the inspector was satisfied that a MPE supported this service. While arrangements to ensure continuity of MPE expertise were described to the inspector in discussions with the MPE and management, these arrangements were not formalised in contract arrangements viewed by the inspector. Therefore the service level agreement or equivalent should be updated to outline the arrangements in place to ensure the continued provision of medical physics expertise at Global Diagnostics (Cork) should the need arise.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

From evidence gathered from documentation reviewed and discussions with staff, the inspector was satisfied that the MPE met the requirements of this regulation. The inspector found that the MPE was involved in quality assurance of medical radiological equipment, patient dosimetry, review and sign off of facility diagnostic reference levels (DRLs) and advice and dose calculation for radiation incidents. The MPE also attended the RSC meetings held twice a year and contributed to staff training on radiation protection.

Judgment: Compliant

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

The inspector was satisfied with the documentation reviewed and information provided by staff, including the MPE, that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was proportionate to the radiological risk posed by medical exposures performed at this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed the systems and processes in place to ensure that service users undergoing medical exposures delivered by Global Diagnostics (Cork) were safe and found that there was a high level of compliance with the regulations assessed. Staff also demonstrated a strong commitment to the radiation protection of service users.

The inspector found from a sample of records reviewed and from speaking with radiography staff, that there was a process in place to ensure that medical radiological procedures carried out at the facility were justified in advance by a practitioner. Records of justification for each procedure were scanned onto the radiology information system and were available to view as per regulatory requirements. Information on the risks and benefits associated with the radiation dose from medical radiological procedures were displayed in posters on the walls of each service user cubicle and in the general clinical areas.

From speaking with staff and reviewing the documentation provided as part of this inspection, the inspector was assured that there was an appropriate quality assurance programme in place and regular performance testing of medical radiological equipment in this facility had been completed, as required by the regulations.

DRLs for adult procedures were approved for use in 2022 and clearly displayed in the X-ray room. Written procedures for standard X-rays conducted at this facility were also displayed in the X-ray room and accessible to staff. The inspector was informed that the numbers of paediatric X-rays conducted in this facility were relatively low providing a very small sample size for the establishment of paediatric DRLs, therefore national DRLs were applied.

Global Diagnostics (Cork) had an effective system in place to determine the pregnancy status of service users that included a review of the justification of the procedure by the relevant practitioner and the referrer as required.

Staff demonstrated a good understanding of the process for the reporting of accidental and unintended exposures and significant events and documentation viewed demonstrated that there was an appropriate system in place to facilitate the tracking, trending and analysis of all radiation incidents and potential incidents.

The inspector found that clinical audits were conducted at this facilty with a focus on improving the radiation protection of service users attending for X-ray there.

One area of improvement was identified in that the information relating to the medical exposure did not form part of the report as required under Regulation

13(2). Management informed the inspector that measures to address this gap were under consideration and was deemed a priority by the undertaking to ensure compliance with this regulation.

Overall, the inspector was satisfied that Global Diagnostics (Cork) had effective systems and processes in place to ensure that service users undergoing medical exposures were safe.

Regulation 8: Justification of medical exposures

The inspector reviewed a sample of written referrals on the day of the inspection and also spoke with a radiographer conducting medical exposures. Evidence gathered demonstrated that procedures were justified in advance by a radiographer and there was a system in place to ensure that records of justification were available for each medical exposure from the date of the procedure as per regulatory requirement. As an additional assurance mechanism, Global Diagnostics (Cork) also conducted audits on compliance with the process of justification.

Information in relation to the benefits and risks associated with radiation was available to service users undergoing medical exposures, on posters in service user waiting areas and individual service user cubicles.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs for common procedures were displayed in the X-ray room. DRLs for adult procedures were established for 2022 (based on 2021 data) and compared to national DRLs at this facility. The inspector was informed by staff and the MPE that the development of paediatric DRLs was a work in progress. Currently, the facility did not record paediatric weight as most examinations conducted were for extremities from minor injuries therefore, data collected was based on age bands and not weight based. The inspector was informed that there were insufficient procedures per age group to establish facility DRLs and therefore national DRLs were applied. Furthermore, it was the intention to conduct a prospective study at the facility for older children undergoing chest x-ray in the near future.

Judgment: Compliant

Regulation 13: Procedures

The inspector was satisfied that written protocols for every type of standard X-ray procedure were available to staff at this facility both in hard and soft copy. These protocols were displayed and readily accessible to radiographers carrying out examinations in the X-ray room. Referral guidelines, iRefer, were viewed by the inspector which were available to referrers and staff on desktop computers.

The inspector was informed that information relating to the medical exposure did not form part of the report as required under Regulation 13(2). However, management informed the inspector that this gap in compliance was currently under review and a project was underway to acquire and implement an appropriate solution to ensure that the requirements of Regulation 13(2) were met.

The inspector found that there was a system of audit in place. The inspector viewed a summary of audits conducted in 2021 and 2022. Some good examples were evident where audit results had informed quality improvement initiatives within the service. One such audit related to the referral for acute knee injuries presenting for X-ray. An audit three years ago identified that 30% of inappropriate referrals for specific knee X-rays were received where a recommended decision making rule to help determine the need for X-ray in acute knee injuries was not utilised by referrers. This was re-audited in 2021 where a 3% improvement was evident which was deemed an insufficient improvement. A follow on action item resulted in an update to the protocol for knee X-rays in May 2022, with a mandatory requirement for inclusion of the decision making rule by referrers. The inspector was informed that once this update to the protocol was embedded in routine referral practice, it would be re-audited.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory of medical radiological equipment and noted that equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by the inspector showed that appropriate quality assurance programmes, including regular performance testing had been implemented at this facility. A system was in place for reporting and recording equipment faults which included follow-up actions and an identifiable responsible person.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector was satisfied that there was an established process to determine the

pregnancy status of service users and this process was documented in the facility radiation safety policy. Records reviewed showed that radiographers had responsibility for making enquiries as to pregnancy status of service users and these records were uploaded to the radiology information system. Staff also informed the inspector that although unusual to see in practice due to the nature of the service provided, there was a process in place where special attention would be given to the justification of relevant procedures where pregnancy cannot be ruled out. In this scenario, re-justification would be recorded following review by the referrer and practitioner on a specific re-justification form.

The inspector observed posters in the service user waiting area and service user cubicles, including multilingual posters, with the aim of increasing the awareness of women to whom this regulation applied.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector reviewed a facility policy which outlined the the process for the management of accidental and unintended exposures and significant events. Incidents and potential incidents were tracked, analysed and categorised for each month with evidence of discussion of radiation incident summary reports as a standard agenda item at the RSC meetings. Management informed the inspector that a new electronic system was underway which would facilitate the move away from a manual recording process to an electronic one.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Global Diagnostics (Cork) OSV-0006468

Inspection ID: MON-0036815

Date of inspection: 26/07/2022

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 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: SLA has been reviewed and relevant contact details of MPE cover has been included in the SLA. These contact details have been communicated to all sites.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Medica have an active project portfolio and a project to enable the recording of patient exposure/dose information is a very high priority active project at present. This is being managed by our Deployments and Projects Manager, with technical oversight by our Solutions Architect. We are currently in the investigatory stage and are considering technical solutions that will automate dose recording on our reports. We have engaged with 2 external vendors and our current PACS provider to understand possible solutions, project steps, timelines and costs. We will select a path forward in the next 4-6 weeks. Given the timescales indicated to us by all vendors we anticipate that the solution could be in place within the following 6 months. Medica are committed to implementing a solution and have allocated resources and budget towards this within 2022/23 to complete this.	

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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	28/02/2023
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	27/07/2022