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 (Navan)
Undertaking Name:	Global Diagnostics Ireland
Address of Ionising Radiation Installation:	Our Lady's Hospital Navan, Moathill, Navan, Meath
Type of inspection:	Announced
Date of inspection:	07 December 2022
Medical Radiological Installation Service ID:	OSV-0006470
Fieldwork ID:	MON-0038063

About the medical radiological installation:

Global Diagnostics Ireland is a subsidiary of Medica Group PLC which provides diagnostic imaging and radiologist reporting services throughout Ireland. Global Diagnostics Ireland are contracted by the Health Service Executive (HSE) to provide a managed computed tomography (CT) service in Our Lady's Hospital, Navan (OLHN). Global Diagnostics (Navan) is staffed by Global Diagnostics Ireland staff which includes a CT Clinical Specialist Radiographer and a Senior CT Radiographer who are supported by a Radiology Services Manager and a Radiation Protection Officer. Global Diagnostics (Navan) provides CT training to HSE radiographers working in the OLHN Radiology Department so that the out-of-hours emergency CT scanning service can be provided.

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
Wednesday 7 December 2022	09:30hrs to 15:00hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of Global Diagnostics (Navan) was carried out on the 7 December 2022 to assess compliance against the regulations. As part of this inspection, the inspector visited the computed tomography (CT) area where medical exposures where provided by Global Diagnostics Ireland.

On the day of inspection, local governance and management arrangements in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital were reviewed by the inspector. Global Diagnostics Ireland, a subsidiary of Medica Group PLC, are contracted by the Health Service Executive (HSE) to provide a managed computed tomography (CT) service in Our Lady's Hospital, Navan (OLHN). On the day of inspection, the allocation of responsibility for radiation protection of service users was described to the inspector for medical radiological procedures carried out at the CT unit. A diagram (organogram) of the governance and management arrangements for Global Diagnostics (Navan) was provided to the inspector in advance of the inspection.

All medical radiological procedures at the hospital took place under the clinical responsibility of an individual entitled to act as a practitioner. Staff and management spoken with communicated that radiologists and radiographers acted as practitioners at Global Diagnostics (Navan). However, while documentation reviewed allocated responsibility to radiologists as practitioners with responsibility for justification of individual medical exposures, the allocation of the other aspects of clinical responsibility was not clearly documented.

The involvement of a medical physics expert (MPE) was identified within the governance structures for medical exposures at Global Diagnostics (Navan) and the MPE acted and provided advice on matters relating to medical physics. Similarly, a practitioner and the MPE were involved in the optimisation process for all medical exposures. The inspector also found that measures had been put in place to ensure that the referrer and a practitioner were involved in the justification process for individual medical radiological procedures.

Overall, and notwithstanding the area of improvement identified above to come into full compliance with the regulations, the inspector was satisfied that Global Diagnostics Ireland had appropriate governance and management arrangements in place to ensure the safe delivery of medical exposure to ionising radiation at the CT unit in OLHN.

Regulation 4: Referrers

The inspector reviewed a sample of referrals and spoke with staff and found that

only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at Global Diagnostics (Navan).

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed and the inspector found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at Global Diagnostics (Navan) were reviewed by the inspector. Documentation, including local policies, procedures, guidelines and records and an organisational chart (organogram) were also reviewed in advance of the inspection.

Global Diagnostics (Navan) was owned and managed by Global Diagnostics Ireland, a subsidiary of Medica Group PLC. Day-to-day operations at Global Diagnostics (Navan) were managed by the Clinical Specialist Radiographer with support from the Radiology Services Manager (RSM), who was the designated manager for this units and also for other Global Diagnostics Ireland sites.

A radiation safety committee (RSC) was also in place and was found to be a forum for providing oversight to the undertaking regarding the radiation protection of service users. The terms of reference of the RSC, in addition to recent minutes, were reviewed as part of this inspection. The designated manager, undertaking representative and other individuals involved in the conduct of medical exposures were members of the RSC. The RSC reported up through the undertaking representative to the Medica Group Advisory Board, who in turn reported to the Medica Group PLC Board. Due to the nature of the relationship in place with the OLHN, formalised communication pathways were found to exist to facilitate effective communication between the two entities. The inspector also reviewed evidence that local informal communication pathways, such as email communication, were also utilised to ensure that information was shared in a timely manner between OLHN and Global Diagnostics (Navan) given the overlapping staffing arrangements.

From speaking with staff and management and reviewing documentation and other records, the inspector was satisfied that individuals entitled to act as practitioners

employed by both the Health Service Executive (HSE) and Global Diagnostics Ireland, took clinical responsibility for medical exposures performed at the facility. However, while it was clear that radiologists were recognised as practitioners and allocated responsibility for justification of individual medical exposures, documentation reviewed did not clearly outline the allocation of the other aspects of clinical responsibility. For example, while staff and management informed the inspector that radiographers were considered practitioners at Global Diagnostics (Navan), the roles and responsibilities of radiographers as practitioners was not clearly included in documentation. Similarly, while the inspector noted that the *Clinical Justification Policy - Navan CT* clearly allocated radiologists clinical responsibility for justification, the other aspects of clinical responsibility allocated to radiologists were not clearly outlined in the polices, procedures and other documentation reviewed by the inspector. In order to come into full compliance with Regulation 6, Global Diagnostics should review and update documentation to ensure it fully aligns with local practice at the unit.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. Additionally, the practical aspects of medical radiological procedures were only carried out by individuals entitled to act as practitioners in the regulations.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, the inspector spoke with staff, management, MPEs and reviewed the service level agreement in place. Consequently arrangements were found to be in place to ensure the continuity of the provision of medical physics expertise at Global Diagnostics (Navan).

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector spoke with staff and management and reviewed documentation and other records to establish the involvement and contribution of an MPE to areas such as, diagnostic reference levels (DRLs), quality assurance (QA) programmes, training in relation to radiation protection and the analysis of events involving or potentially involving an accidental or unintended exposure to ionising radiation. Overall the inspector was satisfied that arrangements were in place to ensure MPE involvement to act or give specialist advice as appropriate on matters relating to medical physics.

Judgment: Compliant

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

On the day of inspection, mechanisms were in place to ensure that an MPE was involved in medical radiological procedures in line with the level of radiological risk.

Judgment: Compliant

Safe Delivery of Medical Exposures

All referrals reviewed on the day of inspection were in writing and stated the reason for requesting the medical radiological procedure. The inspector also reviewed how justification in advance by a practitioner was recorded. Written protocols for every type of standard medical radiological procedure had been established at the unit together with a programme of clinical audit. However, the inspector found that information relating to patient exposure did not form part of the report of medical radiological procedures as required by Regulation 13(2).

A quality assurance programme for medical radiological equipment had been established at Global Diagnostics (Navan). This programme included regular routine performance testing of equipment and records of all quality assurance testing were available to the inspector for review. Trending and analysis of potential incidents was available for review and an incident reporting flow-chart was available to staff in the clinical area.

Local facility DRLs for CT examinations carried out at its Navan CT unit had been established and the inspector observed these DRLs clearly displayed in the control room. The inspector also reviewed a sample of referrals and found that an inquiry regarding the pregnancy status of the patient had been carried out by a radiographer and an answer recorded in writing. However, on review of the *Patient Last Menstrual Period & Pregnancy Policy* the inspector noted that while efforts had been made to ensure alignment of this document with the regulations, an additional

review is necessary to ensure that this policy fully aligns with day-to-day practice and the requirements of the regulations.

Notwithstanding the area for improvement identified, overall, the inspector was assured that appropriate systems to ensure the safe delivery of medical exposures were in place at Global Diagnostics (Navan).

Regulation 8: Justification of medical exposures

Information relating to the benefits and risks associated with medical exposures were placed in the main waiting rooms. Bespoke information leaflets were also sent out with appointment letters to patients attending for CT Colonography studies.

All referrals reviewed were in writing and stated the reason for requesting the particular procedure. Staff and management informed the inspector that medical exposures were justified by a radiologist in advance of each medical radiological procedure. A sample of referrals for medical exposures to ionising radiation were reviewed on the day of inspection and justification in advance was found to have been recorded for each referral reviewed. The inspector also found that radiographers conducting the practical aspects of the CT scan recorded that they had confirmed justification in advance had been carried out before proceeding with the examination. This provided an assurance that only medical radiological procedures that had been justified in advance by a practitioner were carried out at Global Diagnostics (Navan).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Global Diagnostics had established local facility DRLs for CT examinations carried out at its Navan CT facility with regard to the national DRLs. The inspector observed these DRLs clearly displayed in the control room. Staff spoken with described plans to review the range of examinations for which local facility DRLs were established as a quality improvement project to provide an additional assurance to the undertaking that examinations carried out at the facility adhered with the ALARA (as low as reasonable achievable) principle. This planned review was seen as an example of good practice at the facility.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical radiological procedures. Referral guidelines were available to referrers on the hospital's intranet. The inspector also observed a prompt to use these referral guidelines as part of the electronic platform for requesting medical radiological procedures. Inspectors also reviewed a sample of clinical audits carried out at the unit.

On the day of inspection, based on a sample of records reviewed and from speaking with staff, the inspector found that information relating to patient exposure did not form part of the report of medical radiological procedures. The inspector was informed that this non-compliance with the regulations had been identified and was on the risk register for Global Diagnostics Ireland. Management at Global Diagnostics Ireland also communicated to the inspector that they continued to engage with the supplier of their radiology information system picture archiving communication system (RIS PACS) platform and the HSE regarding steps to come into compliance with this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector was satisfied that an appropriate QA programme was in place to ensure that medical radiological equipment at the Global Diagnostics (Navan) was kept under strict surveillance. An up-to-date inventory was also provided to the inspector as requested in advance of the inspection.

Global Diagnostics (Navan) had implemented a quality assurance programme which included a quality assurance assessment annually by an MPE and regular testing of the CT equipment by radiography staff at the unit. Documentation reviewed on the day of inspection demonstrated that regular preventative maintenance and servicing by the equipment vendor was also routinely performed and a prospective maintenance schedule was in place. This provided an assurance to the inspector that the medical radiological equipment at the unit was maintained in good working condition.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the changing rooms and waiting areas at the facility. Radiographers were found to take responsibility for carrying out the inquiry of

patients' pregnancy status, where relevant, in line with the regulations. The inspector also reviewed a sample of referrals and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing.

However, on review of the *Patient Last Menstrual Period & Pregnancy Policy* the inspector noted that while efforts had been made to ensure alignment of this document with the regulations, an additional review is necessary to ensure that this policy fully aligns with the requirements of the regulations and accurately reflects day-to-day practice regarding clear allocation of responsibility for carrying out the pregnancy status inquiry at the unit.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Global Diagnostics Ireland had an electronic incident reporting system in place to record incidents and ensure relevant management are informed of all events involving or potentially involving accidental or unintended medical exposure to ionising radiation. The inspector reviewed the system for recording accidental and unintentional, or potential accidental or unintentional, exposures to ionising radiation and spoke with management and staff regarding the process for reporting at Global Diagnostics Ireland. Trending and analysis of potential incidents was available to the inspector for review and an incident reporting flow-chart was available to staff in the clinical area.

The inspector noted a recent issue where the pathway for reporting accidental or unintentional exposures to ionising radiation had not been adhered to at the unit. However, an investigation had been carried out and corrective actions implemented which provided an assurance to the inspector that Global Diagnostics Ireland had oversight arrangements in place to ensure that notifications of significant events would be reported to HIQA as required by the regulations.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Global Diagnostics (Navan) OSV-0006470

Inspection ID: MON-0038063

Date of inspection: 07/12/2022

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Documentation will be reviewed and published to ensure the roles and responsibilities of radiographers and radiologists as practitioners will be clearly defined and included in documentation and also reflected in the Justification Policy, to reflect the day to day practice. Clinical responsibilities will be clearly defined in the documentation.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Global diagnostics as a private entity are reviewing a range of dose software solutions and are in the final stages of decision making. As Navan CT machine is connected to the NIMIS system we are also awaiting advice from the NIMIS team and the HSE on plans to include the dose on the report automatically.	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:	

The Pregnancy and LMP policy will be reviewed and updated to reflect justification of exposures to comply with the feedback.
Where pregnancy cannot be ruled out but the examination is deemed urgent a re-justification process will be re-enforced to ensure that both patient and referrer sign to ensure the risks of the procedure are explained to the patient and they have given informed consent to proceed.
The Pregnancy and LMP policy will also be updated to clearly define who is responsible for justification of this process on-site.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/03/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	30/06/2023

	procedure.			
Regulation 16(2)	If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical radiological procedure involved, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.	Substantially Compliant		31/03/2023