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:	21 January 2020
Medical Radiological Installation Service ID:	OSV-0006470
Fieldwork ID:	MON-0028254

About the medical radiological installation:

Global Diagnostics Ireland is an Irish owned company 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) from 09:00 to 17:00 Monday to Friday and to allow access to the CT scanner for out-of-hours emergency scanning on a 24-hours a day, seven days a week (24/7) basis. 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.

Global Diagnostics (Navan) conducts approximately 5700 medical radiological procedures annually and provides services to patients in OLHN. Global Diagnostics (Navan) also accepts cross-site referrals from other Health Service Executive (HSE) hospitals such as Our Lady of Lourdes Hospital, Drogheda, Louth County Hospital, Dundalk and general practitioner (GP) referrals are accepted with the approval of a radiologist. A full range of CT examinations can be performed in Global Diagnostics (Navan) with the exception of dental CT. The Lead Radiologist in OLHN acts as the practitioner in charge for Global Diagnostics (Navan).

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 21 January 2020	09:00hrs to 16:00hrs	Kirsten O'Brien	Lead
Tuesday 21 January 2020	09:00hrs to 16:00hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors were satisfied that Global Diagnostics (Navan) had effective governance, leadership and management arrangements in place. There was a clear allocation of responsibilities and senior management had a coordinated approach to ensure the safe delivery of medical exposures. Global Diagnostics (Navan) was owned and managed by Global Diagnostics Ireland, a subsidiary of Centric Health. Day-to-day operations at Global Diagnostics (Navan) were managed by the Clinical Specialist Radiographer with support from the Radiology Services Manager (RSM), who is also responsible for other Global Diagnostics Ireland sites. The RSM reported directly to the Managing Director of Global Diagnostics Ireland who, as a member of the Executive Management Team, reported to the board of Centric Health and is a member of the Centric Health Board Quality Sub Committee. The Quality Committee assists the Board of Centric Health in ensuring appropriate oversight of patient safety, risk management and clinical and operational matters is maintained. A Radiation Safety Committee, of which the Managing Director is also a member, is incorporated into the internal governance structures of Global Diagnostics Ireland as an assurance mechanism for the radiation protection of service users. Inspectors were informed that any concerns and risks arising from the Radiation Safety Committee were escalated to the Executive Management Team and Centric Health Board through the Managing Director.

Radiologists, employed by both the Health Service Executive (HSE) and Global Diagnostics Ireland, take clinical responsibility for medical exposures performed at the facility. Due to the relationship that exists as a result of this arrangement, a dual reporting structure was in place. Following a review of documentation and communication with management, practitioners and other staff, inspectors were assured that Global Diagnostics Ireland had appropriate systems and processes in place to ensure the radiation protection of service users undergoing medical radiological procedures at Global Diagnostics (Navan).

While good management and governance structures were found to be in place, there were also areas of improvement identified during the inspection. While arrangements were in place to ensure that appropriately qualified and recognised individuals, such as practitioners, were involved in the radiation protection of service users, gaps in documentation were identified. For example, polices, procedures and other documentation did not always clearly define or fully reflect the roles and responsibilities of all persons involved in ensuring the safe delivery of medical exposures at Global Diagnostics (Navan). In particular, the role, responsibilities and level of involvement of the Medical Physics Expert (MPE) at Global Diagnostics (Navan) were not formally documented and this should be reviewed with regard to the Regulations.

Regulation 4: Referrers

Global Diagnostics (Navan) received referrals for computed tomography (CT) procedures from doctors working within Our Lady's Hospital, Navan, other HSE hospitals and general practitioners (GPs). Referrals were received primarily in electronic format, through the HSE National Integrated Medical Information System (NIMIS) Radiology Information System (RIS), Picture Achieving and Communications System (PACS), or in hard copy format from GPs. All referrals for medical radiological procedures reviewed on the day of inspection were from an identifiable registered medical practitioners. The referral policy and radiation safety procedures were reviewed and inspectors spoke with staff who demonstrated a good awareness and knowledge of the referral process in line with local policies and procedures.

Judgment: Compliant

Regulation 5: Practitioners

From the records of medical exposures reviewed on the day of inspection, inspectors where satisfied that only those entitled to act as practitioners in the regulations had taken clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Global Diagnostics (Navan) demonstrated that a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation was in place. Inspectors spoke with senior management, practitioners and other staff who could clearly outline and communicate organisational reporting structures. Policies, relevant committee terms of reference, and other documentation were also reviewed.

While the lines of governance and clinical oversight were clearly outlined over the course of the inspection, inspectors noted that there was a dual reporting structure with Our Lady's Hospital, Navan. This dual reporting system was due to the relationship between Global Diagnostics (Navan) and Our Lady's Hospital, Navan for the provision of CT procedures. Global Diagnostics Ireland should assure themselves that adequate processes are in place to ensure this joint reporting structure continues to function as intended, and that a clear understanding of the separation of responsibilities for the radiation protection of service users is maintained.

Judgment: Compliant

Regulation 10: Responsibilities

Through communication with staff on the day of inspection, inspectors were assured that all medical radiological procedures took place under the clinical responsibility of a practitioner, as defined in the regulations. Global Diagnostics (Navan) 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.

While inspectors found evidence that practitioners and persons entitled to carry out the practical aspects of medical radiological procedures were involved in the optimisation of medical exposures, limited evidence of MPE involvement was identified and management were informed of this on the day of inspection. Although inspectors spoke with staff who communicated and demonstrated email records of MPE involvement in the assessment and evaluation of patients doses, the role of the MPE in the optimisation process for medical exposures was not documented in policies or other documentation reviewed.

Radiographers were designated individuals to carry out the practical aspects of medical radiological procedures at Global Diagnostics (Navan). Inspectors were satisfied from records reviewed on the day, and from speaking with staff, that only radiographers registered with CORU, Ireland's multi-profession health regulator, carried out the practical aspects of CT procedures at the facility.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors communicated with staff on the day of inspection who informed them that Global Diagnostics (Navan) had access, if required, to medical physics expertise to ensure the continuity of medical physics expertise at the facility. Inspectors found that these arrangements were not formalised and documentation, including service level agreements and policies reviewed on the day of inspection, did not contain information about the arrangements in place to ensure the continued provision of medical physics expertise at Global Diagnostics (Navan) should the need arise.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Management and staff communicated to inspectors that an MPE registered on the Register of Medical Physics Expert was available to act or give specialist advice at Global Diagnostics (Navan). Inspectors reviewed policies, procedures and guidelines, records of communication and a service level agreement (SLA), and found that while there was evidence of MPE involvement or contribution as required by Regulation 20, it could be improved upon.

Staff spoken with on the day of inspection, indicated that the MPE was contactable as required. However, inspectors found that a formalised and documented process, outlining MPE involvement and their contribution to medical exposure, was not in place. While email communications reviewed showed that medical physics expertise could be accessed, the SLA between the MPE and Global Diagnostics (Navan) was for the provision Radiation Protection Adviser (RPA) rather than MPE services. Additionally, policies, procedures, guidelines and records reviewed did not include information about the role or responsibilities of a MPE. Global Diagnostics (Navan) should implement measures to assure themselves that MPE contribution to medical exposure of ionising radiation at the facility is fully compliant with the regulations.

Judgment: Substantially Compliant

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

Inspectors were informed that while Global Diagnostics (Navan) had access to a Medical Physics Expert (MPE) for consultation and advice as required, this availability was not documented. Medical Physics advice and expertise was provided under a service level agreement (SLA) which was in place for the provision of Radiation Protection Adviser (RPA) services to Global Diagnostics (Navan) rather than MPE services. As a CT service can potentially involve high doses to the patient, Global Diagnostics Ireland should review the current level of MPE involvement to ensure that a MPE is appropriately involved to ensure the safe delivery of medical exposure to ionising radiation.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Global Diagnostics (Navan) had appropriate systems and arrangements to ensure the safe delivery of medical radiological procedures. Inspectors found that a process was in place to ensure that medical radiological procedures carried out at the facility

were justified by a practitioner in advance. A radiologist reviewed all referrals and satisfied themselves that the procedure was the most appropriate for the service user, considering the risks and benefits of the medical exposure. Evidence was readily available to demonstrate compliance with this requirement of the regulations, and in doing so, Global Diagnostics (Navan) demonstrated good use of the Radiology Information System (RIS), Picture Achieving and Communications System (PACS) solutions available to them. Information relating to the risks and benefits associated with the radiation dose from a medical exposure was also provided to service users in the form of leaflets included with their appointment letter and additional information was available in the waiting room if required.

Inspectors also found that diagnostic reference levels (DRLs) were used as a tool to help ensure that medical exposures were appropriately optimised. DRLs were updated annually and clearly displayed in the CT control room. Written procedures for standard CT procedures carried out at Global Diagnostics (Navan) were also available to staff in the control room, in addition to other relevant policies, procedures and guidelines for Global Diagnostics staff. Additionally, Global Diagnostics (Navan) had a system in place to ensure that regular performance testing of their medical radiological equipment was carried out and the CT equipment was kept under strict surveillance as regards radiation protection.

Processes were in place to inquire as to the the pregnancy status of service users. However, while special attention was given to the justification of medical radiological procedures where pregnancy could not be ruled out, the role of the radiologist and or radiographer as a practitioner with responsibility for this step in the process was not clearly defined in documentation. Inspectors also found that information related to the medical exposure did not form part of the report of the medical radiological procedure.

On the day of inspection, while areas where identified where Global Diagnostics (Navan) must take actions to become fully compliant with some regulations, no significant risks to the safety, health and welfare of service users were identified.

Regulation 8: Justification of medical exposures

All referrals reviewed on the day of inspection were in electronic format and staff communicated with inspectors regarding the process for accessing previous diagnostic information using the HSE NIMIS RIS PACS. Staff spoken with on the day of inspection indicated that medical radiological procedures were only carried out when justified and vetted by a radiologist in advance. Records from a sample of medical radiological procedures carried out at Global Diagnostics (Navan) where reviewed during the inspection. These were all in writing, stated the reason for requesting the particular procedure, and were accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment. Additionally, all records reviewed demonstrated that justification in advance was recorded for all medical exposures through the NIMIS RIS PACS vetting module. Inspectors noted

that Global Diagnostics (Navan) had good systems in place to assure themselves that justification occurred in advance of the medical exposure, which included, but was not limited to, a six monthly computed tomography (CT) justification audit.

Global Diagnostics (Navan) provided leaflets containing information about the associated risks and benefits of medical radiological procedures to service users with their appointment letters. Information leaflets were also available in the Global Diagnostics (Navan) waiting area. Inspectors spoke with staff who indicated that they provided additional explanations to patients and other service users as required.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs for computed tomography (CT) examinations were established and reviewed annually. DRLs were displayed on a notice board in the control room. DRLs were also displayed at the CT console as an additional mechanism to raise awareness and promote use. On the day of inspection, there was evidence that appropriate reviews of patient doses occurred to ensure that the typical doses did not exceed the relevant DRLs. Inspectors were informed that Global Diagnostics Ireland were in the process of procuring a electronic dose management software to further assist with this process which could be seen as a positive quality improvement measure.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were available for medical radiological procedures performed at Global Diagnostics (Navan). Global Diagnostics Ireland had adopted referral guidelines which included information relating to patient exposure. Referrers were made aware of the availability of these for use when referring patients for medical radiological procedures to Global Diagnostics (Navan).

On the day of inspection, a sample of medical radiological procedure reports were reviewed and inspectors found that information relating to patent exposure did not form part of the reports of medical radiological procedures. Inspectors also communicated with staff and this finding of non compliance was acknowledged by senior management of Global Diagnostics Ireland.

Judgment: Substantially Compliant

Regulation 14: Equipment

Global Diagnostics (Navan) had an up-to-date inventory of medical radiological equipment at the facility. From evidence reviewed, inspectors were satisfied that medical radiological equipment at the facility was kept under strict surveillance regarding radiation protection. Global Diagnostics (Navan) had implemented and maintained a quality assurance programme and records reviewed by inspectors showed that a programme was in place to ensure regular performance testing was carried out as appropriate. A system was in place for reporting and recording equipment faults which included follow-up actions and an identifiable responsible person. Inspectors were informed that staff had access to the equipment manufacturer's support service to report faults and information relating to this was clearly displayed on a notice board in the control area.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and records relating to special protection during pregnancy were reviewed during the inspection. The electronic ordering system had a prompt in place to remind referrers that this inquiry was a mandatory requirement when referring for relevant medical radiological procedures. Inspectors noted that there were multilingual posters displayed in the changing area and scan preparation room of Global Diagnostics (Navan) to raise the awareness of individuals undergoing medical exposures of the need for special protection during pregnancy.

Inspectors were satisfied that inquiries as to whether the service user was pregnant had taken place and these inquiries were documented by the referrer or a radiographer. However, on review of documentation, inspectors found that policies and procedures did not accurately reflect who carried out the role of the practitioner in pregnancy determination where referrals were received from external referrers. While inspectors where satisfied that special attention was given to justification where pregnancy could not be ruled out, documentation reviewed did not accurately reflect the processes described by staff. Although not considered practitioners by Global Diagnostics (Navan), the radiographer's role in the establishment and recording of pregnancy status was clearly evident. Documentation should be updated to reflect regulatory requirements and local practice. Management at Global Diagnostics (Navan) indicated to inspectors that this policy was in the process of being updated.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Global Diagnostics (Navan) had policies and procedures in place, including a system for recording accidental and unintentional, and potential accidental and unintentional exposures. Inspectors found evidence that reasonable measures were taken to minimise the probability of accidental or unintended exposures. Documentation was also reviewed on the day which related to an investigation of a potential accidental or unintended exposure to minimise the probability of an actual incident occurring.

There was a clear reporting structure in place for the use of the equipment at Global Diagnostics (Navan). Inspectors noted that staff could clearly communicate the dual incident reporting structure that was in place between Global Diagnostics (Navan) and Our Lady's Hospital, Navan However, inspectors noted that there may be complexities with the overlap of responsibility should an incident arise at the site where responsibility was shared by both undertakings. Management at Global Diagnostics (Navan) should continue to ensure that the practical implementation of the reporting structure with Our Lady's Hospital, Navan continues to function as intended. Nevertheless, on the day of inspection, this did not present a safety concern to inspectors.

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	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially 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-0028254

Date of inspection: 21/01/2020

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 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: Global Diagnostics acknowledges the respective responsibilities of the undertaking, the practitioner, the medical physics expert, the referrer and persons entitled to carry out practical aspects for all medical exposures as set out in Regulation 10 and the need to clearly define these responsibilities in local policy. Global Diagnostics are in the process of reviewing and defining the role of their Navan CT medical physics expert (MPE) contract and duties, in line with regulation 10 requirements. The outcome of this review and an updated definition of the MPE role and responsibilities in Navan CT will be clearly documented in the MPE Service Level Agreement as well as the Navan CT Radiation Safety Procedures (RSPs) by 1st May 2020.	
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: Global Diagnostics acknowledges the vital role played by the medical physics expert in the optimisation of dose as a result of medical exposures in Navan CT and hence the requirement for an undertaking to put in place the necessary arrangements to ensure continuity of expertise for medical physics experts. Global Diagnostics are in the process of ensuring continuity of expertise for their medical physics expert in Navan CT in line with regulation 19 requirements. The MPE continuity and succession plan will be clearly documented in the Navan CT MPE Service Level	

Agreement as well as the Navan CT Radiation Safety Procedures (RSPs) by 1st May 2020.

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:
Global Diagnostics acknowledges that for computed tomography a named medical physics expert is required to be involved in such fashion as to meet the requirements of Regulation 20. Key activities of medical physics experts include advising and performing quality assurance activities on medical radiological equipment and reducing the risk to service users from medical exposures to ionising radiation.

Global Diagnostics are in the process of reviewing and defining the role of their medical physics expert contract and duties, in line with regulation 20 requirements. The outcome of this review and an updated definition of the MPE role and responsibilities in Navan CT will be clearly documented in the MPE Service Level Agreement as well as the Navan CT Radiation Safety Procedures (RSPs) by 1st May 2020.

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

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
Global Diagnostics acknowledges the required involvement of medical physics experts in medical radiological practices.

Global Diagnostics are in the process of reviewing and defining the role of their medical physics expert contract and duties, in line with regulation 21 requirements. An outline of the MPE's involvement in ensuring the safe delivery of medical exposure in ionising radiation in Navan CT will be clearly documented in the MPE Service Level Agreement as well as the Navan CT Radiation Safety Procedures (RSPs) by 1st May 2020.

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Global Diagnostics acknowledges the requirement under Regulation 13 to include information relating to patent exposure as part of the reports of medical radiological procedures for the service in Navan CT. Global Diagnostics have liaised with the National NIMIS team who have noted that, while NIMIS is not the lead on the systems solution, NIMIS will seek to implement the recommendations of the HSE Radiation Protection Committee regarding the latest SI 256 directive. Global Diagnostics is awaiting the committee's recommendation on the workflow and systems solution. The tentative timeline for compliance with this regulation is 31st December 2020. Global Diagnostics, as part of our CT service in Our Lady's Hospital Navan, will keep HIQA informed of any change to this timeline.	
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: Global Diagnostics acknowledges the requirement for arrangements for special protection for pregnant women or breastfeeding women in Navan CT that are supported by clear leadership, robust accountability arrangements and good communication. Global Diagnostics are in the process of implementing an updated pregnancy policy in Navan CT based on the relevant legislation and the National Pregnancy Policy (2017) which will ensure full compliance with regulation 16. This will be fully implemented and clearly documented in Global Diagnostics' Patient Last Menstrual Period and Pregnancy Awareness Policy by 1st May 2020.	

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 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Substantially Compliant	Yellow	01/05/2020
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	31/12/2020
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	Substantially Compliant	Yellow	01/05/2020

	given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.			
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	01/05/2020
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Substantially Compliant	Yellow	01/05/2020
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics	Substantially Compliant	Yellow	01/05/2020

	expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation			

	protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	01/05/2020
Regulation 21(2)(b)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c), a medical physics expert shall be involved, and	Substantially Compliant	Yellow	01/05/2020