



**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:	Mater Private Cork
Undertaking Name:	Mater Private Hospital
Address of Ionising Radiation Installation:	City Gate, Mahon, Cork
Type of inspection:	Announced
Date of inspection:	26 October 2021
Medical Radiological Installation Service ID:	OSV-0007969
Fieldwork ID:	MON-0033541

About the medical radiological installation:

The Mater Private Hospital Cork provides a full cardiology service at the Mahon location. Consultant cardiologists provide the cardiology service at the Mater Private Cork which is listed as an installation of the Mater Private undertaking. Radiology services (CT, general radiology, interventional radiology) are contracted to a third party undertaking operating at the same location. The cardiology service is provided in conjunction with the third party radiography service who operate under a service level agreement with Mater Private Cork.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. 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 October 2021	10:05hrs to 15:54hrs	Kay Sugrue	Lead
Tuesday 26 October 2021	10:05hrs to 15:54hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

Following discussions with staff and review of documentary evidence by inspectors, it was demonstrated that there were established radiology governance, leadership and management arrangements in place at the Mater Private Cork. The hospital had a facility specific governance structure that reported upwards to an overarching governance structure of the Mater Private Hospital Network which is the entity declared as the undertaking to HIQA. Inspectors found that there were two co-located undertakings providing radiological services within the hospital, the Mater Private Cork provided interventional cardiology procedures from its interventional cardiology suite while the remainder of onsite radiology services were provided by another undertaking. Radiographer services were contracted by the Mater Private Cork from the co-located undertaking for interventional cardiology procedures. Medical physics expertise (MPE) services were provided by the the Mater Private Hospital Network (the undertaking) to both the Mater Private Cork and also contracted by the co-located undertaking. Reporting arrangements within these higher governance structures were understood by staff who spoke to inspectors.

Inspectors were satisfied there were systems and processes in place to ensure that only persons recognised by regulations were entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. The hospital had also established practices to ensure a radiographer was present with the cardiologist for all medical exposures conducted in interventional cardiology suite. Inspectors spoke with MPEs and found that the hospital was compliant with respect of regulatory requirements to ensure the continuity of MPE services, ensure MPE responsibilities as per regulations were met and that the level of MPE involvement was proportionate to the medical radiological risk of the service.

While inspectors were satisfied that the right professionals were involved in the conduct of medical exposures within interventional cardiology service, the allocation of individual roles and responsibility for the radiation protection of service was not so clear in documentation viewed. For example, inspectors found that more clarity was required in delineating the role and scope of persons entitled to act as practitioners in local procedures that accurately aligned with day-to-day practices during interventional cardiology procedures. In addition, inspectors found that radiation safety procedures developed by the co-located undertaking and adopted for use in the Mater Private Cork were generic in nature, did not define the scope to which they could be applied and were not fully aligned to interventional cardiology practices. The ambiguity presented in documentation reviewed by inspectors was also reflected in conversations with staff.

While the gaps in documentation did not present a radiation risk to the service user, it did however, impact compliance with Regulation 6(3) and Regulation 10(1). Hospital management acknowledged there was a need to improve documentation

following this inspection to provide greater clarity for staff working in the service and ensure compliance with regulations.

Regulation 4: Referrers

From discussions with radiology staff and records viewed by inspectors, it was clear that the referrer for medical radiological procedures conducted in the interventional cardiology suite were requested by the interventional cardiologists performing the requested procedure. Inspectors were informed that patients referred externally or inpatients were reviewed by a cardiologist prior to the procedure. Inspectors were satisfied that the undertaking met the requirements of this regulation.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only persons recognised by Regulation 5 could act in the role of practitioner for the conduct of medical exposures in the cardiology interventional radiology service. While it was clear that aspects of the the practitioner role were shared between the cardiologist and the radiographer, the roles for each were not clearly delineated in documentation viewed or clearly articulated in discussions with staff. This finding was acknowledged by hospital management and accepted as a focus for improvement following on from this inspection.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation, prior to, and during the inspection and spoke with several members of staff and hospital management. From documentation viewed and discussions with staff and management, inspectors found that there were dual governance arrangements in place to ensure that relevant information was communicated to the appropriate undertaking. The hospital had its own multidisciplinary Radiation Safety Committee (RSC) with representation from both undertakings operating within the facility. There was appropriate clinical representation at this forum including the Lead Cardiologist. Inspectors found that co-located undertakings for radiology services at the Mater Private Cork resulted in complex governance arrangements with shared services across two undertakings. For example, the Mater Private Hospital Network was the undertaking for

interventional cardiology services undertaken at the Mater Private Cork. However, hospital management informed inspectors that the hospital was a separate entity with its own local management structure which reported separately to the board of Mater Private Hospital Network. All other radiology services at the hospital were provided by a co-located undertaking. This company was engaged by the hospital to provide radiographers for its interventional cardiology services. Inspectors were informed that the hospital owned the radiological equipment which was licensed for use by the co-located undertaking. Medical Physics services were provided by the Mater Private Hospital Network to both co-located undertakings operating within the hospital.

While staff were aware of governance structures and reporting lines within each of the co-located undertakings at the hospital, the allocation of responsibility for individual roles for the radiation protection of service users in day-to-day practices were not as clearly understood. Inspectors found that there was a lack of clarity in the documentation viewed in relation to the allocation of responsibility for various aspects of medical exposures conducted within the interventional cardiology services provided by the Mater Private Cork. Delineation of specific roles and responsibilities was not clearly outlined in these documents and this lack of clarity with respect of these roles was also evident in discussion with staff during the inspection. Inspectors were informed that the hospital had adopted its Radiation Safety Policy from the co-located undertaking however, this policy did not clearly set out the scope to which the policy could be applied and did not fully align with practices and roles described in interventional cardiology services provided by the hospital. For example, it was not clear from documentation viewed or discussions with staff if cardiologists performing interventional cardiology procedures were recognised as practitioners. Inspectors were informed by staff that 'the operator' in the cardiology interventional suite was the screening cardiologist, although this term does not align with the roles and responsibilities as per the regulations. Further documentation provided to inspectors during the inspection identified that the radiographer and cardiologist shared the responsibility for the justification of interventional cardiology medical radiological procedures indicating that the role of practitioner was shared. Hospital management accepted that improvements were required with respect of documentation outlining the allocation of responsibility as required by Regulation 6(3) to provide greater clarity for staff working in the service.

Overall, while findings related to documentation viewed demonstrated a certain ambiguity which impacted overall compliance, inspectors were satisfied that this finding did not present a radiological risk to service users. Inspectors found that in order to achieve full compliance with this regulation, the hospital needs to review current documentation to ensure that the allocation of responsibility for radiological practices with interventional cardiology service is reflective of day-to-day practices. In addition, the hospital must ensure that all staff working in the service are fully aware of their individual roles and responsibilities in line with regulatory requirements.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that all medical exposures were performed under the clinical responsibility of a practitioner recognised under regulations. Inspectors spoke with a cardiologist who outlined their practitioner role and responsibility which included involvement in the justification through the referral process, conduct of the procedure in the presence of a radiographer, optimisation of the procedure and clinical evaluation of the outcome. However, documentation viewed by inspectors did not fully align with practices described and therefore should be reviewed and updated to clearly define practitioner roles and responsibilities to provide clarity to staff working in the service.

It was clear to inspectors from discussions that practitioners, radiographers and an MPE as per regulations were involved in optimisation. Similarly, recognised referrers and practitioners were involved in justifying procedures conducted in the hospital's interventional cardiology service.

It was policy and practice within the Mater Private Cork that a radiographer was present for the practical aspects of all medical radiological procedures conducted within the interventional cardiology service providing additional assurances relating to the radiation protection of service users. However, inspectors were not fully assured from discussions with staff if there was complete clarity around the delegation of practical aspects and this should be addressed following the inspection to ensure all staff involved in each procedure are clear as to individual roles and responsibilities.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The undertaking had arrangements in place to ensure the continuity and access to MPE services and therefore met the requirements of this regulation.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions and documentation viewed, inspectors were satisfied that the hospital had arrangements in place to ensure there was appropriate involvement and contribution of MPEs as required by regulations.

Inspectors were satisfied that the MPEs were involved in all aspects of medical

exposures as per the regulations. These aspects included quality assurance of medical radiological equipment, dosimetry and optimisation including the application and use of DRLs. Radiation protection training for staff was planned for November 2021. There was evidence to demonstrate that there was MPE representation on the RSC. Inspectors were informed that medical physics were involved in the analysis of significant events.

Judgment: Compliant

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

From documentation viewed and discussions with MPEs, inspectors were satisfied that the undertaking was compliant with this regulation. Inspectors found that MPE involvement in medical radiological practices was evident and the level of involvement provided at the hospital was commensurate with the radiological risk posed by the practice. In addition, staff outlined that MPEs were regularly on site and were available for consultation and advice on matters relating to radiation protection concerning medical exposure.

Judgment: Compliant

Safe Delivery of Medical Exposures

From documentation reviewed and discussions with staff, inspectors were satisfied that staff were committed to improving the radiation protection of service users by ensuring that medical radiological procedures conducted within the interventional cardiology service were kept as low as reasonably achievable. This included evidence of the use and regular review of diagnostic reference levels (DRLs) applied within the service and written protocols for each type of procedure.

Good practices were noted by inspectors in relation to the attention given to the assessment of dose for high dose interventional cardiology procedures where there is a potentially higher risk of tissue reaction outcomes for the service user. Although such occurrences are relatively rare, the processes in place described by staff to inspectors provided assurance of appropriate patient follow up where dose thresholds are reached or exceeded. Inspectors were also satisfied on the hospital's compliance with the requirements of Regulation 17 ensuring that there were appropriate processes in place to identify, record and report any significant events involving tissue reactions as a result of interventional cardiology or indeed any other event meeting the criteria for reporting. A process for tracking and trending of all radiation safety incidents and near misses was also evident on review of

documentation.

An up-to-date inventory and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance (QA) programme was in place and that medical radiological equipment within the interventional cardiology suite was kept under strict surveillance.

Inspectors found good practices on the provision of information relating to the benefits and risk associated with the radiation dose from the medical exposure which was provided during the consent process for each procedure. Inspectors noted supplementary information was also available to service users included in pregnancy posters and in relation to information on interventional procedures displayed in patient recovery and waiting areas. Information relating to the medical exposure formed part of the report for each medical radiological procedure as per regulations.

An area of non-compliance was identified by inspectors in relation to the documentary requirements of the referral process and record of justification. Inspectors found that the process for referring individuals for interventional cardiology procedures needed to be reviewed to ensure that referrals for medical radiological procedures contain sufficient medical data and state the reason for requesting the particular procedure as per Regulation 8(10). Referrals should be readily accessible to radiographer practitioners at the point of care when undertaking pregnancy status assessment and justification. Compliance with Regulation 8(15) was also an area which required improvement. The undertaking should ensure that there is a system and process in place to ensure that records evidencing compliance with Regulation 8 are available to HIQA on request. Furthermore, inspectors found that the service could benefit from a DRL policy specific to the service which was not evident on the day of the inspection.

Overall, inspectors found that there was a strong multidisciplinary approach and a positive culture demonstrated by staff towards the radiation protection and safety of service users undergoing interventional cardiology procedures at the Mater Private Cork. Non-compliances with regulations identified by inspectors related mainly to documentation gaps which when addressed should offer greater support to staff working in the service and ensure full compliance with the requirements of the regulations.

Regulation 8: Justification of medical exposures

Inspectors viewed patient records which demonstrated that information relating to the benefits and risks associated with radiation was provided to patients as part of the consent process. Inspectors observed posters in each patient bay area which provided service users with information relating the radiological risk from a specific interventional cardiology procedures provided in the service.

However, inspectors found from documentation viewed and discussions with staff

that improvements were required to ensure that written referrals were available which stated the reason for the request accompanied by sufficient medical data. Improvements were also required with respect to the documentation of justification in advance as required under this regulation. Inspectors were informed on the day of the inspection that justification was a collaborative approach shared between the screening cardiologist and the radiographer involved in the practical aspects of the medical exposure. The booking form was understood by staff to be the referral document for interventional cardiology procedures. However on review of this record, inspectors were not satisfied that the information contained in records reviewed fulfilled the requirements as set out in Regulation 8 (10), in that, the reason for requesting the particular procedure was not evident and did not include sufficient medical data to enable a justification assessment. In addition, a written referral with appropriate clinical data or reason for the request, was not readily accessible to radiographer practitioners either in hard copy or scanned onto the Radiology Information System (RIS) as a point of reference when undertaking a justification assessment. This issue had been previously highlighted as a potential gap in regulatory compliance in May 2021 RSC minutes which were viewed by inspectors. Staff acknowledged that the referral process differed significantly from the normal referral request process in general radiology services provided at the hospital.

Inspectors identified that the roles and responsibilities in relation to aspects of the justification process were neither fully outlined in local procedures nor clearly understood by staff who spoke with inspectors. From patient records reviewed and from speaking with staff, it was clear to inspectors that an interventional cardiologist oversaw and reviewed patient assessment prior to planning a procedure and thus justified the procedure. However, while this process demonstrated that a referrer recognised by the regulations contributed to the justification process, scenarios presented to inspectors did not provide clarity on the role of radiographer practitioners in justifying procedures or how justification in advance was recorded by radiographers when reviewing patients prior to undergoing medical exposures.

From the processes and systems viewed, inspectors were also not assured that records evidencing compliance with Regulation (15) could be readily accessed should they be requested by HIQA or required for auditing compliance with this regulation. Overall, inspectors identified that documentation relating to the referral process and the record of justification should be reviewed and updated to ensure compliance with Regulations 8(8), 8(11) and 8(15).

Judgment: Not Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff including radiographer, the MPE and an interventional cardiologist. To ensure the radiation protection and safety of patients, the hospital had a policy whereby non-radiological specialists such as

interventional cardiologists only performed medical exposures in the presence of a radiographer. Inspectors found from practices described by staff that the cardiologist and radiographer worked collaboratively to ensure optimisation of the practical aspect of interventional cardiology procedures. For example, medical exposures were performed using collimation, low dose frame rates and specific angulations as per best practice. Inspectors were informed that average fluoroscopy times were kept as low as possible to capture images and non-radiation intravascular imaging was frequently utilised to help reduce patient exposure to ionising radiation. For patients undergoing multiple procedures, where possible, different angulations were used in additional sessions to reduce the risk of skin injury. Furthermore, staff informed inspectors that there they worked closely with the service vendor to help reduce patient doses. Overall, these examples demonstrated strong evidence of good practice related to the optimisation of exposures at Mater Private Hospital, Cork.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that there was a system and process in place for the establishment of DRLs within the interventional cardiology service at the Mater Private Cork. Local facility DRLs for common interventional cardiology procedures were established in January 2021. Inspectors observed these facility DRLs displayed on the walls of the control room in the interventional cardiology suite. A colour coded traffic light system was used to alert staff on threshold doses that required reporting and follow up.

Inspectors were informed that interventional cardiology DRLs were reviewed twice a year and circulated in anonymised way to each of the cardiologists working in the service. Staff informed inspectors that variances in local DRLs were within normal parameters.

Although there was a strong culture of learning from the ongoing review of DRLs, inspectors noted that the hospital could benefit from a DRL policy for interventional cardiology outlining the process for the establishment, review and application of DRLs and the process followed to ensure appropriate reviews and corrective action are taken in instances where typical doses are exceeded for a given procedure or examination.

Judgment: Substantially Compliant

Regulation 13: Procedures

Imaging protocols for each interventional cardiology procedures were evident and developed in consultation with each cardiologist to include individual specifications. Inspectors noted that there were multiple electronic platforms accessible to radiography staff working across the two co-located undertaking radiology services which required individually assigned access to retrieve information. The streamlining of access for these platforms was a potential area for improvement for the undertaking identified by inspectors.

Referral guidelines were accessible on electronic platforms on control room desktop computers. Inspectors viewed patient records and were satisfied that information relating to dose exposures were readily accessible and transferred electronically on to the report of each procedure.

From documentation viewed and discussions with staff, inspectors were satisfied that clinical audit was conducted within the interventional cardiology service provided by the hospital and audit results were discussed at the RSC.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection. It was noted that medical radiological equipment in the interventional cardiology suite was identified as having reached its nominal date of replacement and inspectors were informed that this had been escalated through governance structures of Mater Private Hospital Network to the board. From the documentation reviewed and discussions with staff, inspectors were satisfied that there were appropriate QA and quality control programmes in place which was maintained appropriately and up-to-date. The system for reporting equipment faults was consistently articulated by staff and coincidentally service engineers were onsite to support the service at the time of the inspection. Where relevant, service on radiological equipment was subject to review and QA by an MPE which was evident in a recent X-ray tube replacement carried out in October 2021.

Judgment: Compliant

Regulation 15: Special practices

Inspectors were satisfied that special attention was given to the assessment of the radiation dose received by patients subject to interventional cardiology procedures at the hospital. Staff described a process for the management and appropriate follow up of patients exposed to potentially high skin doses during complex interventional radiology procedures which utilised recognised dose thresholds as

triggers to follow up patients within defined timelines. The systems in place had an automated alarm alerting staff when absolute thresholds were reached. A high dose flow chart was observed identifying the process to be followed. Inspectors were satisfied that a proactive approach was taken by the cardiologist in informing patients of potential associated radiation risks prior to procedure, that patient doses were routinely monitored by a radiographer during the procedure, and patients were appropriately reported and followed up as required.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors found from review of documentation and from speaking with staff that there was established systems in place for the reporting and analysis of accidental and unintended exposures and significant events. Incident reports viewed demonstrated that all radiation incidents and near misses were tracked and trended and communicated to the appropriate undertaking via dual reporting structures. Staff who spoke to inspectors consistently articulated and demonstrated a clear knowledge on the reporting process.

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	Substantially 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	Not Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mater Private Cork OSV-0007969

Inspection ID: MON-0033541

Date of inspection: 26/10/2021

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The hospital has held a number of meetings involving both entities and have designed a joint allocation of responsibilities document for the CATH Lab to reflect the governance outlining individual roles and responsibilities for radiation protection. We have also developed a summary of practitioner's responsibilities document outlining responsibilities of practitioners at each stage of the patient procedure. This contains a signature page for staff to indicate that they have understood and agreed the individual roles and responsibilities. It has been agreed with the co-located undertaking that the overarching radiation safety procedures shall be amended to include site specific details for the CATH Lab of Mater Private Network Cork.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: The summary of practitioner's responsibility document explicitly defines practitioner's roles and responsibilities. This will be circulated to the relevant staff to be signed to acknowledge their understanding and agreement on their roles.</p>	
Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
 The existing Booking Form has been reviewed and is to be amended to include sufficient medical data to enable a justification assessment. A change in process is in progress to allow this form to be available to the radiographer prior to the patient procedure. This Page 18 of 22 will enable the radiographer practitioner to justify each procedure and document the justification on RIS.

Regulation 11: Diagnostic reference levels	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
 A DRL Policy is to be developed by the co-located undertaking consistent with other co-located operational documentation in use in the CATH Laboratory. This will be based on HIQA's published guidance from July 2021.

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	31/01/2022
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	31/01/2022

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Substantially Compliant	Yellow	31/01/2022
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Yellow	31/01/2022
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Yellow	31/01/2022
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any	Substantially Compliant	Yellow	31/01/2022

	medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Yellow	31/01/2022
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	31/01/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	31/01/2022

