



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 Hospital
Undertaking Name:	Mater Private Hospital
Address of Ionising Radiation Installation:	Eccles Street, Dublin 7
Type of inspection:	Announced
Date of inspection:	27 April 2021
Medical Radiological Installation Service ID:	OSV-0007398
Fieldwork ID:	MON-0031298

About the medical radiological installation:

The Mater Private Network provides a full diagnostic radiology, nuclear medicine, cardiology, PET/CT and radiotherapy service at the Mater Private Hospital, Eccles Street for inpatients, outpatients, emergency and day-care department patients.

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 27 April 2021	09:30hrs to 14:30hrs	Kirsten O'Brien	Lead
Tuesday 27 April 2021	09:30hrs to 14:30hrs	Agnella Craig	Support
Tuesday 27 April 2021	09:30hrs to 14:30hrs	John Tuffy	Support

Governance and management arrangements for medical exposures

On this inspection, inspectors reviewed documentation from the radiology, radiotherapy and interventional cardiology departments at the Mater Private Hospital. Inspectors also visited and spoke with staff and management in these areas.

From the evidence gathered, inspectors found that there was effective leadership, governance and management arrangements in place at the Mater Private Hospital. The Mater Private Group Chief Operating Officer (COO) was the designated person responsible for radiation protection for the hospital and sat on the Radiation Safety Committee (RSC). The hospital's RSC, was co-chaired by a consultant radiologist and consultant radiation oncologist and reported to the Board of Directors through the QUEST Committee and the Group Board Quality and Patient Safety Committee. Based on the membership, the terms of reference, and the minutes of the RSC meetings reviewed, inspectors were satisfied that this committee provides an effective mechanism to ensure appropriate oversight of medical radiological procedures at this installation.

From the documents and records reviewed, and staff spoken with, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were assured that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Additionally, the Mater Private Hospital had retained radiographers to carry out the practical aspects of medical radiological procedures in areas outside the radiology and radiotherapy departments. In the absence of new training requirements from the relevant professional regulators, as specified in Regulation 22, this is viewed as good practice in ensuring the radiation protection of patients undergoing medical exposure to ionising radiation at the hospital.

Inspectors were informed of the process in place to ensure involvement and continuity of medical physics expertise at the Mater Private Hospital. From the documentation reviewed inspectors were assured that the level of involvement of Medical Physics Experts (MPEs) was proportionate to the level of radiological risk at the installation and that the MPEs took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Although the overarching governance structures at the hospital provided assurance of the radiation protection of service users, local policies should be updated and communicated to staff to clearly specify the roles and responsibilities of personnel involved in the day-to-day aspects of medical radiological procedures in the radiology and interventional cardiology departments. In particular, the allocation of clinical responsibility for justifying medical radiological procedures to radiographers and cardiologists was not clearly and consistently outlined in documentation reviewed by inspectors. Inspectors did note that documentation in the radiotherapy

department clearly defined the involvement of radiation therapists and their role as practitioners in justifying particular individual medical exposures, such as imaging to verify treatments.

Overall, from the systems and processes in place in the Mater Private Hospital, notwithstanding the documentation issues noted above, inspectors were assured of the governance and management of this medical radiological installation to ensure the safe delivery of medical exposure to ionising radiation at the hospital.

Regulation 4: Referrers

On the day of inspection, all referrals reviewed by inspectors were from referrers as defined in the regulations.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Documentation explaining the governance structures in place for the radiation protection of service users within the Mater Private Hospital were reviewed by inspectors. Inspectors also spoke with staff and managements at the hospital and were assured the undertaking had good structures in place to ensure oversight of all medical exposures conducted within the Mater Private Hospital. The hospital had also ensured that accountability of individual consultants that work in the hospital had been incorporated into the governance and oversight structures of the Mater Private Hospital for the purposes of ensuring compliance with these regulations.

The Group COO was the designated manager with day-to-day operational responsibility for all areas that conducted medical radiological procedures at the hospital. Managerial oversight of all areas by the Group COO was facilitated through an Executive Committee which meets on a weekly basis. Additionally the RSC, which meets twice a year, provided additional oversight and was found to be the main forum for governance for all areas that carried out medical exposures at the hospital. Inspectors reviewed minutes of RSC meetings and found that issues

affecting equipment, quality assurance (QA), clinical audit, patient doses, training and radiation incidents were discussed at these meetings. The RSC had representation on, and reported into the QUEST Committee which met on a monthly basis. The radiotherapy department's radiation audit committee was also represented through QUEST committee membership, in addition to its direct reporting role to the RSC. The QUEST Committee in turn reported to the Group Board Quality and Patient Safety Committee. However, inspectors noted that the undertaking representative, declared to HIQA, was not a member of the board of the Mater Private Hospital. The undertaking representative should be reviewed by the Mater Private Hospital to ensure that the undertaking representative is at an appropriately level to represent the legal entity of this undertaking.

The hospital had measures in place to ensure that only individuals, as defined in the regulations, were allocated responsibility as a practitioner for medical radiological procedures and this was clearly identified in the documentation available for the radiotherapy department. However, inspectors found that all day-to-day practices did not fully align with the hospital's policies regarding individuals that were allocated aspects of clinical responsibility, for example justification of medical exposures in the radiology and interventional cardiology departments. In order to be fully assured, it is important that policies, procedures and guidelines clearly define the allocation of clinical responsibility to practitioners for all medical radiological procedures at the Mater Private Hospital.

Overall, inspectors were satisfied that the overarching allocation of governance arrangements and responsibility for the radiation protection of service users was documented and clearly communicated on inspection. However the Mater Private Hospital should ensure that all documentation accurately and consistently reflects day-to-day practice in respect of the allocation of roles and responsibilities for the radiation protection of service users.

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, medical physics experts, and those entitled to carry out the practical aspects were found to be involved in the optimisation process for medical exposure to ionising radiation. Additionally the practical aspects of medical radiological procedures were only carried out at the Mater Private Hospital by individuals entitled to act as practitioners in the regulations.

As an additional assurance the Mater Private Hospital had retained the presence of a radiographer or a radiologist for the practical aspects of all medical radiological procedures conducted outside the radiology department, typically in theatre and interventional cardiology suites. In the absence of new training requirements being

implemented, as per Regulation 22, this was viewed as a positive additional radiation protection mechanism for service users at the hospital.

Inspectors were satisfied that the Mater Private Hospital had ensured that referrers were involved in the justification process. Additionally, the radiotherapy department's imaging policy included information about the role and responsibilities of radiation therapists in performing adapted and secondary referrals. Similarly, this policy included a clear delineation of what aspects of clinical responsibility were allocated to senior and clinical specialist radiation therapists as practitioners in the Mater Private Hospital.

However, while inspectors were assured that only practitioners as defined in the regulations were involved in the justification process, policies and procedures reviewed did not fully align with day-to-day practices communicated to, and observed by, inspectors in the radiology and interventional cardiology departments. For example, there was a lack of consistency regarding the roles and responsibilities of radiographers and cardiologists in respect of justification of individual medical exposures. Documentation should clearly identify the allocation of roles and responsibilities to ensure that day-to-day practices and local policy reflect each individuals' scope of practice locally.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from communication with staff and a review of relevant policies and other records, that the Mater Private Hospital had adequate processes in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff at the hospital and were satisfied that the Mater Private Hospital had arrangements in place to ensure that the involvement and contribution of MPEs was in line with the requirements of Regulation 20.

MPEs in radiology, interventional cardiology and radiotherapy were found to take responsibility for dosimetry and gave advice on medical radiological equipment. Records reviewed by inspectors also demonstrated that MPEs had contributed to QA and acceptance testing and were involved in optimising medical exposures in the hospital. Additionally, MPEs were involved in providing training in the area of

radiation protection to staff at the hospital.

Judgment: Compliant

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

The Mater Private Hospital had mechanisms in place to ensure that MPEs were appropriately involved in medical radiological procedures. MPEs were found to be appropriately involved in all aspects of medical exposure to ionising radiation conducted at the hospital, in line with the level of radiological risk at this installation.

Judgment: Compliant

Safe Delivery of Medical Exposures

The Mater Private Hospital had implemented an electronic platform to record justification of medical exposures in advance in the radiology department. Inspectors were also satisfied that medical radiological procedures in the radiotherapy and interventional cardiology department were also justified in advance by a person entitled in the regulations to take clinical responsibility for justification. On the day of inspection, only radiographers, radiologists, radiation therapists, radiation oncologists and, where appropriate, specialist consultant medical practitioners such as cardiologists, were found to justify medical radiological procedures.

The hospital demonstrated a strong multidisciplinary approach to improve the optimisation of medical radiological procedures. Diagnostic reference levels (DRLs) were reviewed at least annually, and radiation doses in some areas typically associated with higher radiation doses, such as interventional cardiology, were reviewed on a more regular basis. This special attention to the assessment of dose in such areas was noted as an area of good practice. In the radiotherapy department inspectors were assured that treatments were optimised by individually planning all exposures to the target area, verifying the dose to this area while reducing the dose to nearby organs as much as possible, and ensuring the dose was delivered consistently.

Clinical audit is a key tool in providing assurances to the hospital that all medical exposures are carried out safely and in compliance with the regulations. Inspectors found a culture of clinical audit of medical exposures was embedded in the Mater Private Hospital. Inspectors saw examples of quality improvement initiatives in radiotherapy aimed at optimising the exposure given to patients. A quality improvement initiative reviewed by inspectors focused on the use of spacers in prostate cancer patients, which sought to reduce the dose to organs surrounding

the prostate during treatment. Quality improvement initiatives carried out in the interventional cardiology and radiotherapy departments were viewed as positive indicators of compliance with Regulation 15 to ensure the safe delivery of medical radiological procedures at the installation. In particular inspectors found that the identification and follow up of patients by the hospital where pre-defined radiation dose thresholds were exceeded in interventional cardiology was a particularly positive measure and demonstrated a proactive and commendable approach to the patient safety.

A good incident reporting culture for medical exposures at the installation was facilitated by the availability of a hospital-wide electronic incident reporting system and a weekly hospital-wide incident meeting. Inspectors were satisfied that all incidents and potential incidents involving medical exposures were recorded and analysed to identify trends. Inspectors noted that where trends were identified these were escalated through the RSC and governance structures, as appropriate.

Overall, inspectors were assured that the Mater Private Hospital had good systems in place to support the safe delivery of medical exposures at this installation.

Regulation 8: Justification of medical exposures

The Mater Private Hospital currently receives referrals from both internal and external sources. Only persons as per Regulation 4 are entitled to refer for medical radiological procedures at the Mater Private Hospital. All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

On the day of inspection, inspectors spoke with radiographers, radiation therapists and other practitioners who explained how medical exposures are justified in advance of the medical exposure. Inspectors also noted that the referral and justification process in radiology and interventional cardiology had been identified by the hospital as an area for improvement. Results of a recent clinical audit of the referral process demonstrated improvements in adherence to local policies and procedures and provided assurances that the Mater Private Hospital had mechanisms in place to ensure that all referrals were appropriately justified by a person entitled to act as a practitioner in the regulations.

Inspectors observed the process for recording the justification of medical radiological procedures in radiology using an electronic platform. This platform allowed the practitioner taking clinical responsibility for justification to document their decision in advance of the medical exposure being conducted. Similarly, the process of justifying the pre-treatment computed tomography (CT) scans in the radiotherapy department was explained to inspectors. The process of recording this justification on an electronic system was also observed for a number of patients' records.

Inspectors reviewed information about radiotherapy available for patients and were informed that the radiation oncologists provided information to all patients on the benefits and risks of treatment as part of the consent process and this process was documented in their charts. Information about the benefits and risks associated with the radiation dose from medical exposures in radiology and interventional cardiology was available to patients in the form of leaflets and on the hospital's website. Inspectors were also informed that patients undergoing interventional cardiology procedures were provided with additional information about the risks and benefits of the medical radiological procedure during the consent process.

Judgment: Compliant

Regulation 9: Optimisation

The optimisation of medical exposures for patients undergoing radiotherapy was discussed with staff on the day of inspection. Further documentation relevant to the optimisation process of radiotherapeutic procedures was reviewed by inspectors, including documentation about QA testing and the process for assessing and verifying patient doses. Documentation specific to the optimisation process for patients undergoing treatment for areas such as breast and prostate cancer was also reviewed. Inspectors were assured that treatments are optimised by individually planning all exposures to the target area, while reducing the dose to nearby organs as much as possible and ensuring the dose is delivered consistently.

The results of a reject and repeat analysis which was conducted to determine if adequate diagnostic information was consistently produced in radiology were reviewed by inspectors who noted that findings were disseminated on notice boards in clinical areas and communicated to staff to improve practice. Inspectors also reviewed information leaflets and spoke with staff and were assured that written instructions were provided to patients before leaving the nuclear medicine department about how to restrict radiation doses to persons in contact with the patient.

Furthermore, inspectors reviewed records and spoke with staff, including radiographers, the MPE and interventional cardiologists and found that staff at the Mater Private Hospital optimised the practical aspects of interventional cardiology procedures. For example, the default frame rate or speed of acquiring X-ray images in cardiology examinations were reduced to ensure that doses were kept as low as reasonably achievable for patients attending the service. Inspectors also noted that interventional cardiology doses were routinely discussed at the RSC.

Inspectors viewed the additional and proactive measures to optimise medical exposure to ionising radiation taken by the Mater Private Hospital through a multidisciplinary approach as good practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Diagnostic reference levels (DRLs) have been established for radiological procedures in this hospital and were compared to national levels. On the day of inspection, inspectors spoke with staff and reviewed documentation and policies and were satisfied that DRLs were regularly reviewed and used in the optimisation of medical radiological procedures at the hospital. In particular, inspectors found that radiation doses in interventional cardiology were reviewed monthly and compared to relevant DRLs to ensure that procedures were optimised adequately for the protection and safety of patients.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written protocols for routine examinations conducted in the radiology and radiotherapy departments.

A sample of reports for radiology and interventional cardiology procedures were reviewed by inspectors who were assured that information relating to patient exposure was included on all reports. The inclusion of information relating to patient exposure on all reports in these areas was facilitated through an automated electronic output of the exposure directly onto the report of each medical exposure. In radiotherapy, inspectors found that information relating to the overall treatment dose was included in a letter sent to the referring team.

A positive culture towards conducting clinical audit at the hospital was noted by inspectors. Inspectors were informed the hospital's quality team validated findings of clinical audits and set improvement targets to facilitate quality improvement initiatives. In the radiology and interventional cardiology departments, clinical audits such as reject and repeat analysis, referral audits and reviews and trending of radiation dose received by patients were reviewed by inspectors. In radiotherapy, audits conducted included reviewing the frequency of images for patients receiving treatment and comparing different techniques to establish how doses to sensitive organs can be reduced further. A specific clinical audit committee reviews all audit reports in the radiotherapy department and discusses the implementation of recommendations as appropriate. This radiation audit committee in turn reports to the RSC.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection. While some medical radiological equipment was noted to be past its nominal replacement date, from the records and details provided, inspectors were satisfied that all equipment was kept under strict surveillance regarding radiation protection and all QA was up-to-date. Inspectors also noted that the hospital planned to commence a programme of replacement of medical radiological equipment that had passed the nominal replacement date. This was seen as a positive approach by inspectors and would provide further assurances to the undertaking to further optimise medical exposures in line with technological advancements.

From the documentation reviewed and from speaking with staff, inspectors were satisfied that appropriate QA and quality control programmes were implemented and maintained for each piece of medical radiological equipment at the Mater Private Hospital. This documentation included the policies associated with QA, for example, the quality control programme for the linear accelerators (equipment used in radiotherapy treatments), and the records of initial acceptance testing and regular performance testing carried out in this installation.

From the documentation reviewed and the discussions with staff, inspectors were assured that the undertaking has strict oversight of the surveillance of all radiological equipment in this installation and is in compliance with this regulation.

Judgment: Compliant

Regulation 15: Special practices

Inspectors were assured that the Mater Private Hospital had mechanisms in place to ensure special attention was given to optimisation of medical exposures involving high doses to the patient. For example, the hospital had invested in iterative reconstruction software for CT to ensure that doses were as low as reasonably achievable. Inspectors were also satisfied that radiation doses received by patients using fluoroscopy equipment with three dimensional imaging capability used in theatre for the purposes of guiding and verification were kept under observation and that this equipment was only operated by radiographers who have received specific training for its use.

Special attention was also given to the assessment of the radiation dose received by patients undergoing an interventional cardiology procedure. For example, inspectors were informed that in instances where a pre-defined radiation dose threshold is reached during a procedure, an alert sticker is placed in the patient's chart and each patient is informed to check for any symptoms of a tissue reaction. Furthermore, the hospital had also determined that when a threshold in excess of 7 Gray was

exceeded, the radiation safety officer follows up with the patient directly. While these threshold doses are infrequently seen at the hospital, this quality improvement initiative was viewed by inspectors as a good mechanism to ensure the safety and well being of patients attending the Mater Private Hospital. While no instances of a tissue reaction have been identified by the hospital, these measures also demonstrates the hospital's compliance with Regulation 17. It is important that undertakings have adequate processes in place to identify, record and report any significant events involving high cumulative doses to patients or the occurrence of any tissue reactions.

Furthermore, inspectors saw examples of quality improvement initiatives in radiotherapy aimed at optimising exposures given to patients. A specific quality improvement initiative reviewed by inspectors focused on the use of spacers in prostate cancer patients. The use of spacers sought to reduce the dose to organs surrounding the prostate during treatment. Similarly, inspectors saw evidence that the hospital had mechanisms in place to verify the dose delivered during radiotherapy treatments and that methods to achieve this were routinely discussed at the radiation audit committee.

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 public places such as changing rooms and waiting areas.

Radiation oncologists, radiation therapists and radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy and breastfeeding status where relevant, in line with the regulations. However upon review of day-to-day practice in radiology and interventional cardiology, inspectors found that overarching hospital policy did not recognise radiographers as practitioners. This lack of consistency between the hospital's delegation of clinical responsibility in local radiology polices and day-to-day practice should be reviewed to ensure that the roles and responsibilities of staff carrying out the inquiry into pregnancy status are clearly allocated and understood by staff at the hospital.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

The Mater Private Hospital had an established electronic incident reporting system to record incidents which automatically notified relevant management. A positive

reporting culture was found to be in place at the hospital, and near misses and incidents were available for review on the day of inspection. The electronic reporting system had a mechanism to analyse incidents and potential incidents, and there was evidence that where a trend had been identified it was escalated to the RSC and other management groups as appropriate.

All incidents involving or potentially involving medical exposures were escalated to management by staff. A weekly incident meeting is held at the hospital to discuss any incidents which occurred. This meeting allows for mitigating actions to be implemented to reduce the risk of re-occurrence of any incidents. Inspectors were informed that feedback and learning from incidents was provided to staff by local area management.

From the evidence gathered during this inspection, inspectors were assured that appropriate measures were taken within this installation to minimise the probability of accidental or unintended exposures. Oversight from senior management within this hospital was also evident during this inspection and mechanisms were in place to ensure that all reportable significant events were reported to HIQA in a timely manner.

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	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Mater Private Hospital OSV-0007398

Inspection ID: MON-0031298

Date of inspection: 27/04/2021

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: A board member has been identified who will act as the undertaking representative. The member will be updated on the HIQA portal. The Group Chief Operating Officer will act as designated manager for the Dublin and Limerick sites. The Finance and Operations Director in Mater Private Cork will continue to act as designated Manager for Cork. Date of completion: 01/07/21</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: Hospital policies and procedures will be amended on the Q-pulse platform to outline the day-to-day roles and responsibilities for justification by radiographers who act as practitioners in the interest of the patient and as part of multidisciplinary clinical team. Radiographers act as practitioners within their scope of practice (IIRRT guidelines) under governance structures of the Mater Private. Date of completion: new policies will be approved at the 2nd radiation safety committee meeting in December 2021.</p>	
Regulation 16: Special protection	Substantially Compliant

during pregnancy and breastfeeding	
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <p>Hospital policies and procedures will be amended on the Q-pulse platform to outline the day-to-day roles and responsibilities for justification by radiographers who act as practitioners in the interest of the patient and as part of multidisciplinary clinical team. Radiographers act as practitioners within their scope of practice (IIRRT guidelines) under governance structures of the Mater Private.</p> <p>Date of completion: new policies will be approved at the 2nd radiation safety committee meeting in December 2021.</p>	

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	01/07/2021
Regulation 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	31/12/2021

Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	31/12/2021
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	31/12/2021