



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:	31 May 2023
Medical Radiological Installation Service ID:	OSV-0007398
Fieldwork ID:	MON-0039248

About the medical radiological installation:

The Mater Private Network provides a full diagnostic radiology, nuclear medicine, cardiology and radiotherapy service at the Mater Private Hospital, Eccles Street. A service is provided for in-patients, out-patients, emergency department and day-care patients.

The radiotherapy services provided to patients attending the Mater Private Hospital are:

- External beam radiotherapy, including intensity modulated radiotherapy, image guided radiotherapy, deep inspiration breath-hold, stereotactic ablative radiotherapy and stereotactic radiosurgery,
- Brachytherapy (high dose rate) and
- Prostate seeds brachytherapy (low dose rate).

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
Wednesday 31 May 2023	09:00hrs to 17:00hrs	Kirsten O'Brien	Lead
Wednesday 31 May 2023	09:00hrs to 17:00hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the radiotherapy department at the Mater Private Hospital was carried out on the 31 May 2023. On the day of inspection, inspectors reviewed a sample of records and documentation and spoke with staff and management working at the Mater Private Hospital Group's Dublin hospital.

Overall, inspectors found that appropriate governance and management arrangements were in place for the delivery of the radiotherapy service on the day of inspection. In addition, inspectors noted that roles and responsibilities relating to the radiation protection of service users were carried out by appropriate individuals as recognised in the regulations. For example, only radiation oncologists and radiation therapists could act as a referrer in the radiotherapy department. Additionally, radiation oncologists and radiation therapists were recognised as practitioners and only practitioners carried out the practical aspects of each medical exposure.

However, inspectors identified that allocations of responsibility for radiation protection at the hospital was not always clearly documented. During the inspection inspectors met with management and staff and found that these allocations were more detailed and expansive than what was documented. For example, the formal line management reporting structure for staff working in the radiotherapy department was through the Group Director of Cancer Services, in addition to the day-to-day operational reporting structure for the hospital which involved reporting operational issues to the designated manager who was the Chief Operating Officer (COO) of the Mater Private Hospital Group's Dublin hospital.

Inspectors noted that efforts had been made to supplement existing documentation of the allocation of regulation specific roles through the recent development of the hospital's *Policy on recognition of defined roles and associated responsibilities under Ionising Radiation Regulations (SI 256 of 2018)*. However, this document did not clearly outline how this allocation was practically implemented. In particular, it did not clearly provide an allocation of how the day-to-day aspects of clinical responsibility were conducted through the complementary roles of radiation therapists and radiation oncologists as practitioners. The inclusion of specific information relating to the allocation of clinical responsibility would provide additional clarity about when, where and how staff take clinical responsibility for individual patients. For example, at what points in a patient's pathway justification is carried out, who carries it out and how this is recorded.

Inspectors noted that a medical physics expert (MPE) was appropriately involved in the service in line with the radiation risk of the radiotherapy department. Additionally, a number of areas of good practice were identified over the course of the inspection in relation to the involvement of MPEs. For example, the proactive approach to training physicists to achieve recognition as MPEs to ensure the continuity of medical physics expertise at the hospital in the future. Inspectors also

noted the involvement of the MPE and staff in the radiotherapy department in completing annual quizzes and training relating to the local rules to ensure staff have ongoing awareness regarding radiation protection.

While areas for improvement to documentation were identified on the day of inspection, overall inspectors were satisfied that the Mater Private Hospital had appropriate governance and management arrangements in place to provide for the safe delivery of medical exposures in the radiotherapy department.

Regulation 4: Referrers

From a sample of records reviewed and from speaking with staff, inspectors found evidence that only referrals from those entitled to refer as per the regulations were carried out in the radiotherapy department. Inspectors also noted that the role of the radiation therapist as a secondary referrer was clearly documented and understood by staff spoken with on the day.

Judgment: Compliant

Regulation 5: Practitioners

Only those entitled to act as practitioners as per the regulations were found to take clinical responsibility for medical exposures in the radiotherapy department on the day of inspection.

Judgment: Compliant

Regulation 6: Undertaking

On the day of inspection, inspectors spoke with management and staff at the hospital about the governance and management structures in place for the radiotherapy department. Documentation which included a diagram of the overarching governance structures (organogram) in place at the Mater Private Hospital was submitted to inspectors in advance of the inspection and was discussed with management on the day of the inspection.

While the allocation of responsibility for the radiation protection of service users was communicated to inspectors on the day of inspection, the documentation of the specific reporting relationships at the hospital for the radiotherapy department were identified as an area for improvement to ensure that they fully reflect the full scope

of the structures described by staff and management.

On the day of inspection, a dual reporting structure was found to be in place to oversee the provision of radiotherapy services at the hospital. Radiation therapists and physicists working in the radiotherapy department had a formal line management reporting relationship to the Mater Private Hospital Group's Director of Cancer Services through the Radiotherapy Services Manager (RTSM) and the Chief Physicist respectively. The Group Director of Cancer Services reported to the Deputy Group Chief Executive Officer (CEO) who was the undertaking representative and member of the Board of the Mater Private Hospital. The RTSM also reported to the COO of the Mater Private Hospital Group's Dublin hospital at a day-to-day operational level. The COO of the Dublin facility was the designated manager for the service inspected and had day-to-day oversight of the operational aspects of delivering the radiotherapy service. The operational reporting relationship from the radiotherapy department also included the Group Director of Quality and Patient Experience who in turn had a direct reporting line to the Board. However, the specific details of the reporting relationships for radiation protection were not clearly documented and did not match the allocation of responsibility as described in the documentation provided to inspectors.

In addition to the line management structures in place, a committee reporting structure was also in place. In the radiotherapy department, inspectors found that oversight for the radiation protection of service users was provided by the Radiation Audit Committee (RAC) and the Radiation Safety Committee (RSC), which both reported to the Quality Using Effective Safe Treatment (QUEST) Committee. The QUEST committee in turn reported up to the Mater Private Hospital Group's Board. Inspectors also found that the COO, the Group Director of Quality and Patient Experience and the RTSM were members of both the RSC and the QUEST committee.

From speaking with staff and management, inspectors were assured that only appropriate individuals who were recognised as referrers, practitioners and MPEs carried out these roles and responsibilities as required by the regulations. Inspectors also reviewed the allocation of radiation protection of service users locally in the radiotherapy department. However, the documentation of allocation of responsibilities of personnel carrying out the medical radiological procedures was found to not fully or accurately reflect day-to-day practice in the department.

Inspectors reviewed a newly developed *Policy on recognition of defined roles and associated responsibilities under Ionising Radiation Regulations (SI 256 of 2018)*, which provided assurance that appropriate professional groups were allocated responsibility as practitioners and provided information about the role of radiation oncologists and radiation therapists as referrers. It also allocated practitioner responsibility to radiation oncologists and radiation therapists and outlined the role of the MPE. Inspectors also noted that other documents reviewed did contain supplementary information however, none of the documents reviewed clearly defined the allocation of the different aspects of clinical responsibility for individual medical exposures, such as planning computed tomography (CT) scans.

Inspectors also asked staff about the policies available to them which documented their day-to-day roles and responsibilities for planning computed tomography (CT) scans and found that these documents were not available. Consequently, from all the policies and procedures reviewed as part of the inspection, inspectors were not satisfied that clear documentation was available of how and when radiation therapists or radiation oncologists took responsibility for the different aspects of clinical responsibility for an individual patient, for example, how and when justification in advance was recorded.

Similarly, the policy for inquiring about pregnancy status allocated responsibility to individuals not recognised in the regulations as the referrer or a practitioner. Furthermore, the policy did not capture all steps in this process. This is discussed further under Regulation 16. However, inspectors reviewed evidence on the day of inspection and found that only radiation oncologists or radiation therapists carried out this inquiry which was aligned with the requirements of the regulations and provided assurances that safe care was being provided to service users.

Overall, notwithstanding the areas for improvement relating to the documentation of the allocation of responsibility for the radiation protection, inspectors were satisfied that arrangements were in place at the hospital on the day of inspection for the provision of the radiotherapy service.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, inspectors found that clinical responsibility was only taken by radiation oncologists and radiation therapists in the radiotherapy department at the Mater Private Hospital. Inspectors also were satisfied that both referrers and those entitled to act as practitioners, were involved in the justification of individual medical exposures. Similarly, inspectors found evidence that radiation oncologists, radiation therapists and MPEs were appropriately involved in the optimisation of all aspects of radiotherapy delivered at the hospital. Inspectors also found that the practical aspects of radiotherapy were only carried out by practitioners in the department.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, inspectors were satisfied that the Mater Private Hospital had appropriate measures in place to ensure the continuity of medical physics expertise in the radiotherapy department. Inspectors were informed that additional

physics staff were employed and were in training to become MPEs which was noted as a positive example of proactively ensuring on-going MPE involvement in the service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From speaking with staff and reviewing documentation and records as part of the inspection, inspectors were assured that an MPE was available to act and give specialist advice on matters relating to radiation physics as required by the regulations. For example, inspectors found that an MPE took responsibility for dosimetry and gave advice on medical radiological equipment. Inspectors reviewed the records of quality assurance (QA) carried out on medical radiological equipment in the radiotherapy department and found that an MPE had been involved in the definition and performance of this QA.

Inspectors also found examples of where MPEs contributed to training of practitioners, including the delivery of a training quiz for radiation therapists annually to ensure that competencies regarding the local rules and any updates were met.

Judgment: Compliant

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

Inspectors found evidence that MPEs were closely involved in the radiotherapy service in line with the level of radiological risk as required by the regulations.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection, inspectors reviewed the day-to-day practice at the Mater Private Hospital in relation to the delivery of the radiotherapy service.

Staff spoken with described how medical exposures along a patient's pathway were justified by a radiation oncologist and a radiation therapist. A sample of referrals reviewed were found to be in writing and contained the reason for referring the patient for radiotherapy. Similarly, patients were provided with information about

their treatment plan as part of the consent process. Patients were also provided with additional opportunities to ask questions and were provided with an information packet to take home with them which was seen as an example of good practice.

Inspectors were assured that medical radiological equipment was kept under strict surveillance and that a comprehensive multidisciplinary quality assurance programme had been implemented and was routinely carried out by staff at the department. In addition, inspectors reviewed the measures in place to ensure the optimisation of all exposures carried out as part of an individual patient's pathway. For example, inspectors were informed about an initiative to assist patients in adequately preparing for their CT planning scan when referred for prostate treatment in order to reduce the need for a repeat CT scan.

However, inspectors did note that documentation on establishing a patient's pregnancy status allocated responsibility for carrying out this inquiry to individuals who were not the referrer or a practitioner, as required by the regulations. While inspectors were assured that only radiation oncologists and radiation therapists carried out and recorded the answer to this inquiry, the policy in place did not accurately reflect day-to-day practice.

A system was found to be in place to facilitate the recording and analysis of incidents, or potential incidents, involving accidental or unintended exposures to ionising radiation at the Mater Private Hospital. On the day of inspection, staff spoken with provided assurances to inspectors that appropriate incident management measures were in place which included appropriate analyses and the implementation of corrective actions as required. Furthermore, oversight of incidents that had occurred in the radiotherapy department was provided through the committee reporting structure, including attendance at the weekly Incident Management Committee which was chaired by the Group Director of Quality and Patient Experience. The undertaking was found to have met the requirements of Regulation 17 as a result of evidence provided to inspectors on the day of inspection. However, inspectors noted that processes relating to the submission of information to HIQA should be reviewed to ensure that all relevant information is provided as part of the reporting process for significant events.

Notwithstanding the areas for improvement identified in relation to documentation, overall on the day of inspection, the Mater Private Hospital demonstrated a good level of compliance with the regulations.

Regulation 8: Justification of medical exposures

On the day of inspection, a sample of records were reviewed by inspectors. Inspectors also spoke with staff working in the radiotherapy department about their roles in the justification of medical exposures along the patient's radiotherapy pathway.

All referrals reviewed were from a radiation oncologist and were in writing using an

online booking form which stated the reason for the treatment. Additional information, such as previous radiotherapy, other imaging and pathology were also included and considered as part of the justification process carried out by the radiation oncologist in deciding to refer the patient for radiotherapy. Additionally the radiation oncologist acted as the practitioner and made the justification decision to treat an individual patient. Inspectors found that the radiation oncologist signed each form electronically with their medical council number and this was seen as the record of justification in advance.

Radiation therapists were also found to have a role in the individual justification of specific medical exposures along each patient's pathway. For example, justification in advance of carrying out a planning CT was completed by carrying out a list of tasks on the electronic record and verification system. Similarly, additional verification imaging during treatment was documented on an imaging sheet with the initials of the justifying radiation therapist. On the day of inspection, the record of who had carried out the justification and an example of where this was recorded was observed by inspectors.

Inspectors also spoke with staff regarding how information about the risks and benefits of the medical exposure to ionising radiation were provided to patients in advance of an exposure to ionising radiation. A radiation oncologist provided this information to patients as part of the consent process during an initial consultation. Inspectors were also informed that patients were provided with an information packet specific to their radiotherapy treatment and had the opportunity to further discuss this information with a radiation oncologist during a follow-up phone call if required. Over the course of their treatment, patients also had frequent access to members of the multidisciplinary team in relation to any potential side effects. This access to staff was seen as a positive example of patient care in addition to meeting the Mater Private Hospital's regulatory requirements.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors were satisfied that the Mater Private Hospital had appropriate measures in place to ensure that all exposures carried out in the radiotherapy department were optimised.

Radiation therapists in the planning CT unit described how they optimised each CT exposure through the use of immobilisation aids, and specific scanning protocols for each treatment site. Staff also informed inspectors how, for some cohorts of patients, they completed a short scan in order to assess that bowel and bladder preparation was optimal, before proceeding with a more comprehensive CT scan. This process reduced the doses received by patients when further bowel and bladder preparation was required. CT staff also informed inspectors that the doses from CT planning scans were recorded for each patient's CT planning scan in order

to monitor these doses and ensure that they were kept as low as reasonably achievable while providing adequate information for treatment planning.

Inspectors also spoke with staff in the radiotherapy planning department who explained that all treatment exposures were individually planned, with beam arrangements ensuring that the radiation dose to non-target areas was considered and kept as low as reasonable achievable. Staff explained to inspectors how all treatment plans were reviewed and electronically approved by a radiation oncologist. This electronic patient record system facilitated secure communication between the multidisciplinary team which ensured that each treatment plan was optimised in line with accepted best practice.

Staff also communicated how the medical radiological equipment was kept under strict surveillance and how patient doses were assessed and evaluated. Inspectors also reviewed numerous policies and procedures which outlined how optimisation was best achieved at treatment planning and delivery. The staff and management in the radiotherapy department had also developed a number of protocols on the imaging type and frequency of imaging to be followed for each radiotherapy treatment site. This was to ensure the accurate delivery of the dose to the target area.

Staff working in the CT and treatment units also informed inspectors that they completed an electronic time-out check before each radiation dose was delivered. This optimisation check ensured, amongst other things, that the correct patient was receiving the correct treatment and that the correct imaging modality was being used, thus ensuring the safe delivery of each radiation dose.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, compliance with Regulation 13(1) was assessed. As part of this assessment, inspectors spoke with staff and reviewed a sample of written protocols for radiotherapy exposures. Inspectors were satisfied that written protocols had been established as required by the regulations and were available to staff through a hospital document management system. However, inspectors noted that a number of clinical guidelines required a review and update in order to assure the undertaking that written protocols for frequently treated sites aligned with and referenced current national and international best practice.

Judgment: Compliant

Regulation 14: Equipment

The Mater Private Hospital was found to have appropriate measures in place to ensure that all medical radiological equipment in the radiotherapy department was kept under strict surveillance regarding radiation protection. A QA programme had been established and implemented. Inspectors found that radiation therapists and MPEs were involved in carrying out on-going performance testing and records of this testing were reviewed by inspectors on the day of inspection. Inspectors were further assured that a program of preventative maintenance and performance testing in place was in-line with the age and radiological risk associated with each individual piece of equipment and that these factors had been considered when developing the QA programmes for each linear accelerator (treatment machine) in the department.

Inspectors also found that a handover procedure had been implemented to ensure clarity of responsibility between radiation therapists, MPEs and external servicing personnel. This was identified as an area of good practice to ensure that all staff were aware of when a piece of equipment was deemed suitable for clinical use.

Judgment: Compliant

Regulation 15: Special practices

Inspectors found evidence that staff at the Mater Private Hospital had a number of measures in place to optimise medical exposures of ionising radiation during the planning and delivery of a course of radiotherapy.

Inspectors were informed that certain cohorts of patients were provided with additional patient information sessions to ensure that they had adequately prepared for treatment. For example, information of the relevant bowel and bladder preparation was provided before attending for radiotherapy planning CT and daily treatments. This initiative supported patients to carry out the necessary preparation which had reduced the need for a repeat planning CT scan. Inspectors were also informed that a certain cohort of patients wore a breathing device during CT planning and treatment delivery, which regulated their breathing pattern and therefore aided the accuracy of daily treatment delivery.

During the inspection, inspectors followed up on information previously submitted by the undertaking to HIQA, and observed that a number of actions had been implemented following a radiation incident and this was noted as good practice. For example, a refined CT planning protocol had been introduced to minimise the risk of a certain cohort of patients receiving an unnecessary CT scan. CT staff had also received supplementary training on the use of this refined protocol.

Inspectors were also informed about a quality improvement initiative that had successfully been implemented into the department to standardise imaging for patients undergoing breast radiotherapy treatment. Following a review of all

verification imaging for these patients attending for breast radiotherapy an optimised breast imaging protocol was implemented in the department.

During discussions with clinical staff, inspectors were also informed of specialist techniques that had been recently introduced into the department. These techniques delivered high doses of radiotherapy to a small target area, with the aim of reducing the side effects that can be caused by high doses of radiotherapy. Inspectors observed that a range of clinical documents had been developed by a multidisciplinary radiotherapy team and were based on up-to-date international best practice. These documents provided guidance and support to staff in CT scanning, planning and treating these cohorts of patients.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Notices in public places were observed by inspectors throughout the radiotherapy department to raise awareness of the need to inform staff in the radiotherapy department if there was a possibility that they may be pregnant.

Inspectors were informed that an inquiry regarding the pregnancy status of a patient was carried out during the consent process by the radiation oncologist and patients were also provided with information about the risks of a pregnancy during radiotherapy. An additional inquiry was completed and documented by a radiation therapist before the CT planning scan and this form was then uploaded to the patient's electronic record. The patient was again provided with information about the need to inform a staff member if they were to become pregnant before starting their treatment. Radiation therapists also informed inspectors that they confirm that a pregnancy declaration form has been completed as part of checks carried out before the first day of treatment.

However, while inspectors were assured that only those recognised as a referrer or a practitioner in the radiotherapy department carried out and recorded the answer to the pregnancy status inquiry, documentation reviewed, in particular the *Procedure for Radiation Protection of the Unborn Child*, allocated responsibility for carrying out a pregnancy status inquiry to administration staff as part of the registration procedure. In addition, the policy did not accurately reflect the day-to-day process and the steps carried out by staff which were more detailed than reflected in the documentation provided to inspectors as part of the inspection. For clarity the policies relating to establishing pregnancy status in the radiotherapy department should be reviewed to reflect day-to-day practice to align with the regulations.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

An electronic online system to record and analyse incidents involving, or potentially involving, an accidental or unintended exposure to ionising radiation was found to be in place at the Mater Private Hospital on the day of inspection. Staff who spoke with inspectors also described the reporting process in place. Incidents occurring, or potentially occurring, in the radiotherapy department were discussed at both the RAC and the RSC which both reported into the QUEST committee. Inspectors reviewed the minutes of the RAC and found evidence that this committee included a discussion on incidents and a trend analysis in the radiotherapy department. Incidents were also discussed at a hospital-wide Incident Management Committee which took place weekly and included representation from the radiotherapy department.

While inspectors found that incidents which were reportable to HIQA were reported within the required time lines, inspectors did note that the information provided to HIQA, both as part of the initial notification of the significant event and the summary of the investigation and corrective actions, was an area for improvement. However, assurances were provided to inspectors on the day of inspection that staff and management had conducted an analysis of the reported significant events and put corrective actions in place to reduce the potential for a similar incident to reoccur. Inspectors also noted that some of these corrective measures were comprehensive in nature, such as a multidisciplinary approach to supporting radiation therapists in carrying out their roles.

Notwithstanding the area of improvement to ensure that the Mater Private Hospital provides adequate information to HIQA following a significant event, inspectors were satisfied that the Mater Private Hospital had met the requirements of the regulation as a result of the assurances provided to inspectors on the day of inspection.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	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-0039248

Date of inspection: 31/05/2023

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:</p> <ol style="list-style-type: none"> 1. Created a new Hospital wide Radiation reporting structure diagram that will be incorporated into the documentation structure. 2. Reviewed and updated current documentation (QP-GEN-004_ Policy on recognition of defined roles and associated responsibilities under Ionising Radiation Regulations (SI 256 of 218),) to further reflect responsibilities of personnel carrying out the medical radiological procedures and to clearly define the allocation of the different aspects of clinical responsibility for individual medical exposure. 	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <ol style="list-style-type: none"> 1. Reviewed and updated Document QP-RP-003_Procedure for Radiation Protection of the Unborn Child to comply with legislation and to follow are day to day practice. 	

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	11/07/2023
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject	Substantially Compliant	Yellow	11/07/2023

	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			
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