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:	The Coombe Hospital
Undertaking Name:	Coombe Lying-In Hospital, T/a Coombe Women & Infants University Hospital
Address of Ionising Radiation Installation:	Cork Street, Dublin 8
Type of inspection:	Announced
Date of inspection:	13 June 2024
Medical Radiological Installation Service ID:	OSV-0006844
Fieldwork ID:	MON-0043113

About the medical radiological installation (the following information was provided by the undertaking):

The Coombe Hospital was founded in 1826 and is part of the current Dublin Midland Hospital Group (DMHG) which consists of eight other hospitals. The Coombe Hospital is the largest provider of women and infants healthcare in Ireland. The hospital caters for neonatal, paediatric and Obstetric and Gynaecological adult patients. The catchment area for the Coombe consists of: South County Dublin, Kildare North, Meath South & Wicklow North (plus Hospital Group link to MRHP).

The Radiology Department accepts X-Ray referrals from Coombe inpatient, outpatient, emergency room and private clinic referrers but does not facilitate GP requests for X-Rays for both adults and paediatric patients. The department consists of one general X-Ray Room (no fluoroscopy application) and two portable X-Ray machines (one for portable Adult Radiography and one for portable Paediatric Radiography). All X-Ray equipment was installed in January 2017. On average the department undertakes approximately 2,000 X-Ray examinations and 5,500 ultrasounds per annum. Of the approximate 8,000 live births per annum in the Coombe, there are up to 1,000 admission to NICU. Up to 72% of all X-Ray examinations undertaken in the hospital are carried out portably, mostly in the main NICU and HDU. The majority of X-Rays carried out in the General X-Ray Room are paediatric pelvic X-Rays referred from the out-patient orthopaedic clinic.

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, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

[1] 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.

1. Governance and management arrangements for medical exposures:

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
Thursday 13 June 2024	09:30hrs to 15:40hrs	Margaret Keaveney	Lead
Thursday 13 June 2024	09:30hrs to 15:40hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiological services at The Coombe Hospital on 13th June 2024, to monitor the service's compliance with the regulations. The radiology department consists of a general X-ray unit and two mobile X-ray units, that provide medical exposures of ionising radiation to both adult and paediatric in-patients referred by in-house medical practitioners and to out-patients referred from the hospital's out-patient departments. Inspectors observed that although staff had completed a range of clinical audits to identify areas of good practice, and areas requiring action within the radiology service, these audits had not identified gaps in the undertaking's compliance with regulations as identified by inspectors during the inspection.

The Coombe Lying-In Hospital, T/a Coombe Women & Infants University Hospital was the undertaking for The Coombe Hospital, and had established a radiation safety committee (RSC) which met twice yearly and was chaired by a consultant radiologist. Terms of reference for this committee were reviewed by inspectors and evidenced a multidisciplinary membership, including the hospital's general manager who was also the designated manager, the radiology services manager (RSM), the radiation protection officer (RPO), a medical physicist (MPE), the quality, risk and patient safety (QRPS) manager, the chief operations officer (COO) and a representative from the nurse referrers. The multidisciplinary nature of the membership, in particular the inclusion of the QRPS manager, was identified as an area of good practice in the service. A review of a sample of meeting minutes demonstrated that items such as diagnostic reference levels (DRLs), the quality assurance (QA) programme for equipment, incidents, clinical audit and training were discussed.

Relevant radiation protection matters, discussed at the RSC, were brought to weekly executive management team (EMT) meetings by the general manager, the QRPS manager and the COO, who were also members of this team. The Master of The Coombe Hospital was the chairperson of the EMT, and relevant matters on radiation protection were brought by the chairperson of the EMT to The Coombe Hospital Board, which was the group representing the undertaking. While the undertaking had implemented governance and management structures to oversee and support the radiology service, inspectors observed that these arrangements were not sufficiently effective to ensure that the radiation protection measures in place in the radiology service complied with regulations 6, 8, 11, 13, 14, 20 and 21, as discussed throughout this report. For example, inspectors noted that although an MPE was involved in the service, inspectors were not assured that the undertaking had adequately utilised the MPE in key radiation protection matters, as outlined in Regulation 20 and in a documented agreement between the two parties. Therefore, inspectors were also not assured that the medical physicist's contribution and involvement to the service was commensurate with the radiological risk posed by the practice.

Despite the gaps in the undertaking's compliance with the regulations, overall, inspectors were assured that service users were receiving a safe radiological exposures in The Coombe Hospital. For example, from the review of a sample of radiological procedure records, inspectors were satisfied that appropriate persons as per the regulations were involved in referring and justifying medical exposures completed at the service. Inspectors were also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

During the course of the inspection, inspectors were assured that the undertaking's management team were committed to improving the service and addressing the gaps in compliance with the regulations.

Regulation 4: Referrers

From the review of a sample of medical exposures records and discussions with staff, inspectors were satisfied that referrals, for medical radiological procedures, were only accepted in the service from persons defined in Regulation 4.

The undertaking's management team had developed *Radiation Safety Procedures Medical Radiography* which stated that medical practitioners could refer for medical radiological procedures in the service. The document also stated that radiographers could make secondary and adapted referrals, subject to scope of practice.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied, from a review of patient's medical records on radiological procedures and from speaking with staff, that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in the service. In The Coombe Hospital, only appropriately registered radiologists and radiographers acted as practitioners.

Judgment: Compliant

Regulation 6: Undertaking

From a review of documentation and discussions with staff, inspectors were informed of the undertaking's governance and management arrangements, which provided oversight of radiology service in The Coombe Hospital.

However despite these arrangements, inspectors were not assured that the undertaking had clearly allocated and documented a number of key roles and responsibilities for the radiation protection of service users. For example;

- on the day of the inspection, inspectors were informed that referrals for specific radiological procedures were accepted from appropriately qualified and trained nurse referrers. However, nurses were not documented in the list of professionals allocated the referrer role, which was provided to inspectors. On request inspectors were provided with a policy *Nurse Prescribing of Medical Ionising Radiation*, which allocated the role of prescriber to appropriately trained nurses. To ensure that referrals for medical exposures are made and accepted only from those clearly allocated the role and responsibilities of referrer, the undertaking should ensure that the list of referrers within the service is clear and complete
- it was not clear to inspectors which professional groups had been allocated the role of practitioner in The Coombe Hospital. Although inspectors were satisfied that appropriate personnel were carrying out this role in the service, a clear allocation of key roles is essential in a radiological service
- inspectors were not provided with evidence that the undertaking's team had allocated roles and responsibilities for the optimisation of protection and safety of carers and comforters as required by the regulations. Although a multidisciplinary team had considered the roles and responsibilities in monitoring doses for 'patient and clinical holders' in the *Radiation Safety Procedures Medical Radiography*, this was not sufficient to meet the requirements of the regulations
- under Regulation 13(2), the undertaking must have arrangements in place to ensure that information relating to patient exposure forms part of the report following of the medical radiological exposure. However, in the documentation reviewed, responsibility for oversight of this system had not been allocated
- inspectors observed that radiation protection roles and responsibilities in key radiation protection measures, such as the justification process and inquiring on pregnancy status process, were not clearly allocated and or documented

Inspectors noted that the RSC had been allocated responsibility for the service's compliance with the regulations. However, inspectors were not satisfied that these arrangements were being adequately fulfilled. For example,

- the undertaking had not identified that DRL reviews by the MPE were not being completed in an appropriate time frame
- improved oversight of the implementation of the equipment QA programme was required by the undertakings management team. For example, on the day of the inspection, records of completed equipment QA were not readily accessible and available to key personnel in the service. Inspectors also noted

that all decisions made on the implemented QA programme had not been documented
- similarly, the undertaking's clinical audit programme had not identified gaps in the justification process that were noted by inspectors through a review of patient records

While improvements were required to ensure that the undertaking's governance and management arrangements were adequately fulfilling their responsibilities, and in the documentation of allocated roles and responsibilities, inspectors were satisfied that the appropriate personnel were carrying out radiation protection measures and that service users in the radiology department were receiving safe exposures of ionising radiation.

Judgment: Not Compliant

Regulation 10: Responsibilities

From a review of documents and discussions with staff, inspectors were satisfied that practitioners, as defined in the regulations, took clinical responsibility for the medical radiological procedures in The Coombe Hospital.

Practitioners and the MPE were also noted to be involved in a number of optimisation processes for medical exposures to ionising radiation completed in the service.

Inspectors were also satisfied that the justification process for individual medical exposures involved the referrer and practitioner.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors met with the medical physicist engaged by the undertaking to provide medical physics expertise in The Coombe Hospital. They provided satisfactory assurances that there were arrangements in place to ensure the continuity of medical physics expertise, where and when necessary.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions with staff and a review of documentation, inspectors saw that the undertaking had arrangements in place to ensure that an MPE was involved in the radiological service, as required by the regulations.

Inspectors were satisfied that a medical physicist was involved in some aspects of medical exposures as per the regulations, such as quality assurance of medical radiological equipment and dosimetry, and was available to analyse significant events when required. There was also evidence to demonstrate that the medical physicist attended and contributed to RSC meetings.

However from documentation viewed and discussions with the medical physicist and other staff, inspectors were not satisfied that the undertaking had ensured that the MPE had adequately contributed to radiological service. For example, on the day of the inspection, the management team could not provide evidence that the DRLs established from 2022 data had been reviewed by the MPE. Inspectors also noted DRLs established from 2023 data were not reviewed by the MPE until early June 2024. The contribution of an MPE to the application and use of diagnostic reference levels is a key radiation protection measure in a radiological service.

Although the undertaking had ensured that the MPE had contributed to radiation protection training for staff nurses, they had not ensured that the MPE contributed to training for practitioners and other staff in relevant aspects of radiation protection, as required under Regulation 20 (2), since October 2019. While inspectors were informed that training was planned for the weeks following the inspection, the undertaking should consider availing of the support of the MPE, with regard to more frequent radiation protection training, to help enhance the radiation protection of service users and to address areas for improvement outlined in this report.

Judgment: Substantially Compliant

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

From discussions with staff on the day of inspection, inspectors were satisfied that an MPE was involved in many aspects of the radiological service. However, as per Regulation 20, to ensure full compliance with this regulation, the undertaking must ensure that the MPE contribution and involvement to the service is commensurate with the radiological risk posed by the practice.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

From documentation reviewed and discussions with staff, inspectors were satisfied that the undertaking was committed to improving the radiation protection of service users by ensuring that a number of appropriate safety measures were in place, such as implementing good incident reporting structures and by ensuring that all referrals for medical exposures were accompanied by sufficient information to allow the practitioner to justify the exposure. However, inspectors observed that some action was required in systems for the review of DRLs, the implementation of the quality assurance programme for the radiological equipment, the recording of the justification decision and in the undertaking's approach to clinical audit to ensure it aligned with national procedures.

All referrals reviewed by inspectors during the inspection were 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. However, the record of justification of medical exposures in advance, by a practitioner, was not evident for all medical radiological procedures reviewed by inspectors over the course of the inspection. This is further discussed under Regulation 8 below. The review of medical radiological procedures also highlighted that the dose information from the exposure did not form part of the exposure report. Despite a number of clinical audits being completed within the radiological service, these gaps and other areas requiring action were not identified by the undertaking's management team. In line with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* published by HIQA, the undertaking should ensure that there is a clinical audit strategy for medical radiological procedures performed, which covers all aspects of the radiology service and that audit results and learning are used to improve the delivery and quality of medical exposures of ionising radiation in the service.

Inspectors noted that the undertaking's management team had established diagnostic reference levels (DRLs) for the examination types, most frequently completed for adult and paediatric patients, as required by the regulation. Inspectors observed that for some paediatric examination types, the local DRLs established were grouped by weight while others were not. Inspectors acknowledged that for the examination types not grouped by weight, national DRLs had not been established. However the undertaking should consider establishing local facility DRLs for all frequently performed examinations and procedures that are in line with HIQA guidance which states that paediatric patients should be grouped by weight. Inspectors also reviewed the undertaking's *Local DRLs Establishment Procedure* which stated that local DRLs should be reviewed annually. However, from a review of records, inspectors saw that local DRL data was not reviewed by the MPE or RSC within these timelines. Inspectors also observed that the DRLs most readily available to staff were not the most recent version. This is further discussed under Regulation 11 below.

From the review of records and speaking with staff on the day of inspection, inspectors were not assured that the undertaking had implemented and maintained a quality assurance programme to ensure that the equipment was adequately monitored. Inspectors noted that although the equipment and quality assurance

programmes were routinely discussed at the RSC meetings, the equipment was not adequately kept under strict surveillance.

On the day of inspection, inspectors observed that a number of multilingual notices had been placed in patient changing rooms and waiting areas, to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. As the practitioners, radiographers were assigned the responsibility for inquiring on patients' pregnancy status, where relevant, in line with the regulations. Inspectors reviewed a sample of referrals and found that, where relevant, practitioners had inquired on and recorded in writing the pregnancy status of patients. Although compliant with the regulation, measures could be implemented by the undertaking to provide further assurances that the patient was part of the inquiry process.

Inspectors saw documented evidence that the undertaking had adequate arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. These arrangements included ensuring that the Authority was notified of any significant events.

Despite the gaps in compliance with the regulations identified throughout this report, inspectors were satisfied that The Coombe Hospital had a number of effective processes in place to ensure that patients, undergoing medical exposures of ionising radiation, received a safe service.

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was displayed in poster format in patient waiting areas.

As stated in Regulation 6 above, inspectors were not provided with documented evidence that the responsibilities around the justification process were clearly allocated, however on the day of inspection, inspectors spoke with practitioners who outlined how medical exposures are justified in advance of the medical exposure being completed. Inspectors were informed that this process included staff recording, on the patients triple identification form, that justification in advance had been completed. However, inspectors reviewed a sample of patient records and saw that justification in advance, by a practitioner, had not been recorded for each exposure. Therefore, inspectors were not satisfied that the undertaking was compliant with Regulations 8 (8) and 8 (15). The practice of justification of a medical exposure determines if the net benefits of the exposure outweigh the possible risks and therefore must be in place, as a key radiation protection measure, to indicate that the examination is necessary and useful.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The undertaking's management team had developed a *Local DRLs Establishment Procedure*, which briefly outlined the method and frequency by which local DRLs were established, and also stated that *HIQA diagnostic Reference Levels Guidance* on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation of 2023 was followed in establishing local DRLs. However, from a tour of the radiology department, a review of documents and discussions with staff, inspectors were not satisfied that the undertaking's local procedure or HIQAs guidance document had been adequately followed in the review and use of DRLs in the service. For example;

- inspectors observed that, although 2023 DRL data had been established, the DRL data on display in the console area, and available to practitioners, was established from 2019 exposure data. Inspectors also noted that DRL data was not readily available to staff operating the two portable X-ray units. Staff use of the most up-to-date DRLs is essential for good radiation protection of patients. On the day of the inspection, the management took action to ensure that the recently reviewed 2023 DRL data and nationals DRLs were made available to staff at the point of completing exposures
- although DRLs had been established from 2023 exposure data, inspectors observed that this data had not been provided to the MPE for review until early June 2024, and had not been compared to national DRLs. The regular review of DRLs is a useful tool in optimising images and supporting the delivery of doses, which are as low as reasonably achievable, to patients
- on the day of inspection, the undertaking could not provide inspectors with evidence that the DRL data, established from 2022 exposures, had been reviewed by the MPE. An appropriate system of regular review, and record keeping, should be implemented to identify any doses which consistently exceed relevant local and national diagnostic reference levels, and ensures that they are addressed

In view of the evidence obtained during this inspection, the undertaking was found to be not compliant with Regulation 11, and should take steps to address the gaps identified by inspectors.

Judgment: Not Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed written protocols available for standard medical radiological procedures for both adult and paediatric service users.

Inspectors noted that they were accessible to staff in the clinical area and guided them on the optimised patient positioning, and exposure parameters for different medical exposures. Inspectors also noted that appropriate referral guidelines were available to staff, for reference. Both measures ensured that the undertaking was meeting the requirements of Regulations 13 (1) and (3).

However, inspectors reviewed a sample of reports on medical exposures carried out in the service, and found that information relating to patient exposure did not consistently form part of the report, as required by Regulation 13(2).

From a review of documentation, inspectors saw that although the undertaking's management team had developed a strategy document as part of their clinical audit programme for the service, it did not align with the national procedures published by HIQA in November 2023. In addition, inspectors noted that although a number of clinical audits had been completed in the service, such as audits on the assessment of dose, adherence to checking pregnancy status, and the clinical justification of medical exposures was completed by staff, these audits had not effectively captured the gaps in compliance identified by inspectors during the course of the inspection.

In order to comply with Regulation 13, the undertaking must ensure that information relating to patient exposure is available to service users and also strengthen the clinical audit programme in the service, to ensure that it identifies the areas for improvement and assist in the safe delivery of medical exposures to service users.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory of the medical radiological equipment in use in the service was provided to inspectors in advance of this inspection.

The undertaking's management team had developed a *Policy on QA/QC*, which stated that the medical radiological equipment in use in the service was to undergo quarterly and biannual performance testing by radiography staff and annual testing by the MPE and the equipment manufacturer. Inspectors also noted that the equipment quality assurance (QA) programme was an agenda item in the RSC meetings.

However, despite these arrangements, inspectors were not assured that the medical radiological equipment in The Coombe Hospital was kept under strict surveillance or that the undertaking had implemented and maintained an appropriate quality assurance programme. For example, during the inspection, a review of quarterly QA testing records showed that although all test results were within an acceptable range, in some instances duplicate test records for a specific quarter were available, which showed differing test results.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, inspectors observed that posters in multiple languages were displayed in public areas to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

From the patient records reviewed on the day of inspection, inspectors noted that the radiographer, as a practitioner, inquired about and recorded the pregnancy status in writing for relevant patients, as per the regulations. During discussions with staff inspectors were informed that the patient was also required to sign the inquiry form, however the review of a sample of records demonstrated that patient had not signed the forms. While inspectors were assured that staff were complying with their regulatory responsibility to inquire on and record the pregnancy status of relevant patients, the undertaking's management team should ensure that the local process, including evidence of the patients involvement in the inquiry, is appropriately documented and implemented, to ensure that staff practices on inquiring on pregnancy status are consistent and in line with good radiation protection measures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The undertaking had a system in place for the recording and review of any incidents and near misses, involving accidental or unintended exposures to ionising radiation, in the service. Inspectors were informed that as an incident or near miss occurred, it was recorded by the staff member who then informed the RSM. The RSM subsequently informed the Clinical Risk Department in The Coombe Hospital, and both teams then liaised to investigate and address the incident.

From a review of documentation, inspectors observed that incidents or near misses involving medical exposures were discussed at the twice yearly RSC meetings, and any learning and actions agreed to prevent future occurrences to other service users. For example, following a number of similar near misses, the undertaking's management team developed a new process to expedite some referrals for exposures. Inspectors were also informed that a new information and communication technology system was being considered to further minimise the risk of similar potential incidents occurring. This improvement approach to incident management demonstrated good practice, which promoted the radiation safety of patients attending the service.

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, as amended. 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	Not Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for The Coombe Hospital OSV-0006844

Inspection ID: MON-0043113

Date of inspection: 13/06/2024

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, as amended.

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	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiation Safety Procedure (RSP) Manual has been updated to include RANP's as referrers and elaborates on the definition of Radiographers as Practitioners. Comforters and carers definition has been reinserted into the RSP to align with European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and amendments. The undertaking has also ensured that all roles and responsibilities in key radiation protection measures are now clearly allocated and documented. The dose footer which was absent for one Radiologist only has been reinstated as of 16th June 2024 and confirmation has been sent to HIQA 26th June 2024. All Radiographers who undertake X-Ray examinations (permanent and locum) had been spoken to immediately after the inspection findings regarding justification and pregnancy status confirmation. This has been monitored consistently since the time of inspection. JIA tickbox has been added to the audit protocol for justification (previously content of the request was reviewed solely). Audits will now be reviewed as part of the RSCM to provide assurance and governance, and to ensure that all aspects of the service are adequately monitored. QA and DRL's now have a completion date assigned for the year. Protected time and date of the QA have been appointed (second month per quarter-Feb-May-Aug-Nov).	
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:	

Update to MPE SLA; A monthly meeting will be arranged with the MPE and RPO (to include the RSM) and TOR and an agenda will be set for this meeting. Dates will be discussed twice per annum and agreed upon for a six month period pro rata. MPE to discuss with Educational co-ordinator dates and availability for radiation protection training for relevant staff. Educational co-ordinator also advised of availability of HSELand training on this subject matter, however as the content does not include neonates this is not a substitute for MPE training.

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: As per regulation 20, updated SLA to increase scheduled communication with the MPE.	
Regulation 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: All Radiography staff have been made aware/reminded of their responsibility and the requirement to tick the justified in advance box or in the instance where it is an emergency paper referral for a new admission to NICU "justified in advance or JIA" must be recorded. This happened immediately after the inspection and has been monitored since this time.	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: DRL's to be completed in Dec of each year, deadline will be issued six months prior to date of completion. These will be reviewed and signed by the MPE with a completion	

date of 31st Jan for discussion and actioned minute at the first RSCM of each year. Current most up to date national and local DRL's completed in 2023 are now available on display in the Radiology Exposure room and attached to the two mobile machines.

Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Singular Radiologist without dose footer, this was rectified (16/6/24) and sent to HIQA 26/6/24. New SOP completed which includes HIQA created checklist and manual for inclusion with the already in situ Coombe Hospital test tool to carry out audits.	

Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: A scheduled QA/QC procedure will be created for the calendar year in November each year going forth; coinciding with DRL submission for review (This has been completed for Q3 and Q4 2024). This will allow undertaking of quarterly QA in the second month per quarter (Feb-May-Aug-Nov) and designated dates and protected time for the RPO has been allocated. Update to QA/QC programme will include an SOP for Senior Radiographers to ensure Radiographer testing is carried out at a consistent timeframe (in the event of sick leave/cyber attack/pandemic etc where the department fell behind previously) in absentia of the RPO. Exclusion of daily tube warm up and the justifiable reason for this in the setting of a maternity facility without fluoroscopy will be included in the updated QA/QC programme.	

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.	Not Compliant	Orange	01/09/2024
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	Not Compliant	Orange	14/06/2024

	specific objectives of the exposure and the characteristics of the individual involved.			
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	Orange	14/06/2024
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.	Not Compliant	Orange	01/09/2024
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given	Not Compliant	Orange	01/09/2024

	examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	26/06/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	14/06/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	01/09/2024
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility	Substantially Compliant	Yellow	31/12/2024

	for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and	Substantially Compliant	Yellow	31/12/2024

	installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	31/12/2024