



**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:	Connolly Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Mill Road, Abbotstown, Dublin 15
Type of inspection:	Announced
Date of inspection:	17 April 2024
Medical Radiological Installation Service ID:	OSV-0007352
Fieldwork ID:	MON-0040998

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

Connolly Hospital is part of the RCSI Hospitals Group with a catchment population of over 331,000 covering Dublin West, North Kildare and South Meath. Connolly Hospital is a major teaching hospital providing a range of acute medical and surgical services, day care, outpatient, diagnostic and support services. The hospital has a current bed complement of 391 beds. Emergency services are provided 24 hours, seven days a week (24/7). Connolly Hospital is part of the EuroSafe Imaging initiative to promote quality and safety in medical imaging. Referrals for medical radiological procedures are accepted for inpatients and outpatients. General practitioner (GP) referrals are also accepted on a walk-in and appointment basis. Connolly Hospital performs approximately 105000 medical radiological procedures annually across a variety of modalities including; computed tomography (CT), interventional radiology, fluoroscopy and general radiography. The hospital has one interventional suite, one fluoroscopy room, and four general X-ray rooms, three of which are digital. The hospital has five mobile machines, one of which is digital, and a dedicated ceiling suspended X-ray unit located in the resuscitation area of the emergency department. The fluoroscopy room and interventional suite provide inpatient and outpatient services for a range of procedures involving barium studies, peripherally inserted central catheter (PICC) line insertions and complex interventional studies. The department also performs the following non-ionising radiation imaging; magnetic resonance (MR) imaging and ultrasound.

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 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 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
Wednesday 17 April 2024	09:00hrs to 16:15hrs	Margaret Keaveney	Lead
Wednesday 17 April 2024	09:00hrs to 16:15hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

On 17 April 2024, inspectors completed an inspection of the radiological services at Connolly Hospital to follow up on the compliance plan of the previous inspection completed in March 2020, and to monitor the service's ongoing compliance with the regulations. During the inspection, inspectors saw that the undertaking, who is the Health Service Executive (HSE), had made good efforts to progress compliance with the regulations. However, inspectors also noted that in some radiological services action was required to ensure that roles and responsibilities were clearly allocated. These and other findings of non-compliance with the regulations are discussed under Regulations 6, 8, 10 and 14 throughout this report.

The radiology department of Connolly Hospital consists of a computerised tomography (CT) unit, five general X-ray rooms, two fluoroscopy rooms, six mobile X-ray units and two mobile fluoroscopy units. Medical exposures of ionising radiation are provided to in-patients referred by in-house medical practitioners and to out-patients attending the hospital's emergency and out-patient clinics, and to other patients referred by external medical practitioners.

From discussions with the management team and a review of organisational charts, inspectors noted that the undertaking had governance and management arrangements in place to provide oversight of the radiology service in the hospital. The team had established a radiation safety committee (RSC), which met twice annually, to discuss items such as the quality assurance programme for equipment, reported incidents, diagnostic reference levels (DRLs), clinical audit and staff training. The meetings were chaired by the General Manager of the hospital, who was also the Designated Manager. The RSC meetings were also attended by, amongst others, a Consultant Radiologist, the Radiology Services Manager (RSM), the Radiation Protection Officer (RPO) and Medical Physics Experts (MPEs). As per the compliance plan of the previous inspection, the undertaking had invited representatives from the Quality and Safety department, theatre and nurse referrers to attend the meetings. This ensured that all areas involved in the delivery of medical exposures discussed issues and received updates on the radiology service.

Inspectors were informed that the undertaking's management team had also established a radiation task force (RTF), which met twice annually at a minimum and was attended by the RSM, RPO and MPE. This group provided support to the RSC by addressing day-to-day radiation protection issues, and by preparing reports and updates to discuss at the RSC meetings. Members of this group were central to the effective incident management and equipment monitoring systems in the service.

From discussions with the management team, inspectors were informed that radiation protection matters discussed at the RSC, were subsequently discussed at the hospital's Executive Management Team meetings, also chaired by the Designated Manager. This team then provided the Royal College of Surgeons Ireland

(RSCI) group with a monthly report on radiation protection matters. The RCSI group met with the HSE's undertaking representative at Acute Hospital Group meetings. These reporting arrangements satisfied inspectors that the undertaking could be made aware of any radiation protection issues arising in this service. However, despite this improvement since the previous inspection, inspectors identified that further action was required in the clear allocation of roles and responsibilities, of staff working in the service, in order to comply with Regulation 6: Undertaking.

Inspectors observed that the RTF team had lead and completed a range of clinical audits to identify areas of good practice, and areas requiring action in the radiology service. Inspectors were also informed that the team were reviewing their approach to and documentation on clinical audit, to ensure that they aligned with the national procedures on clinical audit published by HIQA in November 2023. Inspectors observed that the RTF team had also made good efforts to provide service users with clear information on the doses received during an exposure, and the risks and benefits associated with these exposures. This information was displayed on posters throughout the service. Inspectors were also informed that the MPE team had provided all staff with training in radiation protection both in-person and on-line. These initiatives were identified as areas of good practice within the service.

A sample of radiological procedures records were reviewed by inspectors during the inspection and showed 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.

Inspectors were assured that MPE involvement in the service was proportionate to the radiological risk posed by the service, and that in actioning their compliance plan of the previous inspection, the undertaking had implemented improved arrangements to assure the continuity of this service.

Notwithstanding the actions required to achieve full compliance with the regulations, inspectors observed that there were many good radiation protection measures in place in Connolly Hospital, to ensure the safe delivery of exposures to service users.

Regulation 4: Referrers

The role of referrer had been allocated to medical practitioners, while hospital approved nurses could also act as referrers for a specified general X-ray procedures. Inspectors were also informed that radiographers could make adapted and secondary referrals for medical exposures.

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

Judgment: Compliant

Regulation 5: Practitioners

Inspectors noted that only those entitled to act as practitioners were found to take clinical responsibility for medical exposures completed in Connolly Hospital. In this facility radiographers and radiologists had been allocated the role of practitioner, which is in line with Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that the undertaking had established governance and management arrangements, to provide oversight of radiation protection measures in place in the radiology service in Connolly Hospital.

However despite these arrangements, inspectors noted that action was required to ensure that all roles and responsibilities on radiation protection were clearly allocated and documented in the relevant documentation, and that they aligned with the regulations. For example;

- From a review of service user's records on medical exposures, inspectors noted that for a sub-set of exposures completed for orthopaedic assessments and theatre procedures, the undertaking had not allocated the evaluation of the clinical outcome of the exposure to a practitioner. This is further discussed under Regulation 10: Responsibilities below.
- The *Justification for Procedures Policy in CHB* outlined the roles and responsibilities of referrers and practitioners involved in the justification process, however it did not include the roles and responsibilities when completing this process for exposures completed in theatre. Inspectors also noted that these allocated roles and responsibilities were not documented in any other relevant policy or procedure provided to the inspectors.
- During discussions with staff in the interventional fluoroscopy suite, inspectors were informed of a process for identifying patients that may receive high skin doses during exposures. However, inspectors were not provided with documentation that guided and supported staff on their roles and responsibilities in these processes. A clear allocation of roles and

responsibilities is a key part of the overall radiation protection of services users in a high dose service.

- On review of a number of documents including the local *Radiation Safety Procedures*, it was not clear to inspectors which groups of professionals, as defined in Regulations 4 and 5, had been allocated the roles of referrer and practitioner in the radiology service. For example, it stated that registered dentists could act as referrers and practitioners in the service, when in practice referrals were not accepted from these groups of professionals and they were not acting as practitioners.

Inspectors noted that the document quality management system in the radiology department required action. For example;

- Inspectors were not satisfied that personnel had been adequately assigned responsibility with regard to the document management system in the service. This is necessary to ensure that there is appropriate oversight of all procedures and protocols available to staff in the department, and that there is a system in place to ensure that, when updated, the author, approver and version number is clear on all documents. An effective document management system is a key element of radiation protection of service users and of monitoring a service's compliance with the regulations.
- From the review of a number of documents, inspectors also observed that improvements were required to ensure that, where roles and responsibilities had been allocated, they are clear and available to staff. For example, the *Pregnancy Policy for CHB* mentioned details in Appendix i and ii for staff to refer to when enquiring on pregnancy status of service users, however these appendices were not included in the policy.

While improvements were required in the allocation of roles and responsibilities in some areas, and in the documentation to support staff in these roles, inspectors were satisfied that many good processes in place to ensure that service users in the radiology department received safe exposures of ionising radiation.

Judgment: Not Compliant

Regulation 10: Responsibilities

From discussions with staff and a review of documents, inspectors were satisfied that referrers, practitioners and the MPE team were aware of their responsibilities in the optimisation of doses delivered to service users during medical exposures. Similarly, recognised referrers and practitioners were involved in justifying medical exposures completed in Connolly Hospital.

Inspectors were assured that medical exposures were performed under the clinical responsibility of a practitioner, as defined by the regulations, for CT and for most

general radiography exposures completed in this service. However, from discussions with the management team, a review of the documented roles and responsibilities and a review of radiology reports, inspectors were not satisfied that a practitioner had been allocated clinical responsibility for the clinical evaluation of the outcome of exposures completed for a sub-set of exposures completed for some orthopaedic and theatre procedures. This was discussed with the management team on the day of the inspection as an area that required action, in order to fully comply with the regulations.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

From discussions with staff and a review of a service level agreement, inspectors were satisfied that actions, set out in the compliance plan of the previous inspection, had been implemented and that there were now appropriate arrangements in place to ensure the continuity of medical physics expertise in Connolly Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were informed that a team of MPEs were involved in and contributed to radiological practices and the radiation protection of services users in Connolly Hospital, and the current professional certification records for the team were reviewed by inspectors on the day of inspectors.

There was good evidence that the MPE team took responsibility for dosimetry and contributed to a range of responsibilities relating to medical radiological practices in Connolly Hospital, as per Regulation 20(2). A review of documentation and various records showed that they were involved in the optimisation of medical exposures, and contributed to the quality assurance (QA) and acceptance testing of medical radiological equipment. The team had also contributed to the review and approval of local diagnostic reference levels (DRLs) for each piece of equipment, and provided advice and dose calculation for radiation incidents.

Inspectors noted that an MPE attended and contributed to the RSC and RTF meetings, and were informed that they provided staff training in relevant aspects of radiation protection, by holding both online and in-person training sessions for all staff involved in the radiology service in the hospital.

Judgment: Compliant

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

From discussion with staff and documentation review, inspectors were satisfied that MPE involvement in medical radiological practices was proportionate to the level of radiological risk associated with practices in Connolly Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors saw that the undertaking's management team was committed to improving the radiation protection of service users, by ensuring that medical radiological procedure doses were kept as low as reasonably achievable. This was achieved through written protocols on standard exposures and referral guidelines available to staff, by regularly reviewing diagnostic reference levels (DRLs) and by implementing service improvements as a result of incident analysis and learning. However, inspectors noted that some action was required to achieve full compliance with Regulations 8 and 14.

From a review of documentation, inspectors noted that the justification process differed for the different imaging modalities, and observed that in the CT and general X-ray console areas, posters on the justification process specific to that area were displayed to guide and support staff. This was identified as an area of good practice in the service. However, inspectors also noted that for exposures completed in theatre, records evidencing that justification in advance had been completed were not available for exposures completed before March 2024. This is further discussed under Regulation 8 below.

From a review of QA reports, inspectors were satisfied that there was an equipment QA programme in place in the service. Since the previous inspection in March 2020, more frequent QA testing of the CT unit had been implemented, and an improved monitoring system for the QA programme was introduced by the RPO. This was identified as an area of good practice within the service. However, inspectors were not satisfied that all medical radiological equipment in use in the service was kept under strict surveillance. This is further discussed under Regulation 14 below.

Inspectors were assured that there was a process in place to determine the pregnancy status of service users, where relevant. From a review of service user records and clinical audits, inspectors were assured that this process was safe and effective. Inspectors also reviewed records that evidenced that there were good

arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Overall, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

On the day of the inspection inspectors reviewed a sample of written referrals for medical exposures and saw that each clearly stated the reason for the referral and was accompanied by sufficient medical data to allow the practitioner to determine if the procedure was justifiable. From discussions with practitioners, inspectors were informed that there were systems in place to ensure that, medical exposures were justified in advance of being completed by the referrer and practitioner, and that the justification decision was recorded.

The justification process was monitored through an audit programme by the undertaking's management team. This monitoring system had recently identified that, up to early March 2024, the justification decision had not been recorded for exposures completed in theatre. Inspectors noted that this was a good example of how clinical audit can identify gaps in compliance with the regulations, and thereby improve the service. Although inspectors were satisfied that the justification process was now recorded for all exposures completed in theatre, records evidencing that it had been completed prior to early March 2024 were not available to inspectors and therefore the undertaking was not compliant with Regulation 8(15).

Inspectors observed that the management team had made good efforts to inform service users on the risks and benefits associated with the dose from medical exposures. The team had developed *Patients Safety Guide* posters, which were displayed in all waiting areas, and had made good efforts to ensure that the information, contained in the posters, was presented in a way that it could be easily understood by service users. This was identified as an area of good practice in the service.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for common radiological procedures completed in Connolly Hospital, and from a review of the data inspectors noted that most were below national DRLs. For two procedures, where the 2023 DRL data was found to be above national levels, inspectors were informed that the RTF team had initiated an investigation, and had subsequently introduced measures that had reduced exposure doses. Inspectors were informed that the doses associated with these

procedures were to be reviewed again in the short-term to ensure that the measures introduced continued to be effective. This continuous monitoring by the management team was identified as an area of good practice in the service.

During a tour of the department, inspectors observed that the DRL information was displayed in all console areas, and staff who spoke with inspectors demonstrated an awareness of how to use the data when completing medical exposures of ionising radiation.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of the medical radiological equipment in Connolly Hospital, and noted that a quality assurance programme for this equipment had been established and maintained. The programme included regular performance testing by the Radiation Protection Officer (RPO) and radiographers, and annual testing by the MPE team. Inspectors also reviewed records of acceptance testing for all radiological equipment that had been completed before the equipment had been put into clinical use.

From discussions with staff, inspectors were satisfied that there were effective systems in place to ensure that appropriate personnel were informed of any equipment performance issues, and that any such issues were promptly addressed.

Inspectors noted, from the equipment inventory, that three pieces of radiology equipment had passed the timeline at which they should be considered for routine replacement. Inspectors were informed that some upgrades had been made to the equipment, and additional testing and measures had been implemented to improve the performance of this equipment and to ensure that it was more closely monitored. However, records of additional oversight and testing of this equipment was not available to inspectors. Therefore, inspectors were not satisfied that the undertaking had clearly defined and documented arrangements in place to ensure that all medical radiological equipment in use past routine replacement dates was kept under strict surveillance.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were satisfied that there were appropriate measures in place to minimise the risks, associated with potential foetal irradiation, during medical exposures of female patients of childbearing age.

The management team had developed a Pregnancy Policy for CHB which, notwithstanding the minor updates required as detailed under Regulation 6, provided guidance and support to staff. It stated that practitioners were responsible for inquiring on and recording in writing the service user's pregnancy status, where relevant, and from discussions with radiographers, inspectors were satisfied that radiographers, as practitioners, were aware of their specific responsibilities in this area. From a review of a sample of radiological procedure records for relevant service users, were satisfied that inquiries were made and recorded where relevant. The management team within the radiology department had developed flowcharts on this process, which were displayed in all console areas, to support staff. This was identified as an area of good practice in the service.

Inspectors also observed that the management team had placed notices to raise awareness of the special protection required during pregnancy in advance of medical exposures, in numerous service user waiting areas.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed the local *Radiation Incident Policy in CHB*, and saw that it outlined the process for the management of accidental and unintended exposures and significant events, including information on the requirement to notify HIQA of certain significant events. Since the previous inspection, a system had been introduced by the radiology management team on how to report and manage a potential radiation incident, and inspectors noted that the policy had been updated to include guidance for staff on this system. During the inspection, staff who spoke with the inspectors demonstrated good awareness of the incident reporting pathways outlined in the incident policy.

The *Radiation Incident Policy in CHB* stated that when an incident or potential incident occurs it is recorded by staff and then analysed by the management and MPE teams. Inspectors were informed that the Quality and Safety team were also promptly informed of any such incidents, and that all were discussed at the quarterly RTF and biannual RSC meetings, where actions and investigations were discussed and agreed. Inspectors were also informed that the radiology department's management team and the Quality and Safety team met routinely to ensure that all radiation incidents were being appropriately managed, and that all incidents were discussed at the hospital's monthly Quality and Safety meetings. Inspectors were also informed that the radiology department's management team had, when required, met with the emergency department (ED) manager to provide feedback to ED referrers on actual and potential incidents resulting from the referral process. This team approach to incident management and learning was identified as good practice within the service.

During the inspection, inspectors were informed that radiation incidents meeting certain criteria were subsequently discussed at fortnightly Local Incident Management meetings which were chaired by the General Manager of Connolly Hospital, and that through the RCSI Hospital Group's Serious Incident Management Framework, they were reported to the undertaking representative.

Prior to the inspection, inspectors had noted that the number of incidents and potential radiation incidents reported, were comparatively low to the number of medical exposures completed in the radiology service. During the inspection, inspectors were informed that the management team believed that this was due to good adherence by staff to policies and processes, and the effective measures implemented when an incident did occur. For example, inspectors saw from the review of service user records on exposures completed that a new check had been introduced following a recent incident, which strengthened the justification process. This willingness to implement appropriate process changes to manage radiation incidents was identified as an area of good practice in 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	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	Substantially Compliant
Regulation 11: Diagnostic reference levels	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 Connolly Hospital OSV-0007352

Inspection ID: MON-0040998

Date of inspection: 17/04/2024

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <ul style="list-style-type: none"> • As of April 17th 2024 responsibility for clinical evaluation of outcome and for ensuring radiation dose information is included on report has been allocated to radiographers working as practitioners. • For Theatre specifically the RPO who holds a recognised qualification in plain film reporting will undertake this role, in their absence a suitably qualified delegate will undertake this role. • Outpatient plain films: additional resources have been allocated to Radiologists to ensure all examinations have a clinical outcome and dose report. <p>All theatre studies carried out prior to this date will be retrospectively completed by a radiographer working as a practitioner and will be completed by August 31st 2024 at latest.</p> <p>Ongoing audit monthly/bimonthly will continue to take place to ensure compliance, audit to be completed by RPO or delegate. This audit, and any corrective action QIPs, will form part of standing agenda item for the Radiation Safety Committee for oversight and governance purposes.</p> <p>The CHB Radiation Safety Procedures Document & The Local Rules for Theatre Document have been updated to allocate responsibility for clinical evaluation of outcome and ensuring radiation dose is included on report to radiographers working as practitioners.</p> <ul style="list-style-type: none"> • From March 1st 2024 the Justification for Procedures Policy in CHB have allocated responsibility for completing the justification process for exposures completed in theatre to radiographers working as practitioners. <p>Ongoing audit initially monthly and phased to bimonthly after six months. This audit, and any corrective action QIPs, will form part of standing agenda item for the Radiation Safety Committee for oversight and governance purposes.</p> <ul style="list-style-type: none"> • An SOP on the Management of Skin Burns Post Fluoroscopy/IR has been drafted and is currently under review. Once approved this SOP will be made available to all relevant 	

staff; this will be completed by 30th June 2024. The Radiation Protection Task Force will sign off on SOP. This will be reviewed by RSC at meeting.

- The Radiation Safety Procedures (Local Rules) have been updated to define “Connolly Hospital Referrers” clarifying that Dentists do not act as Referrers in CHB completed by 31st May 2024.

- The RSM and Deputy RSM have taken responsibility for the document quality management system ensuring consistent format used for all documentation including: date updated, the author, approver and version number on all documents [responsibility allocation evidenced by minutes of RPTF meeting May 15th 2024]

Documentation will be reviewed by RPTF for sign off, SOP’s and policies are clear and available to all relevant staff on shared drive folder with access controls in place for relevant staff.

Regulation 10: Responsibilities

Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:

- As of April 17th 2024 responsibility for clinical evaluation of outcome and for ensuring radiation dose information is included on report has been allocated to radiographers working as practitioners.

- For Theatre specifically the RPO who holds a recognised qualification in plain film reporting will undertake this role, in their absence a suitably qualified delegate will undertake this role.

- Outpatient plain films: additional resources have been allocated to Radiologists to ensure all examinations have a clinical outcome and dose report.

All theatre studies carried out prior to this date will be retrospectively completed by a radiographer working as a practitioner and will be completed by August 31st 2024 at latest.

Ongoing audit monthly/bimonthly will continue to take place to ensure compliance, audit to be completed by RPO or delegate. This audit, and any corrective action QIPs, will form part of standing agenda item for the Radiation Safety Committee for oversight and governance purposes.

The CHB Radiation Safety Procedures Document & The Local Rules for Theatre Document have been updated to allocate responsibility for clinical evaluation of outcome and ensuring radiation dose is included on report to radiographers working as practitioners.

Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>Justification process is in place since March 2024; this is recorded for all exposures completed in theatre. Ongoing audits taking place monthly for 6 months and then bimonthly to ensure compliance.</p> <p>These audits and outcomes will form part of standing agenda item on RSC for review.</p>	
Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment:</p> <p>Equipment inventory highlighting any equipment that is beyond its nominal replacement date will be reviewed and approved off at each RSC as standing agenda item. Physics QA reports will also indicate where appropriate if equipment is beyond its nominal replacement date.</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.	Not Compliant	Orange	31/08/2024
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	Substantially Compliant	Yellow	31/03/2024

	exposure, and shall provide such records to the Authority on request.			
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	31/08/2024
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	30/06/2024