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:	CHI at Connolly
Undertaking Name:	Children's Health Ireland
Address of Ionising Radiation Installation:	Blanchardstown, Dublin 15
Type of inspection:	Announced
Date of inspection:	26 April 2023
Medical Radiological Installation Service ID:	OSV-0006025
Fieldwork ID:	MON-0039309

About the medical radiological installation:

Children's Health Ireland at Connolly is a part of the Children's Health Ireland (CHI) Group, which also includes CHI at Temple Street, CHI at Crumlin and CHI at Tallaght. CHI at Connolly is a primary care facility which provides outpatient and urgent care paediatric services to children aged between 3 months and 16 years. The major specialities at CHI at Connolly includes general paediatrics, out-patient services including orthopaedics, rheumatology and physiotherapy. Additionally, allergy clinics, phlebotomy and therapy counselling services are provided to outpatients.

The CHI Connolly Radiology Department provides general X-ray, mobile radiography, dental and ultrasound imaging to patients. The general, mobile and dental units all use ionising radiation. Referrals for medical radiological procedures in CHI at Connolly are received from General Practitioners, Urgent Care Consultants, Urgent Care Non Consultant Hospital Doctors, Advanced Nurse Practitioners and Clinical Nurse Specialists (who have been approved locally to refer within their defined scope of practice) and Radiographers (adapted and secondary referrals only). All general radiography is led by a Clinical Specialist Radiographer, with the support of a multi-disciplinary team.

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 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. 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 26 April 2023	09:30hrs to 15:45hrs	Margaret Keaveney	Lead
Wednesday 26 April 2023	09:30hrs to 15:45hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiological service of Children's Hospital Ireland (CHI) at Connolly to monitor the service's compliance with the regulations. On the day of inspection, inspectors visited the facility's general radiography (X-ray) rooms.

The undertaking for the facility is the Children's Hospital Ireland (CHI), and inspectors saw that there were appropriate governance and management arrangements in place to ensure good oversight of the radiation protection of service users. However, action is required by the management team of CHI at Connolly to achieve compliance with regulations 6, 11 and 13, and this is discussed further in the report.

The radiology department in CHI at Connolly consists of two general X-ray units, a mobile X-ray unit and an orthopantomogram (OPG) unit, that provide medical exposures of ionising radiation to paediatric out-patients. The department is led by a clinical specialist radiographer (CSR) who is supported by the Radiation Service Managers (RSM) in CHI at Temple Street and CHI at Crumlin, the CHI's medical physics expert (MPE) team, CHI's team of radiologists, an operations manager and radiography staff.

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.

MPE involvement in the service was determined to be proportionate to the radiological risk posed by the service, and the undertaking had robust arrangements in place to assure the continuity of this service.

Overall, inspectors were assured that service users were receiving a safe radiological service at CHI at Connolly.

Regulation 4: Referrers

From discussions with staff and a review of a sample of medical exposures records, inspectors was satisfied that only referrals for medical radiological procedures, from persons defined in regulation 4, were made at this service.

The *Referral for Radiological Imaging Policy: CHI at Connolly* clearly outlined who

can refer for medical radiological procedures at the facility. This included general practitioners, doctors working within CHI, advanced nurse practitioners and clinical nurse practitioners, whose scope of practice to refer was defined by a CHI implementation group, and radiographers who were allocated responsibility to make secondary referrals and adapted referrals.

Inspectors spoke to a number of staff who were able to explain the scope in which they could refer patients for medical exposures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from the documents reviewed and from speaking with staff that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures at CHI at Connolly.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed governance structure organograms, received prior to the inspection, which did not provide adequate clarity on governance and management roles within CHI at Connolly. However, from a review of further documentation and discussions with staff on the day of the inspection, inspectors were assured that, overall, there was a clear allocation of roles and responsibilities for the radiation protection of service users in place in the radiology service.

CHI has established a number of forums at local and group level to ensure that they have adequate oversight of the radiological services in the facility. A Radiation Safety Working Group (RPWG), attended by a radiologist, the radiation protection officer, CSR and RSM and MPE staff, met quarterly to discuss items such as radiation safety incidents, dose optimisation, clinical audit and to review procedures**.** Inspectors saw that this group reported to the CHI group's overarching Radiation Safety Committee (RSC), which is chaired by the undertaking representative, who is also the chief executive officer of CHI. Radiation safety incidents are also discussed at the local Quality and Patient Safety (QPS) meeting, which reports to the group's Quality, Safety and Risk Management (QSRM) Executive Committee, which in turn reports to the Board of CHI.

The Clinical Director of CHI at Connolly assumed the role of the undertaking's designated manager (DM) in the facility. Inspectors were informed that they attend the group's RSC and QSRM committee meetings.This gave the DM oversight of

radiation safety issues in CHI at Connolly, and allowed them to ensure that the undertaking was adequately informed of any such issues.

Despite these governance and management structures, inspectors were not assured that the undertaking had appropriate arrangements in place to ensure that the regular review of diagnostic reference levels (DRLs) was completed by staff responsible for this task. DRLs must be regularly reviewed to ensure that they are contributing to dose optimisation for patients undergoing a medical exposure of ionising.

Also, during the course of the inspection, inspectors reviewed a number of documents that required action to ensure that all responsibilities were allocated to appropriate staff. For example;

- The *Optimisation of Medical Exposures* policy did not clearly outline who was responsible, where practicable, for obtaining previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposures
- The *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* also did not clearly state who was responsible for discussing and recording the pregnancy status with the patient, and explaining to the patient the risks of radiation exposure to the foetus

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, only persons entitled to act as a practitioner, as defined in the regulations, carried out the practical aspects of and took clinical responsibility for the medical radiological procedures at the service.

Practitioners and the MPE were noted to be involved in the optimisation process for medical exposures to ionising radiation.

Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from discussions with staff and a review of documentation that the undertaking had arrangements in place to ensure access to and continuity

of MPE services. The CHI's MPE team, which consisted of a number of staff members, provided the facility with continuous access and support.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of the MPEs at CHI at Connolly, and were satisfied that the involvement and contribution of the MPE team in the service met the requirements of the regulation.

Inspectors noted that the MPE team assumed and completed a range of responsibilities across the service, as outlined in regulation 20(2). Inspectors observed that they were involved in quality assurance of medical radiological equipment, patient dosimetry, sign off of facility diagnostic reference levels (DRLs) and provided advice and dose calculation for radiation incidents. The MPE team members attended the local RPWG and group level RSC meetings, at which they provided and received updates on their responsibilities.

A MPE was assigned the role of radiation protection advisor (RPA) at the facility, which satisfied inspectors that the MPE and the RPA liaised, as appropriate.

Judgment: Compliant

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

From documentation viewed and discussions with the MPE and management staff, inspectors were satisfied that the level of MPE involvement in medical radiological practices was commensurate with the radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors saw that the undertaking was committed to improving the radiation protection of service users through the implementation of numerous dose optimisation initiatives. However, inspectors were not assured that systems were in place to ensure that local facility DRLs were regularly reviewed or that patient exposures formed part of the

procedure report.

During the inspection, all referrals reviewed by inspectors 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. The justification of medical exposures in advance, by a practitioner, was evident for all medical radiological procedures reviewed by inspectors over the course of the inspection.

From a review of documentation, inspectors were satisfied that relevant local facility DRLs had been established, and were used for all medical radiological procedures conducted in the service. However, as previously stated in this report, there was no evidence to support that these DRLs were regularly reviewed. This is further discussed under Regulation 11 Dose Reference Levels, below.

Inspectors saw that written protocols for all radiological procedures had been developed and were easily accessible to staff in the clinical areas. Inspectors also observed that a range of clinical audits had been completed to identify areas of good practice, and areas requiring action to ensure the safe delivery of medical radiological exposures to service users. However, from a review of a sample of exposure reports inspectors saw that patient exposures did not form part of the report.

From a review of records and speaking with a number of staff on the day of inspection, inspectors were satisfied that the undertaking had implemented a robust quality assurance programme for all equipment in use in the service, to ensure that it was safe for use and fit for purpose. From a review of governance meeting minutes, inspectors saw that quality assurance programmes were routinely discussed at these meetings.

Inspectors were assured that there was a process in place to determine the pregnancy status of service users, where relevant. From a review of patient records and clinical audits, inspectors were assured that this process was monitored and adhered to by staff.

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 undertaking had oversight of incidents that occurred on the facility and that the Authority was notified of any reportable events.

Regulation 8: Justification of medical exposures

On the day of the inspection, all referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data to enable the practitioner to adequately 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 available to service users by means of information leaflets and posters in waiting areas.

The *Referral for Radiological Imaging Policy: CHI at Connolly* outlined most aspects of the justification process and who was responsible for carrying out this process in the service. Although some clarity on responsibilities in this policy were required, inspectors were satisfied from speaking with staff that adequate information was taken into account by practitioners when making the justification decision.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, inspectors spoke with staff and reviewed documentation that showed that the management team at CHI at Connolly had processes in place to ensure that all medical radiological procedure doses were kept as low as reasonable achievable. This included establishing and using DRLs. However, these DRLs should be regularly updated as detailed under Regulation 11.

A *CHI Optimisation of Medical Exposures* policy was in place which outlined the overarching approach to optimisation at CHI at Connolly. This approach included a focus on optimisation in the radiographer's induction programme and during training in other CHI facilities. It also outlined CHI's approach to the implementation and maintenance of a quality assurance programme that included regular quality control (QC) testing, and identified a person to action any issues that were identified during QC and QA testing.

Inspectors also reviewed documentation and results of a recent cross-site review and comparison of exposure factors which was completed to ensure that all patients attending a CHI radiology service receive a comparable standard of care. This integrated approach to dose optimisation across the CHI group was identified as an area of good practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors observed that DRLs had been established for common paediatric radiological procedures completed at CHI at Connolly, and were comparable to national DRLs, where established. DRL charts were displayed in console areas and staff spoken with demonstrated an awareness of how to use the DRLs when completing medical exposures of ionising radiation.

The undertaking's *Policy on Establishing DRLs* was in line with the regulations in

stating that they should be regularly reviewed. However, inspectors observed that that the facility's DRLs were not regularly reviewed. From a review of documentation and discussions with staff, inspectors observed that the DRLs in use on the day of inspection had been established in 2019 and were based on ionising radiation procedures that had been completed in another CHI radiology department, that had similar equipment in use. Although inspectors saw that a comprehensive review of the DRLs for paediatric procedures had been completed in the facility in April 2023, the DRLs from this review were not in use on the day of inspection.

Judgment: Not Compliant

Regulation 13: Procedures

Inspectors noted that written protocols for each standard radiological procedure were provided in the service and were on display in the console areas of the X-ray rooms for easy access by staff. Inspectors reviewed a sample of these protocols, and saw that they provided adequate information to staff to allow them to deliver safe medical exposures to paediatric patients. Inspectors also observed that referral guidelines were available to referrers.

Inspectors noted that the management team at CHI at Connolly viewed clinical audit as an important tool to identify areas for improvement and of good practice, in order to ensure the safe delivery of medical exposures to service users. Inspectors reviewed a number of clinical audits, completed by the CSR and radiation protection officer (RPO), and saw that they were discussed and actioned at the local RPWG, with results and learning also shared at the group's RSC. Inspectors noted that there was a clinical audit schedule in place for 2023, which covered areas such as adherence to the pregnancy policy and various aspects of the justification process. Staff also informed inspectors that there was monthly auditing of incomplete referrals, identified at the vetting process, and that the audit results were discussed at daily 'risky huddles' and efficiently fed back to relevant staff in CHI at Connolly.

Although inspectors noted many safe radiation protection practices in CHI at Connolly, inspectors reviewed a number of records of reports on medical exposure procedures and saw that information relating to patient exposure was not included on the reports. Therefore, the undertaking did not met the requirements of regulation 13 (2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that the undertaking had established a robust quality assurance programme (QA) to ensure that all medical radiological equipment, in use in the service, was kept under strict surveillance. The RPO and the MPE team were assigned responsibility for developing and implementing the QA programme, which was supported by a policy outlining to staff their responsibilities in relation to this programme. The programme included annual testing by the MPE and regular performance testing by radiographers. Inspectors reviewed QA records which verified that the testing programme was effectively implemented with testing timelines adhered to.

Inspectors also found evidence that effective systems were in place to ensure that any performance issues with the medical radiological equipment were actioned. In addition, inspectors were satisfied that acceptance testing was carried out on equipment prior to the first clinical use.

In advance of the inspection inspectors received an up-to-date inventory of medical radiological equipment.

Judgment: Compliant

Regulation 15: Special practices

Inspectors observed that the management team at CHI at Connolly had in place a number of practical techniques to ensure that paediatric patients were appropriately protected during exposures to ionising radiation.

From discussions with practitioners, and observations in clinical areas, inspectors were informed that a play specialist and various ancillary play items were available to patients to aid them to remain as still as possible during exposures. There was also a sensory room available to paediatric patients with sensory and communication challenges, which also assisted in relaxing patients prior to undergoing medical exposure of ionising radiation. These facilities also contributed to optimising exposure times and ensuring that all doses received were as low as possible, while obtaining suitable diagnostic imaging.

Inspectors also observed that appropriate medical radiological equipment was in use in the department, and that consideration had been given to continuously improving the optimisation process for paediatric patients. For example, inspectors were informed that the purchase of a single detector X-ray unit had been approved, which would aid the speedy acquisition of of single-shot spinal and lower limb X-ray images. Inspectors were also informed that the results of an audit of knee and ankle X-ray examinations for paediatric patients in the CHI group had resulted in changes to the imaging procedure in CHI at Connolly, and improved optimisation, for this cohort of patients.

Inspectors were also informed that a multi-disciplinary team, consisting of the CSR,

Consultant Radiologist, RSM and MPEs met in advance of completing any non-standard paediatric imaging requests to ensure that the medical exposure was safely and effectively carried out.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed a notice, in a number of languages, was displayed in the service user waiting area to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. From a review of two medical records, inspectors saw practitioners had inquired on and recorded in writing the pregnancy status of patients. This was in line with the local pregnancy policy, which stated that practitioners were assigned the responsibility for inquiring on patients' pregnancy status, where relevant.

Overall, inspectors were assured that appropriate measures were in place to ensure the protection of patients that were pregnant while attending the radiology service in CHI at Connolly. However, as discussed under Regulation 6 Undertaking, action was required to ensure that the pregnancy policy clearly outlined the personnel responsible for enquiring on patients pregnancy status and to ensure that it aligned with the requirements of the regulations.

Judgment: Substantially 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. Staff who spoke with inspectors were able to clearly describe how they accessed and used this system.

From a review of documentation and discussions with the management team, inspectors observed that incidents were discussed at the local QPS meeting, which met monthly and the local RPWG, which met quarterly. All such incidents were also then discussed at the CHI RSC meeting, which was attended by the Designated Manger of CHI at Connolly and chaired by the undertaking representative.

Inspectors also observed that if an incident occurred and a gap in a process was identified, that had not previously been known, an investigation report was completed to address the gap. Inspectors were informed that such an investigation was completed, irrespective of whether the incident was reportable or otherwise.

This continuous improvement approach to incident management demonstrated good practice, which promoted the radiation safety of patients attending the facility.
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 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Substantially 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 CHI at Connolly OSV-0006025

Inspection ID: MON-0039309

Date of inspection: 26/04/2023

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: To provide further reassurance and clarity on the radiation protection governance in CHI at Connolly, an organogram has been updated and details the local structures in place. It highlights the support the Clinical Specialist Radiographer (CSR) has from their line manager and the RPA, MPE and RPO. It also outlines the committees on which the CSR sits where radiation protection issues can be highlighted and escalated where required. The overarching governance of the CHI Radiation Safety Committee is also demonstrated. As per the Delegation document shown to inspectors during the inspection, the establishment and review of DRLs is delegated to the RSC to oversee and RPA, MPE, RPO, and the CSRs to establish and review. The DRLs for CHI at Connolly have been reviewed and updated for 2023 and the latest versions are now in use. In addition, the units used have been amended to match that of the X-ray system. The DRL policy has also been edited to explicitly state that annual reviews of DRLs will be carried out and this will be overseen by the CHI RSC. Furthermore, a new dose audit has been introduced to CHI Connolly where a different anatomical region is audited each month in comparison to the DRLs. This audit has a trigger level at which a review of a specific DRL will be undertaken. In relation to "obtaining previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposures", a line has been added on page 7 of the Referral for Radiological imaging Policy at Connolly which states "Radiographers in CHI at Connolly review each referral in advance of its performance, and perform a detailed review of the patient's prior imaging history in order to collate all the necessary and relevant clinical information for justification. They also have an opportunity to further discuss an examination with patients." CHI feels that this is the appropriate location for this detail to be captured. Finally in relation to defining roles in relation to the pregnancy question, Section 5.1 and 5.2 of CHI Pregnancy Policy already clearly defined the responsibilities of the referrer and practitioner regarding the discussing and recording of pregnancy status. Some ambiguity in the document may have arisen due to the use of the word 'operator'. This term has	

been removed from the latest version of this policy in order to provide additional clarity around roles and responsibilities.

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
The DRLs have been reviewed and updated for 2023 (attached). These updated values are now in use at CHI at Connolly. The units used have been amended to match that of the x-ray systems.

The DRL policy has also been edited to explicitly state that annual reviews of DRLs are to be carried out (see attached DRL Policy document).

Furthermore, a new dose audit has been introduced (also attached) to CHI at Connolly which audits a different anatomical region each month in comparison to the local DRLs. This audit has a trigger level at which a review of a specific DRL will be undertaken.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
In order to come into compliance with Regulation 13, CHI believe an automated dose monitoring /reporting process must be implemented across all modalities using the PACS/RIS systems. There is a national plan to progress an automated dose recording capability within the RIS PACS platform. In the interim, all imaging reports currently direct the referrer to the image for the dose delivered during the exposure.

Furthermore, work to communicate with referrers around typical CHI doses, optimisation methods and the use of referral guidelines is continuing. Once ratified at the CHI RSC in July 2023, an information leaflet on these topics will be sent to all CHI referrers. This will also be available on the CHI website.

In addition, CHI Medical Physics are also working with the RIS PACS provider to devise an interim solution to be used nationally until the national dose tracking software comes online. However, the difficulties associated with grouping paediatric doses into bands as currently recommended for adult patients are well recognised.

Overall the solution using the automated dose monitoring /reporting process by HSE is

what CHI aims to achieve full compliant with this regulation, which should be implemented in Q1 2024.	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: The Stage 1 report states that "The Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures also did not clearly state who was responsible for discussing and recording the pregnancy status with the patient, and explaining to the patient the risks of radiation exposure to the foetus". Section 5.1 and 5.2 of this document already clearly defined the responsibilities of the referrer and practitioner regarding the discussing and recording of pregnancy status. Some ambiguity in the document may have arisen due to the use of the word 'operator'. This term has been removed from the latest version of this policy in order to provide additional clarity around roles and responsibilities.	

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	09/06/2023
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	09/06/2023

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	31/03/2024
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	09/06/2023