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 Temple Street
Undertaking Name:	Children's Health Ireland
Address of Ionising Radiation Installation:	Temple St, Dublin 1
Type of inspection:	Announced
Date of inspection:	15 June 2022
Medical Radiological Installation Service ID:	OSV-0006027
Fieldwork ID:	MON-0035044

About the medical radiological installation:

Children's Health Ireland (CHI) at Temple Street is a part of the Children's Health Ireland (CHI) Group, which also includes CHI at Crumlin, CHI at Connolly and CHI at Tallaght.

CHI at Temple Street is an acute national paediatric hospital. Major specialities at CHI at Temple Street include neonatal and paediatric surgery, neurology, neurosurgery, nephrology, orthopaedics, ear, nose and throat (ENT) and plastic surgery. The Radiology Department provides inpatient and outpatient diagnostic imaging services to paediatric patients across a wide range of modalities. The imaging modalities using ionising radiation in CHI at Temple Street include: General X-ray, including dental X-ray, Computed Tomography (CT), Nuclear Medicine, Interventional Radiology, Dual-energy X-ray absorptiometry (DXA) scanning and a Fluoroscopy service.

In CHI at Temple Street, referrers for medical radiological procedures are: General Practitioners, Hospital Consultants, non-consultant hospital doctors (NCHDs), Dentists, Advanced Nurse Practitioners and Clinical Nurse Specialists (who have been approved locally to refer within their defined scope of practice) and Radiographers. All modalities are led by Clinical Specialist Radiographers with 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 15 June 2022	09:30hrs to 15:25hrs	Noelle Neville	Lead
Wednesday 15 June 2022	09:30hrs to 15:25hrs	Kirsten O'Brien	Support
Wednesday 15 June 2022	09:30hrs to 15:25hrs	Lisa Corrigan	Support

Governance and management arrangements for medical exposures

An inspection was carried out at CHI at Temple Street on 15 June 2022 by inspectors to assess the hospital's compliance with the regulations. As part of this inspection, inspectors visited several clinical areas within the radiology department including CT, DXA, fluoroscopy and nuclear medicine, spoke with staff and management and reviewed documentation.

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). CHI was the undertaking for CHI at Temple Street. CHI at Temple Street had a local radiation safety committee (RSC). This committee met twice a year and reported to the wider CHI RSC that included all four CHI sites. The undertaking representative for CHI was a member of the CHI RSC which ensured oversight of radiation protection across the CHI sites. The CHI RSC reported to the OneCHI Quality, Safety and Risk Management Executive Committee and the CHI Chief Executive Officer who in turn reported to the CHI Board. Inspectors were provided with a document titled *Delegation of Radiation Protection* which clearly demonstrated CHI's delegation of responsibility to different members of the CHI at Temple Street RSC and referrers and practitioners.

Inspectors were satisfied from reviewing a sample of referrals and speaking with staff that referrals for medical radiological exposures were only accepted at CHI at Temple Street from individuals entitled to refer as per Regulation 4 and that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at the hospital. In addition, all medical exposures for ionising radiation at CHI at Temple Street were carried out under the clinical responsibility of an individual entitled to act as a practitioner as required by Regulation 10.

In relation to Regulations 19, 20 and 21, inspectors were satisfied that adequate processes were in place at CHI at Temple Street to ensure the continuity of medical physics expertise at the hospital. Inspectors noted strong involvement in, and oversight of, radiation protection by medical physics experts (MPEs) across a range of responsibilities including dosimetry, committee involvement, strict surveillance of medical radiological equipment, optimisation, incident management and training of staff.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at CHI at Temple Street and the hospital had clear and effective governance and management structures to ensure the radiation protection of service users.

Regulation 4: Referrers

CHI at Temple Street had a policy titled *Referral for Radiological Imaging Policy* which was published in June 2022. This policy clearly outlined who can refer for particular medical radiological exposures at the hospital and included general practitioners, hospital consultants, non-consultant hospital doctors (NCHDs), dentists, advanced nurse practitioners and radiographers. Inspectors were satisfied from reviewing a sample of referrals and speaking with staff that referrals for medical radiological exposures were only accepted at CHI at Temple Street from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at CHI at Temple Street.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms and spoke with staff and management in relation to the governance arrangements in place at CHI at Temple Street.

CHI was the undertaking for CHI at Temple Street and CHI at Temple Street had a local RSC. Inspectors reviewed the terms of reference for this committee and noted that it had multi-disciplinary membership including the hospital's clinical director who was also the designated manager, risk manager, radiology department director, radiography services manager, medical physics expert, radiation protection officer and representatives from other areas within the hospital including theatre. This committee met twice a year and reported to the wider CHI RSC that included all four CHI sites. The undertaking representative for CHI was a member of the CHI RSC which ensured oversight of radiation protection across the CHI sites. The CHI RSC reported to the OneCHI Quality, Safety and Risk Management Executive Committee and the CHI Chief Executive Officer who in turn reported to the CHI Board.

Inspectors were also provided with a document titled *Delegation of Radiation*

Protection which clearly demonstrated CHI's delegation of responsibility to different members of the CHI at Temple Street RSC and referrers and practitioners. For example, areas of responsibility which were delegated included practical aspects of a procedure, DRLs, equipment replacement programme and providing risk information for patients. Staff assigned responsibility in this document included MPEs, radiology services managers, medical doctors, radiographers and dentists.

Overall, inspectors were satisfied that clear and effective governance and management structures were in place at CHI at Temple Street to ensure the radiation protection of service users at the hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that all medical exposures for ionising radiation at CHI at Temple Street were carried out under the clinical responsibility of an individual entitled to act as a practitioner as per Regulation 5. Inspectors were also satisfied from a review of a sample of referrals, documentation and speaking with staff that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological exposures.

The practical aspects of medical exposures were only carried out by persons entitled to act as practitioner. Inspectors also noted that practitioners and MPEs were involved in the optimisation process for medical exposures.

In addition, CHI at Temple Street had retained the presence of radiographers together with other non-radiology specialities in areas such as theatre, where medical exposures were conducted. In the absence of new training requirements being implemented, as per Regulation 22, this is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of MPEs at CHI at Temple Street and were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors noted strong involvement in, and oversight of, radiation protection by MPEs across a range of responsibilities outlined in Regulation 20(2) at CHI at Temple Street. MPE's took responsibility for dosimetry including carrying out a range of dose audits. MPEs were members of several committees including the hospital RSC, the CHI RSC and the hospital's medical equipment replacement programme. Inspectors were informed that MPEs gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of this equipment. MPEs also contributed to the preparation of technical specifications for medical radiological equipment with a particular focus on paediatric suitability.

MPEs were involved in several optimisation projects. These included the application and use of DRLs and the optimisation of exposure factors across the CHI hospitals. In addition, MPEs at the hospital carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection.

Inspectors noted that MPEs also liaised with the hospital's radiation protection adviser as required by Regulation 20(3).

Judgment: Compliant

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

Inspectors were satisfied that MPEs were appropriately involved at CHI at Temple Street, with the level of involvement commensurate with the radiological risk posed by the hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited several clinical areas within the radiology department including CT, DXA, fluoroscopy and nuclear medicine, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at CHI at

Temple Street.

Inspectors noted several examples of good practice at the hospital. Staff and management informed inspectors that alternative non-ionising imaging modalities were considered where possible, such as ultrasound and magnetic resonance imaging (MRI), to limit paediatric service user's exposure to ionising radiation. Where medical exposure to ionising radiation was required, inspectors were satisfied that CHI at Temple Street had processes in place to ensure that the most appropriate dose for each individual was delivered.

The hospital had measures in place to ensure that appropriate medical radiological equipment and practical techniques were used and special attention was given to the assessment and verification of dose and administered activity for children undergoing medical exposure to ionising radiation at the hospital. Given that CHI at Temple Street provide an imaging service to paediatric service users, it was assuring to inspectors that staff at the hospital demonstrated an awareness of dose constraints. In addition, inspectors found from speaking with staff and management that CHI had proactively assessed the radiation dose received by individuals acting as carers and comforters at the hospital.

Inspectors also noted examples of improvements that should be made to ensure compliance with the regulations. For example, inspectors were satisfied that the hospital had a process for justification of medical radiological procedures. However, while inspectors were assured that justification was carried out in advance and a record retained for modalities such as CT and nuclear medicine, inspectors found that a record of justification in advance was not available for general X-ray procedures. For compliance with Regulation 8, a record of justification in advance must be retained for a period of five years from the date of the medical exposure. Therefore, the hospital should implement a system to ensure a record of justification is retained for all medical exposures as required by Regulations 8(8) and 8(15).

Inspectors were also satisfied that CHI at Temple Street had established, regularly reviewed through dose audit and used DRLs at the hospital. However, the hospital should ensure that local DRLs are established in a manner that is consistent with the specific weight groupings used for national DRLs to allow for meaningful comparison of dose, and compliance with Regulation 11.

In relation to Regulation 13, written protocols were in place at CHI at Temple Street for standard medical radiological procedures and the hospital had adopted referral guidelines which were available to staff and referrers. In addition, inspectors reviewed an extensive list of clinical audits ongoing and completed at CHI at Temple Street which involved multi-disciplinary input. While efforts had been made by the hospital to comply with Regulation 13(2), inspectors determined that these measures, as detailed under Regulation 13, were not sufficient to meet compliance. CHI as the undertaking for CHI at Temple Street, must ensure that appropriate measures are implemented at the hospital to ensure compliance with the requirements of Regulation 13(2).

Overall, inspectors noted several examples of good practice during the inspection

and were satisfied that CHI at Temple Street demonstrated that systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

CHI at Temple Street had a document titled *Referral for Radiological Imaging Policy* which was published in June 2022. This policy clearly outlined the justification process and who was responsible for carrying out this process at the hospital. Inspectors were informed by staff and management that justification in advance was carried out by a practitioner, and inspectors found that a record of justification in advance was retained for modalities such as CT and nuclear medicine. However, inspectors found that a record of justification in advance was not available for general X-ray procedures. Inspectors were informed that these records were not uploaded to the radiology information system due to workload pressures and instead a sample was audited before these records were destroyed. For compliance with Regulation 8, a record of justification in advance must be retained for a period of five years from the date of the medical exposure. Therefore, the hospital should implement a system to ensure a record of justification is retained for all medical exposures as required by Regulations 8(8) and 8(15).

Inspectors were satisfied from reviewing a sample of records that referrals were in writing and stated the reason for the medical radiological procedure. Staff and management informed inspectors that alternative non-ionising imaging modalities were considered where possible, such as ultrasound and magnetic resonance imaging (MRI), to limit paediatric service user's exposure to ionising radiation. In addition, CHI at Temple Street provided risk and benefit information to service users in relation to medical radiological procedures and information was also available on posters which were displayed in waiting areas of the hospital.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors were satisfied from speaking with staff and management and reviewing documentation that CHI at Temple Street had processes in place to ensure that the most appropriate dose for each individual medical exposure to ionising radiation was delivered. The hospital had a policy titled *Optimisation of Medical Exposures* which was approved in February 2020. This policy outlined the optimisation process in place at the hospital and demonstrated how optimisation began during the procurement process with the selection of medical radiological equipment involving a multi-disciplinary team. This was noted as a good example of optimisation as technological advancements and capabilities of equipment were considered during

the procurement process to ensure that doses were kept as low as reasonably achievable.

Inspectors were informed that when deciding on a new CT scanner for the hospital, consideration was given to factors including the capability of these scanners to acquire images in a timely manner in order to reduce the effect of motion and reduce the need for repeat imaging for the benefit of the service user. Similar consideration was also given to non-ionising radiation modalities, such as MRI, which demonstrated a commitment to optimisation by the hospital. The use of MRI at CHI at Temple Street meant that more service users could undergo imaging with this modality, thereby reducing the need for imaging using ionising radiation.

A quality assurance programme was in place at the hospital including processes to ensure that medical radiological equipment was kept under strict surveillance. Inspectors were satisfied that the assessment and evaluation of doses was a priority for all involved in carrying out medical exposures to ionising radiation and dose audits were routinely carried out at the hospital.

Inspectors were informed by staff of techniques used to optimise the practical aspects of medical exposures for paediatric service users. For example, in the nuclear medicine department, staff contacted parents or guardians of service users in advance of their appointment to explain the procedure and ensure the correct steps to prepare for the procedure were carried out. This communication also included information about the risks and benefits of the procedure and guidance in relation to the exposure of carers and comforters of the service user. In addition, written instructions were provided to parents or guardians before leaving the hospital in relation to precautions to take following the procedure.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

CHI at Temple Street had a *Policy for Establishing Local Diagnostic Reference Levels* which was approved in February 2020. This policy noted that local DRLs can provide a good guide for radiography staff on appropriate exposure factors for different radiology procedures, can be used to lower patient exposures and overall doses, while maintaining adequate diagnostic image quality and can be used to alert staff of any procedures where the dose was not appropriately optimised or exposure factors were not selected correctly. The policy set out the method for establishing local DRLs and also the requirement to review these periodically as required.

Inspectors reviewed a range of local DRLs in place at CHI at Temple Street for a variety of modalities, including fluoroscopy, theatre, general X-ray, CT and nuclear medicine. However, on review of documentation, inspectors noted an inconsistency in the grouping of some paediatric local DRLs with that of national DRLs. While inspectors were satisfied that CHI at Temple Street had established, regularly

reviewed through dose audit and used DRLs at the hospital, the hospital should ensure that local DRLs are established in a manner that is consistent with the specific weight groupings used for national DRLs to allow for meaningful comparison of dose.

Judgment: Substantially Compliant

Regulation 12: Dose constraints for medical exposures

Inspectors found from speaking with staff and management that CHI had proactively assessed the radiation dose received by individuals acting as carers and comforters at CHI at Temple Street. The findings from these assessments were used to develop policy and procedure documents for carers and comforters across all CHI sites in line with the requirements of this regulation.

Inspectors noted that conducting these assessments across various modalities at the hospital, including those associated with delivering a higher radiation dose, such as CT and nuclear medicine, was an area of good practice. This provided assurance to CHI that there was good oversight of the radiation doses received by individuals acting as carers and comforters at the hospital.

In addition, given that CHI at Temple Street provide an imaging service to paediatric service users, it was assuring to inspectors that staff at the hospital demonstrated an awareness of dose constraints and their role as a tool to ensure the optimisation of radiation doses for procedures involving comforters and carers at the hospital.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at CHI at Temple Street for standard medical radiological procedures as required by Regulation 13(1). The hospital had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3).

Inspectors reviewed an extensive list of clinical audits ongoing and completed at CHI at Temple Street from January 2021 to June 2022 which involved multi-disciplinary input. CHI at Temple Street demonstrated that a wide range of clinical audit was taking place across various modalities including general X-ray, nuclear medicine, CT, theatre and fluoroscopy. These included audits of dose, pregnancy, optimisation, patient leaflets, referrals and justification. Inspectors noted that the hospital viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical

exposures to services users.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors were informed that while measures had been put in place by the Health Service Executive (HSE) to come into compliance with this regulation, these measures had not been implemented by practitioners at CHI at Temple Street as they were not deemed to be applicable to paediatric procedures. As an interim measure, a statement was included in the report of a medical exposure indicating that dose information is available on the image. Inspectors were also informed that the hospital had planned to communicate with referrers around typical CHI doses, optimisation methods and the use of referral guidelines as an interim solution to meeting compliance with Regulation 13(2). While acknowledging the efforts made by the hospital to comply with Regulation 13(2), inspectors determined that these measures were not sufficient to meet compliance. CHI as the undertaking for CHI at Temple Street, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at CHI at Temple Street as required by Regulation 14(1). The hospital's radiation safety procedures outlined the quality assurance programme in place at the hospital. Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for each unit of equipment as required by Regulation 14(2). Inspectors reviewed records of performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Inspectors noted that some medical radiological equipment at the hospital was identified as being past nominal replacement dates. However, the hospital had a medical equipment replacement programme to track and escalate equipment needing replacement and management assured inspectors that this equipment was routinely monitored and meeting all quality assurance and performance tests.

Judgment: Compliant

Regulation 15: Special practices

CHI at Temple Street had measures in place to ensure that appropriate medical radiological equipment and practical techniques were used and special attention was given to the assessment and verification of dose and administered activity of children undergoing medical exposure to ionising radiation at the hospital.

Staff at the hospital communicated various measures that had been put in place to ensure that any medical radiological procedure carried out was justified and optimised. In particular, inspectors noted the various techniques used at the hospital not only demonstrated compliance with the regulations but also demonstrated good practice in this area. For example, the hospital used the services of the play department for children who may need some re-assurance before having a procedure. CHI at Temple Street also ensured that parents or guardians of service users were aware of what a medical exposure to ionising radiation involved. This is of particular importance as many medical radiological procedures may require an infant or child to stay still for a period of time.

Another area of good practice noted by inspectors was the use of clinical indication based protocols in CT. For example, the use of alternative imaging parameters for the procedure and tailoring the area to be imaged to the region of interest to ensure that the dose was kept as low as reasonably achievable. The development and use of clinical indication based protocols was seen as a positive optimisation technique which should be considered by all other sites, particularly those imaging paediatric service users.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

CHI at Temple Street had a policy titled *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* which was approved in December 2021. This policy was based on the national policy with some changes made following research into this area and was approved by the CHI at Temple Street RSC and the CHI RSC. The policy included specific staff responsibilities, for example, the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age.

Inspectors were satisfied that a referrer or practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in waiting areas to raise awareness of the special protection required during pregnancy in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents, that CHI at Temple Street had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures.

CHI had a cross-site policy titled *Incident Report in CHI Radiology* which was approved in June 2022. The development and review of this policy involved a multi-disciplinary team including medical physics, radiology and quality, safety and risk management. Inspectors found that the incident reporting policy clearly outlined the process for incident reporting at CHI at Temple Street. The policy outlined HIQA's requirements for incident reporting including relevant timelines and thresholds for significant events of accidental or unintended exposures. Inspectors noted that CHI at Temple Street did not have any reportable incidents requiring reporting to HIQA at the time of the inspection.

Inspectors noted that incidents were trended by modality and incident type, lessons learned from each incident were recorded, and incidents and potential incidents were discussed at each RSC meeting. In addition, inspectors were satisfied that there was a positive culture of reporting amongst staff who communicated the process for reporting incidents involving, or potentially involving accidental and unintended exposures to ionising radiation.

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	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	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 12: Dose constraints for medical exposures	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for CHI at Temple Street OSV-0006027

Inspection ID: MON-0035044

Date of inspection: 15/06/2022

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 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: In order to come into compliance with Regulation 8, CHI at Temple Street are making the following changes to their workflows for general X-ray. 1. Currently all GP referrals are vetted by a Senior Radiographer prior to an appointment being issued. At this time, the radiographer reviews the clinical indications, any previous imaging and justifies the most appropriate exam to be undertaken. The updated workflow will document this justification in advance on the GP request which will be scanned into the patient record which is kept for the lifetime of the patient. An updated SOP has been established for this procedure. 2. For all electronic general radiography requests (Emergency Department, In-patients, Medical Out-Patients, Surgical Out-Patients) the justification in advance will be recorded in the exam notes on the NIMIS request by the performing radiographer.	
Regulation 11: Diagnostic reference levels	Substantially Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: In order to come into compliance with Regulation 11, CHI at Temple St will ensure all DRL's established from this point forward will be done following the groups set out by the national DRLs. In particular a review of the CT DRL's is planned following the installation of the new CT scanner which will go into clinical use in Aug 2022. The DRL's will be set out to as to allow comparison with the national DRL, where available. Data collection to begin Sept 2022 following installation of new CT scanner. Initial CT DRLs will	

be set 31st Dec 2022 with a full review planned Q2 2023 following 6 months of patient throughput in the new scanner.

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. The National Radiation Protection Committee (NRPC) and NIMIS are currently developing an implementation plan to progress an automated dose recording capability within the NIMIS platform. In the interim, an auto-text workflow has been established for use with adult patients. However, as stated in this report, this interim solution is not suitable for the paediatric cohort of patients seen in CHI. To address this nationally and for CHI, CHI Medical Physics are working with the NRPC and NIMIS. They recognise the difficulties associated with grouping paediatric doses into bands and so are devising other methods which may be used as an interim measure until the national dose tracking software comes online. When developed, this interim solution will be put in place in CHI until the overall solution using the automated dose monitoring /reporting process is in place. In the meantime, work to communicate with referrers around typical CHI doses, optimisation methods and the use of referral guidelines is continuing. Communication to referrers to happen by 30th Sept 2022. Interim solution with national team planned for Q4 2022 / Q1 2023. Overall solution using the automated dose monitoring /reporting process TBC by HSE / NIMIS national team.

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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	01/09/2022
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	01/09/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and	Substantially Compliant	Yellow	31/12/2022

	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.			
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	31/03/2023