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:	Tallaght University Hospital
Undertaking Name:	Tallaght University Hospital
Address of Ionising Radiation Installation:	Tallaght, Dublin 24
Type of inspection:	Announced
Date of inspection:	17 September 2025
Medical Radiological Installation Service ID:	OSV-0007409
Fieldwork ID:	MON-0044778

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

Tallaght University Hospital is a teaching hospital affiliated to Trinity College Dublin. Located in south-west Dublin, the hospital is a provider of local, regional, supra-regional and national medical and surgical speciality departments catering for a direct catchment area of 110,000 and broader catchment area of 697,000. Tallaght University Hospital has an adult Emergency Department and is a National Urology Centre, a Regional Dialysis Centre and a Regional Orthopaedic Trauma Centre. The clinical referral base includes General Surgery, Colorectal Surgery, Hepatobiliary and Pancreatic Surgery, Vascular Surgery, Urology, Orthopaedics, Gynaecology, ENT, Gastroenterology, Hepatology, Neurology, Endocrinology, Rheumatology, Medical Oncology and Haematology, Radiation Oncology, Cardiology, Respiratory Medicine and Emergency Department.

Diagnostic facilities include two magnetic resonance imaging (MRI) scanners, three computed tomography (CT) scanners, two single-photon emission computed tomography (SPECT) CT gamma cameras, three ultrasound (US) rooms, a fluoroscopy suite, and an interventional radiology (IR) suite. The IR suite provides urologic, gynaecologic, vascular and oncologic interventions under ultrasound, CT and fluoroscopic guidance. Other subspecialties include musculoskeletal ultrasound and interventions, cardiac CT and MRI, neuroradiology, gastrointestinal and genitourinary including women's imaging and prostate imaging with fused MRI/US transrectal biopsy and CT colonography. The radiology department staff includes consultant radiologists, radiographers, radiology specialist registrars (SPRs), nursing staff, radiography department assistants (RDAs), health care assistants (HCAs) and clerical administrative staff. The Medical Physics Department are also on-site within the Radiology Department.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

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

About the inspection report

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

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 17 September 2025	09:30hrs to 16:30hrs	Lee O'Hora	Lead
Wednesday 17 September 2025	09:30hrs to 16:30hrs	Kay Sugrue	Support
Wednesday 17 September 2025	09:30hrs to 16:30hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiology services at Tallaght University Hospital on 17 September 2025 to follow up on the compliance plan from the previous inspection completed in June 2023 and to monitor the service's ongoing compliance with the regulations. As part of this inspection, inspectors visited the radiology department including the computed tomography (CT), interventional radiology and cardiovascular departments. Inspectors communicated with staff in the clinical areas and reviewed imaging records from all areas involved in the provision of medical exposure to ionising radiation.

Inspectors were informed that most of the compliance plan actions from the previous inspection had been completed. Inspectors found that there were established governance arrangements in place that included multiple forums to facilitate the communication of radiation safety issues up to the undertaking. However, through the course of this inspection, issues in relation to the clear allocation of responsibility were evident in documentation and in some practices. For example, individuals, not recognised by the regulations, were allocated practitioner role for the clinical evaluation of the outcome of some fluoroscopy procedures and not all aspects relating to the allocation of responsibly were clearly allocated in documentation viewed. Additionally, improvements were required to ensure that all reports of medical radiological procedures consistently included information relating to patient exposure and that the medical physics expert's (MPE) engagement and contributions aligned with the regulations.

Despite governance and management arrangements being in place, the evidence collected at the time of inspection highlighted that these structures had failed to consistently and systematically monitor regulatory compliance. As a result, many areas of non-compliance were noted. However, on the day of inspection these were not associated with any current service user safety concerns but nonetheless must be addressed by the undertaking in a timely manner.

Regulation 4: Referrers

Following a review of radiology referral documentation, a sample of referrals for a range of medical radiological procedures and by speaking with staff, the inspectors were satisfied that University Hospital Tallaght only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed a sample of referrals, associated justification documentation and records of clinical evaluation of the outcome for a range of medical radiological procedures on the day of inspection.

Inspectors were informed and noted from records reviewed that, for a small number of fluoroscopically guided procedures, the clinical evaluation of the outcome was assigned to individuals not recognised by the regulations as practitioners.

Subsequently, inspectors were not satisfied that the undertaking ensured that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Substantially Compliant

Regulation 6: Undertaking

Tallaght University Hospital was identified to inspectors as the undertaking and the Deputy Chief Executive Officer (DCEO) of the hospital was the individual responsible for the radiation protection of service users at Tallaght University Hospital. The DCEO reported directly to the Chief Executive Officer (CEO) and Executive Management Team (EMT) of Tallaght University Hospital.

The Clinical Director of Radiology was assigned as the designated manager and chaired the Radiation Safety Committee (RSC). Inspectors noted that documents reviewed highlighted the purpose of the RSC as the main platform to provide governance for radiation protection and to set out policies and procedures for the safe use of ionising radiation. The RSC reported to the Quality Safety Risk Management (QSRM) committee annually via an MPE report and the Clinical Director of Radiology also sat on the monthly QRSM committee meetings. The QRSM, in turn, reported to the EMT.

Further communication pathways between the relevant staff and the undertaking consisted of a monthly radiology report from the RSC Chair to the EMT and a monthly Radiology Directorate Meeting which the DCEO attended.

While there were governance and oversight structures in place, they were not sufficiently effective to identify issues with the allocation of responsibility detailed in radiation safety practice documentation. The inconsistencies noted in the documentation viewed and the lack of evidence regarding the monitoring of compliance with the regulations indicated that governance, management and leadership structures in the area of radiation safety must be strengthened.

Specific issues that need the immediate attention of the undertaking to ensure a clear allocation of responsibility and guidance, consistent practice and oversight include:

- Greater assurance that all aspects of clinical responsibility, particularly the clinical evaluation of the outcome of a medical exposure, as discussed under Regulation 5, to ensure the allocation to an individual entitled to act as a practitioner is in line with the regulations.
- A comprehensive review of documentation to ensure that the definition of practitioner aligns with the regulations. Throughout documents reviewed, professions not recognised by the regulations were noted as practitioners, namely Registered Advanced Nurse Practitioners and MPEs. However, inspectors were satisfied that neither of these professions were assigned responsibility for any aspects of clinical responsibility in practice.
- Implementation of formal procedures, policies and guidance (PPG) that outline the allocation of responsibility or the process that staff at the hospital must follow to consider and apply for generic justification of a new practice to HIQA. It is imperative that the undertaking provide a clear allocation of responsibility for this process in Tallaght University Hospital to ensure compliance with Regulation 7.
- Greater oversight and quality management of professional registration was also required to ensure there is a system to collate and monitor relevant up-to-date professional registration records for referrers, practitioners and MPEs allocated with responsibilities for medical radiological procedures.
- More robust document version control of imaging protocols. Imaging protocols reviewed as part of this inspection lacked the relevant information to identify staff responsible for review and review dates to ensure there is appropriate oversight and approval.
- Many documents relating to radiation protection, reviewed by inspectors, were found to be unclear and in some instances contained contradictory and inconsistent information. These included but were not limited to the following:
    - Clinical audit documentation *Radiology Department Clinical Audit Strategy Guideline* and *The Process for developing a Clinical Audit Strategy for Radiological Procedures involving Ionising Radiation in Tallaght University Hospital* as these were not consistent in their definitions of the responsibilities and reporting pathways of the clinical audit group (CAG), definition of audit topics and audit prioritisation processes. They also lacked clarity on how radiology clinical audit fed into the wider hospital audit structures.
    - The document *Establishing Local Diagnostic Reference Levels (LDRLs) for Tallaght University Hospital Radiology - Protocol* contained contradictory information in relation to sample sizes used to establish local facility DRLs at Tallaght University Hospital, a lack of clarity on the age range of paediatric patients and did not provide a clear process to be followed by staff to investigate local facility DRLs that consistently exceeded national DRLs.
    - Inconsistencies in the definition and responsibilities of a practitioner and the definition of paediatric patients was evident in the document

Female patients' pregnancy status and the Procedure to prevent an inadvertent ionising radiation exposure of the unborn child arising from ionising radiation received during medical diagnostic examinations. This document was also noted as being overdue a review and staff informed inspectors that it was currently under review.

- Documents relating to equipment provided to inspectors (see Regulation 14), did not clearly and cohesively outline Tallaght University Hospital's approach to radiology equipment quality assurance (QA). Details regarding standards and criteria of acceptability, time lines, tests, tolerances etc. were not available for all radiology equipment QA carried out by Tallaght University Hospital.

Finally, as discussed further under Regulation 13(2), the inspectors were not assured that the undertaking had established and communicated to the relevant staff a consistent, documented approach to ensure that information relating to patient exposure formed part of the report for every medical radiological procedure done at Tallaght University Hospital. It is imperative that the undertaking ensures, through the clear allocation of responsibility, that all regulatory requirements are met in a well defined manner.

Judgment: Not Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that the undertaking ensured that medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations, in the majority of clinical areas and associated imaging modalities reviewed on the day. However, inspectors were informed and subsequently noted from records reviewed, for a small number of fluoroscopically guided procedures, that the clinical evaluation of the outcome was assigned to individuals not recognised by the regulations as practitioners.

Again, this was highlighted to the undertaking on the day of inspection as an area that needed to be addressed in a timely manner.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to inspectors by staff. At the time of inspection, a single MPE provided the service with a high level of good will. After reviewing all evidence available on the day, and discussing current arrangements with staff and

management, inspectors were not satisfied that continuity arrangement were robust or allowed for unforeseen staff leave. However, inspectors were informed that the current arrangement was temporary and professional certification update and recruitment processes were underway. These processes must be prioritised by the undertaking to meet the requirements of the regulations.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

The professional registration certificate from the Irish College of Physicists in Medicine (ICPM) was reviewed by inspectors and was up to date. From reviewing the documentation and from the interactions with staff, inspectors were not satisfied that the undertaking had arrangements in place to ensure the contribution of MPE was completely in line with the requirements of Regulation 20. For example, inspectors were informed that an MPE was not always involved in the application and use of DRLs as discussed under Regulation 11. Similarly, the contribution of the MPE in the definition and performance of QA of the medical radiological equipment was not well defined or consistently articulated by staff as described under Regulations 6 and 14.

Judgment: Substantially Compliant

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

Given the non compliances associated with Regulation 6, 11, 14, 19 and 20, the inspectors were not assured that the undertaking had ensured that the MPE was appropriately involved for the service provided at Tallaght University Hospital. Inspectors noted that some work is required by the undertaking to ensure that the role of the MPE is well defined and satisfies all requirements of Regulation 20, therefore ensuring that the MPE is appropriately involved with all aspects of the service provided by Tallaght University Hospital.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed a sample of referrals for all areas where medical exposures were carried out. The inspectors were satisfied that Tallaght University Hospital had

reliable and consistently applied processes in place to ensure that all medical procedure referrals were accompanied by the relevant information. Similarly, inspectors were assured that the majority of referrals reviewed were justified in advance by a practitioner and that practitioner justification was recorded. However, a small number of images undertaken in theatre, had no record of justification by a practitioner.

Inspectors were satisfied that DRLs were established, regularly reviewed and used by staff in the clinical area to ensure service user dose optimisation. However, the corporate approach to DRL investigations needs to be addressed immediately by the undertaking to ensure a consistent approach for all staff.

Records of acceptance and performance testing for all radiological equipment at the hospital provided could not assure the inspectors that the undertaking had kept all radiology equipment under strict surveillance. However, MPE and radiographer QA was noted and the undertaking must formally quantify this and clarify associated responsibilities of all staff involved.

The undertaking had employed multidisciplinary systems and platforms for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice. These processes were consistently articulated by staff who spoke with inspectors and were used to actively improve service user outcomes. This was noted as an area of good practice.

Despite some areas identified in this report which need to be addressed by the undertaking, inspectors noted that, at the time of inspection, the non compliances had not adversely affected the safe delivery of medical exposures at Tallaght University Hospital. The inspectors were also assured that staff in the clinical areas demonstrated a commitment to the safe delivery of medical exposures and continual improvement of the radiology services provided.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referrals from all clinical areas on the day of inspection using the hospital's radiology picture archiving and communications system (PACS) and the cardiology department's cardiovascular information system (CVIS). From the records reviewed, the inspectors were assured that the undertaking had employed systems and processes to justify each medical exposure. The record of justification was observed by inspectors in the majority of imaging records reviewed including DXA, general radiography, CT, interventional radiology and nuclear medicine. However, for a small number of fluoroscopic procedures done in theatre, inspectors noted that there was no record of justification, as per the method outlined in the document *RSP - Justification of Radiology Referrals for Adult Patients Procedure.*

This was highlighted to the undertaking as an area that needed to be addressed in a timely manner and, in line with the findings of this report and previous reports, should be monitored for compliance going forward.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRLs and after staff communication, inspectors were satisfied that Tallaght University Hospital had systems in place to ensure that DRLs are established and compared to national levels. However, inspectors were not assured that the process established by the undertaking was clear or consistently applied once a local facility DRL exceeded a national DRL.

Records were available for some instances where local facility DRLs exceeded national DRLs but these were essentially checklists with little details of the methodology used, the multidisciplinary team involved, the precise cause, the corrective actions identified or the individual responsible for implementing corrective actions. Staff informed inspectors that the approach taken once a local facility DRL exceeded a national DRL was not always consistently applied highlighting the lack of clarity in associated documentation.

In one instance, inspectors were informed of an example where a local facility DRL exceeded a national DRL. This initiated a detailed investigation and subsequent optimisation strategy managed by a clinical specialist radiographer. However, this was outside of the DRL process, and no records were available of the subsequent investigations, investigation team or corrective actions. Nevertheless, inspectors were satisfied that this example yielded an appropriate reduction of the local facility DRL to below that of the national DRL.

As highlighted under Regulation 6, it is imperative that the undertaking provide a clear process to be followed once a local facility DRL exceeds a national DRL. This process must clearly outline the relevant steps, staff involved and individual responsibilities and align with HIQA's publication *Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation*. All records of DRL investigations must be retained for a period of 5 years from the date of review and be provided to HIQA on request.

Overall, inspectors were satisfied that the undertaking ensured that DRLs were established, compared to national levels, displayed in clinical areas and used by staff in the clinical area. However, work was required to ensure that when local facility DRLs exceeded national DRLs a clear, consistent process is defined and followed, and all subsequent records of review and corrective actions are maintained for a period of five years from the date of the review.

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspectors were satisfied that written protocols for every type of standard medical radiological procedure were available, satisfying in this case, the regulatory requirements of Regulation 13(1). However, the potential for improvements in protocol version control as mentioned under Regulation 6, was highlighted to staff and management on the day of inspection.

After a review of imaging records, inspectors were satisfied that information relating to patient exposure was included on all nuclear medicine and cardiology reports reviewed on the hospital PACS and CVIS systems. In some reports reviewed for CT procedures, the reporting radiologist had transcribed the associated dose length product (DLP) for the procedure which also satisfied the requirements of Regulation 13(2). The majority of radiology practitioners used a modified version of a national template developed to ensure compliance with Regulation 13(2). Unfortunately, all modified versions of this national template radiation exposure template reviewed on the day of inspection did not satisfy the requirements of Regulation 13(2) as they only provided links to information relating to patient exposure and therefore this information did not form part of the report. This was highlighted to the undertaking as an area that needed to be addressed in a timely manner and, in line with the findings of this report and previous reports, should be monitored for compliance going forward.

Although inspectors were satisfied that clinical audits were carried out within the radiology department, and while some documentation was provided on the day of inspection, the associated audit strategy had not been formally ratified or communicated to staff. Therefore, the undertaking had not yet adopted a system which ensured that clinical audits were carried out in accordance with HIQA's national procedures. This non-compliance is discussed in further detail under Regulation 6.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were informed that both MPE and radiographer QA was routinely used at Tallaght University Hospital. Staff who spoke with inspectors on the day of inspection reported that all MPE and radiographer QA was up to date. However, evidence of all QA records were not available to inspectors on the day and annual overview records of MPE QA testing did not align with what was articulated to inspectors. Given the lack of a clear allocation of responsibility for QA, the lack of articulated clarity and understanding of associated responsibilities, the lack of an

overarching definition of the corporate QA programme used and incomplete QA records available on the day, inspectors could not be assured that all radiological equipment in use by Tallaght University Hospital was kept under strict surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Despite the issue highlighted with the documentation surrounding Regulation 16, as highlighted under Regulation 6, all processes articulated by staff in the clinical area and records reviewed suggested that staff at Tallaght University Hospital used a consistent process for enquiring about and recording pregnancy status for relevant patients.

Multilingual posters were observed throughout the clinical area. The inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Ultimately, staff communication, processes observed and records reviewed satisfied the inspectors that the undertaking had systems in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded, therefore satisfying the requirements of Regulation 16.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records and radiology incident group minutes, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures at Tallaght University Hospital.

Evidence was available to show that incidents were discussed at the appropriate committee levels within the radiology departments, by the RSC and through alternative pathways detailed in Regulation 6, as required. Inspectors were assured that one area noted for improvement highlighted at an inspection completed in June 2023, namely the reporting of potential accidental or unintended exposures, had been addressed by the undertaking.

Inspectors were satisfied that a comprehensive system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Tallaght University Hospital. Inspectors were consistently informed of the process that the undertaking employed

to inform HIQA of accidental and unintended exposures and significant events. This was seen as an area where the undertaking had made consistent improvements since initially assessed in August of 2020 and again inspected in 2023.
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	Substantially Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially 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 Tallaght University Hospital OSV-0007409

Inspection ID: MON-0044778

Date of inspection: 17/09/2025

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 5: Practitioners	Substantially Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: A Radiologist will act as Practitioner & take responsibility for the medical exposure provided during VideoFluoroscopy. This action will be completed by 30/11/2025.	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The DCEO, Lead Radiologist for research and the RSM will review and update the policy and research proforma to ensure it is clear in the 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. To be completed by 31/01/2026. Any reference to ANP & MPE as Practitioners in 77 PPPGs will be removed by RSM's by 31/03/2026. Justification of new practice SOP will be written by MPE to prescribe the process for staff to follow in TUH by 31/03/2026. The radiology directorate will establish a full Professional registration repository for referrers, practitioners & MPEs. This will allow for full oversight & management of any staff with allocated responsibilities for medical radiological procedures. This action will be completed by the RSM's by 31/12/2025 and will be monitored on an going basis by the RSM's	

Imaging protocols will be formatted into formal PPPG templates to ensure there is a clear timeline for review and the staff responsible for each modality, action to be completed by relevant CSR by the 30/12/2025

Clinical Audit PPPG will be re-written to reflect the new clinical audit program, responsibilities, the reporting pathway and the how Radiology clinical audit will be included in the Hospital Clinical Audit structures. Action to be completed by Chair of the clinic audit group, and will be completed by the 31/12/2025.

The DRL SOP will be rewritten to include consistent sample size information, definitive paediatric patient age ranges. It will also include a defined DRL investigation pathway to ensure there is a clear investigation and remedy process when Local DRLs exceed National DRLs. Action to be completed by MPE by 31/12/2025.

The LMP SOP has been rewritten by the RPO and CT CSR, it is with Radiology stakeholders for final sign off. Action to be closed by 31/12/2025.

MPE will assume responsibility for all QA in the Radiology Directorate and the QA SOP will be rewritten to reflect this practice. Action to be completed by MPE by 31/03/2026.

PACS CSR is working with NIMIS provider on a solution to include all doses on Radiation reports automatically. This will be completed by 31/03/2026.

In the event that the above is unsuccessful we will amend our Radiology reports to include information on Radiation Dose.
This action will be completed by Radiology Clinical Director by the 31/03/2026.

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
A Radiologist will act as Practitioner & take responsibility for the medical exposure provided during VideoFluoroscopy. This action will be completed by 30/11/2025.

Regulation 19: Recognition of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:

TUH now have 2nd certified MPE, this will allow for the continuity for medical physics expertise. This action was completed on the 24/09/2025.

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: MPE will assume responsibility for all QA in the Radiology Directorate and the QA SOP will be rewritten to reflect this practice. Action to be completed by MPE by 31/03/2026 MPE will assume responsibility for establishment of DRLs and investigation of DRL non-compliance. Relevant SOPs will be updated to reflect this, action to be completed by 31/12/2025

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

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: MPE will assume responsibility for all QA in the Radiology Directorate and the QA SOP will be rewritten to reflect this practice. Action to be completed by MPE by 31st March 2026 MPE will assume responsibility for establishment of DRLs and investigation of DRL non-compliance. Relevant SOPs will be updated to reflect this, action to be completed by 31/12/2025

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: A Communication has been issued to all Radiographers related to the Justification of Medical exposures protocol, action completed by RPO on 18/09/2025.

Radiology Clinical Director issued communication to Surgical Director to advise of the requirement for referring clinicians to include justifiable clinical indications on the referral to facilitate the radiographers justify the medical exposure, this action was completed 05/11/2025.

In situations where the appropriate clinical indications are not available on NIMIS the radiographers will contact the referring clinician by phone and update the indications, action completed (5/11/2025).

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
The MPE will assume responsibility for establishment of DRLs and investigation of DRL non-compliance. Relevant SOPs will be updated to reflect this, action to be completed by 31/12/2025. The MPE will investigate any LDRL that exceeds NDRL, and a report will be submitted to the radiation safety committee and DCEO monthly directorate meeting. To be completed by 30/11/2025.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Imaging protocols will be formatted into formal PPPG templates to ensure there is a clear timeline for review and the staff responsible, by the CSR for each modality, action to be completed by the 30/11/2025.

PACS CSR is working with NIMIS provider on a solution to include all doses on Radiation reports automatically. This will be completed by 31/03/2026.

In the event that the above is unsuccessful we will amend our Radiology reports to include information on Radiation Dose.
This action will be completed by Radiology Clinical Director by the 31/03/2026

Clinical Audit PPPG will be re-written to reflect the new clinical audit program, responsibilities, the reporting pathway and the how Radiology clinical audit will be included in the Hospital Clinical Audit structures. Action to be completed by Chair of the clinic audit group, and will be completed by the 31/12/2025.

Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: MPE will assume responsibility for all QA in the Radiology Directorate and the QA SOP will be rewritten to reflect this practice. Action to be completed by MPE by 31/03/2026.	

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 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Substantially Compliant	Yellow	30/11/2025
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or	Substantially Compliant	Yellow	30/11/2025
Regulation 5(c)	A person shall not take clinical responsibility for	Substantially Compliant	Yellow	30/11/2025

	an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).			
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	31/01/2026
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its	Substantially Compliant	Yellow	18/09/2025

	behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	05/11/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	30/11/2025
Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure	Substantially Compliant	Yellow	31/12/2025

	that appropriate corrective action is taken without undue delay.			
Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	31/12/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	31/03/2026
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	31/12/2025
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	31/03/2026
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the	Substantially Compliant	Yellow	24/09/2025

	continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and	Substantially Compliant	Yellow	31/03/2026

	installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	31/03/2026