

Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	St James's Hospital
Undertaking Name:	St James's Hospital
Address of Ionising Radiation Installation:	James's street, Dublin 8
Type of inspection:	Announced
Date of inspection:	26 March 2025
Medical Radiological Installation Service ID:	OSV-0007408
Fieldwork ID:	MON-0042956

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

St James's Hospital is Ireland's largest acute academic teaching hospital and is part of the Dublin Midlands Hospital Group. The Hospital's fundamental purpose is the delivery of health treatment, care and diagnosis as well as health promotion and preventative services at local, regional and national levels. Our academic partner is Trinity College Dublin. By international standards, St James's Hospital is a substantial acute hospital service provider. The Hospital provides acute, emergency, specialist services and residential care, across a vast range of medical and surgical specialties and places high emphasis on excellence of delivery, research, innovation and education. The Hospital is one of eight adult designated national cancer centres in the country. It is the largest in terms of activity encompassing a number of national cancer care services.

The DiagIm Directorate (Department of Diagnostic Imaging) provides a diagnostic imaging service to the patients and clinicians of St. James's Hospital. Imaging services provided include computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, mammography, nuclear medicine, positron emission tomography/computed tomography (PET/CT), interventional radiology, and general X-ray. A radiographic service is provided to the cardiac catheterisation lab, endovascular suite, endoscopy, dual-energy X-ray absorptiometry (DXA) and theatres. The department performs approximately 175,000 examinations per annum. A significant amount of the complex departmental activity relates to oncology. A diagnostic imaging service is also provided to GP's and other hospitals primarily within the HSE Dublin and midlands group. The majority of GP referrals are referred electronically through Healthlink, the national web-based messaging service. A picture archiving and communication system (PACS) was introduced in 2006. In 2015, the department integrated this system with the national PACS network (NIMIS). The department uses a radiology information system (RIS) which integrates seamlessly with the Hospital's electronic patient record (EPR). The EPR supports electronic ordering of radiology referrals by Hospital referrers. The provision of education and training is a key function of the directorate. The department has well-

developed academic structures with established links to Trinity College Dublin and the Faculty of Radiology, RCSI. A training programme for specialist radiology registrars is delivered in addition to on-going clinical training of undergraduate and postgraduate radiography students.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

³ HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 26 March 2025	09:30hrs to 15:00hrs	Emma O'Brien	Lead
Wednesday 26 March 2025	09:30hrs to 15:00hrs	Kirsten O'Brien	Support
Wednesday 26 March 2025	09:30hrs to 15:00hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiological services at St James's Hospital on 26th March 2025 to follow up on the compliance plan from the previous inspection in July 2022 and to monitor the services' ongoing compliance with the regulations. Inspectors noted that most of the compliance plan actions from the previous inspection had been completed with the exception of Regulation 13(2) and this is discussed further in the report under Regulation 13.

During this inspection inspectors visited the computed tomography (CT), general X-ray, mammography, nuclear medicine, interventional radiology and cardiology units, spoke with staff and management and reviewed documentation.

Inspectors were satisfied that there were appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day-to-day operations in the facility up to the undertaking.

A sample of radiological procedure records reviewed by inspectors showed that appropriate persons as per the regulations were involved in referring and justifying medical exposures completed at the service. Similarly, only those entitled to act as practitioner, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

From the records viewed and discussions with staff, inspectors were satisfied that the undertaking had ensured contingency arrangements for the continuity of medical physics expertise in the facility. Inspectors saw strong evidence of medical physics expert (MPE) involvement in all areas of MPE responsibilities as per the regulations and were therefore satisfied that the level of MPE involvement was proportionate to the level of radiological risk posed by the service.

Although many of the roles and responsibilities relating to radiation protection had been allocated within the service, inspectors identified that action was required by the undertaking to ensure that roles and responsibilities when requesting medical radiological procedures in theatre were clear and understood by all staff. This is further discussed under Regulation 6 in this report.

Notwithstanding this gap in compliance inspectors were satisfied that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at St James's Hospital.

Regulation 4: Referrers

From discussions with staff in the radiology department in St James's Hospital and from the sample of records reviewed, inspectors were satisfied that St James's Hospital only accepted referrals from appropriately recognised referrers.

In addition to medical practitioners, radiographers and nurses were also considered referrers in this facility. The specific circumstances in which radiographers could perform adapted and secondary referrals were outlined in local policies viewed by inspectors.

Information identifying individual nurses and their scope of practice was observed by the inspectors and this information was made available to the relevant staff in the clinical area.

Judgment: Compliant

Regulation 5: Practitioners

Following the review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and from speaking with staff and management, the inspectors were satisfied that the undertaking had systems in place to ensure that only appropriate individuals as per Regulation 5 acted as practitioners at St James's Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors spoke with staff and management working in the radiology service at St James's Hospital, and reviewed documentation and other records to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures. The overall responsibility for the radiation protection of service users lay with the hospital board, represented by the chief executive officer (CEO).

Documentation reviewed by the inspectors prior to and during the inspection demonstrated that there were clear lines of communication within the clinical governance and management structures in St James's Hospital. These documented arrangements aligned with those described by staff to the inspectors. The undertaking had an established radiation safety committee (RSC) which was responsible for recommending radiation protection measures to comply with regulatory requirements. The RSC reported directly to the quality and patient safety committee which, in turn, reported to the hospital board through a sub-committee. The CEO, or a nominee, attended the RSC meetings and also attended the quality

and patient safety committee meetings and board meetings. The radiation protection advisor, who was also an MPE, attended the RSC meetings and was the person responsible for escalating any radiation protection issues through the monthly quality and safety governance meetings.

Inspectors were satisfied that the undertaking had implemented an appropriate process to oversee and manage the justification of any new practices in the department, in line with regulatory requirements. Although no new practices had been introduced in the department since 2019 this proactive planning was seen as an example of good practice in the radiation protection of service users.

Inspectors viewed the *Radiation Safety Guidelines* document which provided information on the roles and responsibilities of staff, including referrers, practitioners and MPEs, in the radiation protection of service users. From a review of the clinical areas and from discussions with staff inspectors were satisfied that, in most areas, the undertaking had appropriately allocated responsibilities to staff, and that day-to-day practice aligned with documented policies, procedures and guidelines. The *Justification of Medical Exposures* document outlined the circumstances in which radiographers could act as referrers, specifically for adapted and secondary referrals for plain radiographs. However, on the day of the inspection, inspectors identified a gap in the understanding of responsibility for medical radiological procedures performed in theatre. Inspectors were not satisfied that the undertaking had ensured staff were clear on their role in completing the written referral by the referrer for these theatre procedures as the process described by staff for this cohort of patients did not align with the local policies or procedures viewed by inspectors.

In order to ensure compliance with the requirements of Regulation 6 the undertaking must ensure that the roles and responsibilities of staff are clearly defined and allocated for all modalities. The undertaking must also ensure that local policies and procedures reflect day-to-day practice in order to support staff in carrying out their duties.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at St James's Hospital by individuals entitled to act as practitioners in the regulations.

The undertaking, St James's Hospital, had retained the presence of radiographers in areas where medical exposures were conducted outside of the radiology department. In the absence of training requirements prescribed by a training body approved by the Medical Council, as per Regulation 22, this was viewed as good

practice to ensure the protection of service users from medical exposure to ionising radiation.

Practitioners and MPEs were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

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 at St James's Hospital as required by Regulation 19.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the involvement and contribution of MPEs, in the radiology department of St James's Hospital, met the requirements of this regulation. A review of documentation and discussions with staff demonstrated that the MPE team were involved in the quality assurance (QA) and acceptance testing of medical radiological equipment, the selection of new equipment, patient dosimetry and in the dose calculation and review of radiation incidents. They were also involved in dose optimisation, for example through the review and sign off of facility diagnostic reference levels (DRLs). The MPEs who spoke with inspectors on the day of the inspection also outlined their role in the training of practitioners and other staff in the service in relevant aspects of radiation protection.

Additionally, arrangements were in place to ensure that an MPE liaised with the radiation protection advisor in the service, which met the requirements of Regulation 20(3).

Judgment: Compliant

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

From a review of documentation and discussions with staff, inspectors were satisfied that MPE involvement in the medical radiological service at St James's Hospital was proportionate to the level of radiological risk in the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors were assured that the undertaking was committed to the radiation protection of service users at St James's Hospital. This was achieved in many ways including the optimisation of medical exposures and the implementation of an effective clinical audit strategy.

Inspectors were satisfied that written protocols were available for all standard radiological procedures and that referral guidelines were available to staff. However, inspectors noted that action was required by the undertaking to achieve full compliance with Regulation 13(2), as dose information was not available on patient reports for some imaging modalities. This is further discussed under Regulation 13 below.

Inspectors found a number of improvements had been made since the previous inspection to achieve compliance with Regulation 14, including the review and update of the system used to plan and monitor QA testing of the medical radiological equipment. Inspectors were satisfied that the equipment was now kept under strict surveillance, with an appropriate QA programme in place.

During the inspection all referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data to allow 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 the sample of medical radiological procedures reviewed by inspectors over the course of the inspection.

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

The management team had made good efforts to create a culture of incident awareness and reporting in the service. While inspectors were assured that there was an effective system in place to record and analyse incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation, improvements are required in the reporting of near miss events. This is further discussed under Regulation 17.

Overall, despite the gaps in compliance with Regulations 13 and 17, inspectors were satisfied that the undertaking had good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users in St James's Hospital.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure.

Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users on a range of notices displayed throughout the radiology department.

A document titled *Justification of Medical Exposures*, which had recently been revised in December 2024, was in place at St James's Hospital. This document outlined the justification procedure in place at the hospital for each modality.

Inspectors reviewed a sample of records for all modalities and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

Regulation 9: Optimisation

The optimisation of medical exposures was discussed with staff on the day of inspection. Documentation and other records, such as policies and clinical audit reports, were also reviewed. Inspectors found that there was good multidisciplinary team involvement in optimisation which included relevant practitioners and MPEs.

In the nuclear medicine department inspectors viewed a bespoke leaflet that provided patients undergoing radionuclide treatment with information on the risks of ionising radiation and appropriate written instructions on restricting doses to persons in contact with the patient as far as reasonably achievable, meeting the requirements of Regulation 9(7) and 9(8).

The St James's Hospital *Diagnostic Reference Levels* policy was also reviewed as part of the inspection. The use of DRLs at the hospital demonstrated the commitment of staff in the optimisation of medical radiological procedures and is discussed under Regulation 11. Inspectors observed that, where necessary,

corrective actions to ensure the optimisation of the practical aspects of medical exposures were put in place.

The undertaking had also established and implemented a QA programme as described in Regulation 14. A high radiation dose interventional procedures policy was also established and implemented as discussed under Regulation 15.

From the evidence viewed during this inspection, inspectors were satisfied that the optimisation of medical radiological procedures was prioritised at the hospital by staff, to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors viewed the *Diagnostic Reference Levels* policy document, the most recent version of which was updated in May 2024, which set out the responsibilities of staff in respect of DRLs, and also the method for establishing, reviewing and using DRLs.

Following a review of DRL information, the inspectors were satisfied that DRLs were established for all modalities in St James's Hospital, were compared to national levels and were used in the optimisation of medical radiological procedures at this hospital. Inspectors also noted that DRLs were displayed prominently in the clinical areas as a reference for staff.

Within the radiology service, there was a multi-disciplinary approach to the review of DRLs, with a DRL committee established to discuss local facility DRLs for all modalities and ongoing DRL reviews. Membership of this committee included MPEs, the radiation safety officer (RSO), radiographers and radiologists. Inspectors noted the use of DRL reviews and subsequent multidisciplinary optimisation strategies to reduce patient dose associated with a number of medical radiological procedures in the service. This was seen as a positive use of regulatory required dose reviews to promote good radiation safety practice and patient dose optimisation.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at St James's Hospital for standard radiological procedures as required by Regulation 13(1). Referral guidelines were also adopted at the facility and were available to staff and referrers as required by Regulation 13(3).

In addition, inspectors noted a range of clinical audits which were ongoing and complete at St James's Hospital. These audits included referral audits, last menstrual period (LMP), patient ID, local DRLs, justification and image quality audits. As required by HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, a document titled *Clinical Audit Strategy for Medical Exposures* was also in place at the hospital since June 2024. This document outlined the essential criteria needed to perform clinical audit in the radiology department at St James's Hospital. A multidisciplinary radiological clinical audit working group had also been established and was responsible for preparing an annual clinical audit plan, advising and organising staff education and training in clinical audit, monitoring clinical audit activities and implementing recommendations from clinical audit activities.

Inspectors reviewed a sample of imaging reports from all modalities in St James's Hospital and, similar to the previous inspection in July 2022, found that information relating to patient exposure was not available on some reports including general radiology, CT and on reports for procedures completed in theatre. To ensure compliance with Regulation 13(2) the undertaking needs to implement measures to ensure that information relating to patient exposure forms part of the report of all medical radiological procedures carried out at St James's Hospital.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at St James's Hospital was provided to HIQA in advance of this inspection. Inspectors noted that a number of improvements in relation to equipment QA had been implemented since the previous inspection and were satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1).

Since the previous inspection in July 2022 inspectors noted that the scheduler used to plan and monitor annual QA testing of the equipment had been reviewed and updated to include all of the medical radiological equipment in use in the service. This scheduler used a traffic light system to visually indicate when annual QA was near or overdue. Inspectors were satisfied that any equipment listed on the scheduler that had annual QA yet to be completed had dates assigned.

In addition to the annual QA completed by the MPE's, the undertaking had allocated the responsibility for the regular performance testing of the medical radiological equipment to the radiographers and the RSO in the service. The RSO described the system implemented to plan and monitor this QA. From a review of a sample of QA records and from discussions with staff inspectors were satisfied that performance testing of the equipment was up-to-date and that robust systems were in place to ensure accurate oversight of all QA.

From a review of minutes of recent RSC meetings inspectors were satisfied that equipment QA was discussed regularly and QA performance was monitored through the use of a 12 month rolling average key performance indicator (KPI). Inspectors also noted from the minutes of these meetings that any equipment that was approaching or beyond the nominal replacement date was discussed at the meeting and the RSC was responsible for sanctioning approval for continued clinical use of this equipment.

From the evidence available, inspectors were satisfied that a quality assurance programme for the equipment had been established and implemented and that all medical radiological equipment was kept under strict surveillance by the undertaking.

Judgment: Compliant

Regulation 15: Special practices

On the day of inspection, staff informed inspectors about the radiation protection measures in place for service users undergoing medical exposures involving interventional radiology, such as in the cardiac catheterisation laboratory and interventional fluoroscopy suite.

Inspectors noted that a high radiation dose interventional procedures policy was in place and that this policy was used by staff to ensure that special attention was given to the assessment of dose if specific thresholds were reached. In situations where specific high dose thresholds were reached, the practitioner followed up with the patient after the procedure to enquire if any tissue reactions had been experienced. Additionally, inspectors were informed by staff that information on the risks and benefits associated with interventional procedures was given by the practitioner to the patient prior to each procedure.

From the evidence reviewed on the day of the inspection inspectors were satisfied that the undertaking was compliant with Regulation 15.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Notices to raise awareness of the special protection to be applied for relevant service users who may be pregnant were observed in waiting areas and procedure rooms of each area visited by inspectors. Inspectors reviewed a sample of medical radiological procedure records for women of childbearing age across a range of modalities. The records showed an inquiry had been made in advance of each

procedure by the practitioner which was signed by the service user confirming their pregnancy status. This record was uploaded and maintained on the radiology information system. The evidence demonstrated the undertaking's compliance with Regulation 16.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The *Safety Incident: Reporting & Management Policy* viewed by inspectors outlined the process for reporting incidents, and this process was also clearly articulated by staff and management to the inspectors on the day of the inspection. Additionally, inspectors were satisfied that there were arrangements in place to notify HIQA of any incidents that meet the threshold of a significant event.

Inspectors viewed minutes from recent radiation safety committee meetings and noted that incidents were discussed at each meeting as a standing agenda item. Incidents were categorised and trended and presented in a report for each of these meetings. Inspectors also noted that the 2024 incident trends had been compared to HIQA's 2023 incident report. This effort to compare local facility incident trends to national data was seen as an example of good practice in this facility in the management of radiation safety incidents.

Staff who spoke with inspectors on the day of the inspection commented that they regularly received feedback on emerging trends and the outcome of incident investigations. Inspectors also noted that quality improvement plans were implemented as a result of incident learning and management. For example, inspectors were informed of an ongoing hospital-wide patient identification quality improvement initiative as it had been identified that a number of incidents occurred due to mis-identification of patients.

From discussions with staff and a review of radiation safety documentation inspectors were informed of occasions when radiographers could adapt referrals where, for example, the left side was requested incorrectly for an image required on the right side on the primary referral from the medical practitioner. While this was seen as an example of good practice in the service these instances were not being captured as near miss events. The recording and analysis of all near misses offers the potential to identify a hazard or risk and implement corrective actions to help prevent a more serious incident from occurring. While inspectors were satisfied that a system was implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures improvements are required to ensure that all near misses are recorded and analysed to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure, as required by Regulation 17(1)(a).

Despite the requirement to improve near miss reporting in the radiology department, inspectors were satisfied that there was a robust process in place for reporting incidents and, also, that there was multidisciplinary involvement in the investigation of incidents and in the development and implementation of quality improvement plans as a result of incident trending.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	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	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	Substantially Compliant

Compliance Plan for St James's Hospital OSV-0007408

Inspection ID: MON-0042956

Date of inspection: 26/03/2025

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: SJH:DiagIm019 outlines roles and responsibilities in relation to justification. The policy has been reviewed and amended to improve clarity on allocation of responsibility and the processes that should be followed. Current policy is that specialist teams should place the electronic request for imaging when it is required for image guided procedures. This request should be placed in advance of the procedure. However, the policy does include a provision for a radiographer to place the request on behalf of a Consultant if they find that an electronic referral has not been placed. The electronic request reflects the fact that the Consultant remains as the referrer. All specialist teams have been reminded that they are responsible for placing requests for imaging on EPR. In addition, all radiographers have been reminded that, if they are placing the request on behalf of a Consultant, the basis on which they are doing so should be reflected in the drop down text selected in the field 'Order Communication Type'.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: An internal audit previously carried out on CT reports had found that there was good compliance with Regulation 13(2). However, on the day of the inspection it was noted that practice was variable across other modalities and in particular, the inspectors found poor compliance, with the requirement, for general x-ray. All radiologists have since been reminded that all radiology reports must comply with regulation 13(2). They have also been offered and provided with technical support to modify their report templates to include a reference to radiation dose. An audit was carried out immediately after the	

inspection to establish a baseline for reports relating to general x-ray. This audit will be repeated in 6 months to see if practice is compliant. SJH will continue to monitor compliance using audit and education to improve practice.

Regulation 17: Accidental and unintended exposures and significant events

Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

We note the inspector's findings of good practice in relation to SJH policy which allows radiographers to adapt referrals where referral errors have been identified. We thank the inspectors for suggesting that there is an opportunity for improvement by ensuring that these instances are always reported as near misses. All radiographers have been reminded to report these near misses on DATIX.

Near misses are trended and reported at the radiation safety committee in the same way that incidents are. Particular attention will be paid to see if the number of referrer errors (relating to incorrect anatomy), reported via DATIX, aligns with the numbers of adapted referrals captured on EPR. This will be audited later in the year. SJH policies already state that near misses should be reported using DATIX but it appears from the inspector's findings that this is not always done. This will be addressed through communication, education and audit.

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	12/05/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Not Compliant	Orange	31/05/2025

	radiological procedure.			
Regulation 17(1)(a)	An undertaking shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,	Substantially Compliant	Yellow	12/05/2025