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:	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:	20 July 2022
Medical Radiological Installation Service ID:	OSV-0007408
Fieldwork ID:	MON-0035038

About the medical radiological installation:

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. 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 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 180,000 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 Dublin Midlands Hospital Group.

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 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 20 July 2022	09:30hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 20 July 2022	09:30hrs to 15:30hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the positron emission tomography computed tomography (PET CT), computed tomography (CT), general radiography and dual energy x-ray absorptiometry (DXA) departments and spoke with staff and management. On this inspection, inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility at St James's Hospital for the protection of service users undergoing medical exposures. St James's Hospital was the undertaking with overall responsibility for the radiation protection of service users resting with the Chief Executive Officer (CEO) of the hospital. St James's Hospital operated in a wider hospital group, the Dublin Midlands Hospital Group, but was an independent undertaking within this group. Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. A Radiation Safety Committee (RSC) played a fundamental role in the the governance system, advising the Hospital Board and ensuring regulatory compliance within the undertaking. The RSC reported to the Hospital Board via the Quality and Patient Safety Committee and multiple alternate communication and escalation pathways were available within the undertaking to address all issues relating to the protection of service users undergoing medical exposures at St James's Hospital. However despite inspectors being assured that governance and management arrangements for medical exposures were well defined and fit for purpose, St James's Hospital had failed to inform the Authority in a timely manner of changes to essential personnel allocated responsibility for the protection of service users. Also, records reviewed suggested that RSC attendance did not align with the RSC terms of reference (TOR). These areas for improvement were discussed during the inspection with senior management.

Following review of documents and records, and speaking with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

Inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Evidence of professional registration and arrangements to ensure continuity of MPE expertise was also supplied to inspectors. From the documentation reviewed and after speaking with staff, inspectors were assured that the level of involvement of MPEs was proportionate to the level of radiological risk at the installation and that MPEs took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, despite minor areas for improvement, inspectors were satisfied that a clear allocation of responsibility for the protection of service users ensured the safe

conduct of medical exposures at St James's Hospital.

Regulation 4: Referrers

Following review of referral documentation and a sample of referrals for medical radiological procedures and from speaking with staff, inspectors were satisfied that St James's Hospital only accepted referrals from appropriately recognised referrers. St James's Hospital utilised a bespoke electronic patient record (EPR) which made professional registration details of all referrers readily available for each individual referral and this was seen as a positive use of digital platforms to help strengthen the identification of appropriately qualified referrers.

In addition, the specific situations when radiographers could act as referrers was detailed in the documentation reviewed in advance of this inspection and included examples of when radiographers could amend referrals or complete a secondary referral. Staff who spoke with inspectors demonstrated a good understanding of the referral process for radiographers.

St James's Hospital also accepted referrals from registered nurses working at the hospital. Inspectors reviewed documentation and spoke to staff and management in relation to nurse referral and were satisfied that St James's Hospital employed well defined and understood measures to ensure that only appropriately qualified registered nurses referred patients for medical radiological exposures in line with the regulations and local policy**.**

Judgment: Compliant

Regulation 5: Practitioners

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that St James's Hospital had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

St James's Hospital operated as a body corporate undertaking. Overall responsibility for the radiation protection of service users was with the Hospital Board,

represented by the CEO. The undertaking employed a RSC tasked with ensuring practise at the hospital satisfied the appropriate statutory requirements. This committee also advised the Hospital Board and its officers of their obligations with regard to radiation safety issues.

The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspectors during the course of the inspection. The RSC reported directly to the Quality and Patient Safety Committee which, in turn, reported to the CEO and Hospital Board through a sub-committee. Multiple alternate pathways of communication also existed within the governance structures of the undertaking. The Radiology Clinical Director, Radiation Protection Advisor (RPA) and Radiological Service Manager (RSM) all had individual monthly meetings with the Hospital Chief Operations Officer (COO) who reported directly to the CEO and the Board. Also, St James's Hospital held a monthly directorate meeting attended by the CEO which provided another communication pathway for relevant issues to be brought to the attention of the Board if required.

During the inspection process inspectors were informed that the undertaking representative and CEO had changed in June 2020 and HIQA was not informed of this change at that time. It is imperative that undertakings keep HIQA up to date with changes to essential personnel allocated responsibility for the protection of service users within their service. This information was updated by the undertaking immediately following the inspection.

Inspectors noted that, as specified in the RSC's TOR which require the presence of the CEO or their deputy, the CEO or their deputy were not present at the last three RSC meetings for which minutes were supplied. While inspectors were satisfied that alternate lines of communication existed between the RSC and the CEO as discussed above, the undertaking should consider ensuring RSC attendance is as specified in the TOR or alternatively review the membership requirements specified in the TOR of the RSC as appropriate.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From speaking with staff and management and reviewing the radiation safety procedure documentation and a sample of referrals for medical radiological procedures, inspectors were satisfied that the undertaking had ensured that all medical exposures took place under the clinical responsibility of a practitioner. Similarly inspectors were assured that the optimisation process involved the practitioner and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of MPE at the hospital were described to inspectors by staff and management spoken with on the day. Staff who spoke with inspectors reported that they had adequate access to medical physics expertise and inspectors were satisfied that the undertaking had adequate processes in place to ensure the continuity of medical physics expertise at this facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. Inspectors were assured that the involvement and contribution of MPEs at St James's Hospital was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at St James's Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by St James's

Hospital ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals from a range of departments, inspectors were assured that the undertaking had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Service user information on radiation risks was available throughout the radiology department on the day of inspection. This information was specific to procedures delivered by the facility as well as the different modalities and risk benefit information was observed for computed tomography (CT), general radiography, fluoroscopy and dental radiology on the day of inspection.

DRLs were established, used and reviewed. St James's Hospital undertook extensive multidisciplinary DRL reviews and implemented corrective actions resulting in significant patient dose reductions across a range of procedures including the CT Brain procedure and a number of barium procedures. This use of local DRL review to closely monitor, and in certain cases, optimise service user radiation doses was seen as a positive use of regulatory required reviews to optimise service user outcomes.

One area of improvement noted by inspectors related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of all patients' reports as required. However, some methods had been devised to manually record this information in the absence of an automated process and the undertaking should consider the utilisation of this or similar methods to ensure compliance with the requirements of Regulation 13(2).

Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the undertaking had implemented a quality assurance program. Bespoke equipment management solutions aided the undertakings ability to keep equipment under strict surveillance. However, at the time of inspection a number of pieces of equipment were overdue performance testing and in some cases no dates were set to address this. The undertaking must endeavour to ensure locally set QA key performance indicators (KPIs) are consistently met and outstanding QA is prioritised to ensure it is addressed in a more timely manner.

Inspectors were satisfied that the undertaking had implemented measures to minimise the likelihood of incidents for service users undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and multidisciplinary analysis of events involving or potentially involving accidental or unintended medical exposures. This system was overseen and facilitated by the hospital's Quality and Safety Improvement Directorate (QSID) and records reviewed highlighted the integrated approach of the undertaking to the analysis and mitigation of accidental and unintended exposures and significant events.

Overall, inspectors were assured that St James's Hospital had comprehensive systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to

the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors spoke with staff and management who explained how medical exposures are justified in advance of the medical exposure. All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

The record of justification of medical radiological procedures that was recorded by a practitioner in advance of the procedure was also available for all medical radiological procedures reviewed. The undertaking employed a radiology information system (RIS) which was integrated with the hospital's electronic patient record (EPR). The EPR supported electronic ordering of electronic radiology referrals and record keeping of paper based radiology referrals. This EPR system also linked directly with the national integrated medical imaging system (NIMIS). Inspectors found that the integration of these systems facilitated seamless access to all relevant information relating to individual patients undergoing medical exposures at the hospital.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of these posters were also available to service users in the X-ray department, and inspectors were informed that these pamphlet versions were routinely supplied to service users with appointment letters for radiological procedures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of documentation and records, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the clinical areas.

Inspectors also reviewed extensive records of a comprehensive multidisciplinary approach to the investigation and implementation of corrective actions by the undertaking when local facility DRLs exceeded national DRLs. The associated corrective actions had resulted in significant dose reductions with no loss of image

quality across a range of Barium procedures as well as the CT brain procedure for one CT scanner. For example, inspectors were informed that equipment, protocol and case load reviews and subsequent corrective actions resulted in dose reductions of 25-30% across a range of barium procedures. Inspectors were also supplied with a dose audit for the CT brain procedure which also yielded a significant patient dose reduction after corrective actions were implemented.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for standard radiological procedures carried out at St James's Hospital were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff in the clinical areas who spoke with inspectors clearly articulated how these protocols were made available to them.

Inspectors spoke to staff and reviewed a sample of imaging reports in a number of clinical areas on the day of inspection. Inspectors saw evidence that information relating to patient exposure formed part of the report for CT, nuclear medicine, PET CT and DXA. However inspectors observed, and were informed by staff, that this was not the case for general radiography and therefore information relating to patient exposure did not consistently form part of the report of all medical radiological procedures, as required by the regulations.

The specific referral guidelines used in this facility were documented in radiation safety documentation supplied in advance of this inspection and inspectors were informed and observed that these referral guidelines were made available digitally for the relevant staff on the hospital's intranet system.

Documentation and records reviewed satisfied inspectors that St James Hospital routinely audited various aspects of radiation safety practice including medical procedure justification, policy compliance, image quality and patient dose.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of equipment which was verified on site. Equipment inventory was a standing agenda item of the RSC and this was also used to discuss and record decisions to use radiology equipment beyond nominal replacement dates.

Inspectors found a good example in relation to the systems employed to track and

ensure oversight of QA testing for medical radiological equipment at the hospital. The medical physics and bioengineering (MPBE) department employed a QA scheduling plan which planned annual QA testing and highlighted when QA was near due or overdue. The records viewed by inspectors were comprehensive, using a traffic light system to visually indicate when QA was near due or overdue. Inspectors were informed that overdue QA was also addressed in fortnightly MPBE meetings and documentation reviewed highlighted that a report on QA testing was a standing agenda point for the RSC. Furthermore, St James's Hospital employed a 12 month rolling average key performance indicator (KPI) to monitor performance in this area with a target of 100%.

Inspectors also observed a bespoke equipment management system which allowed comprehensive testing, maintenance and fault logs for all radiographic equipment. Inspectors found that this was a comprehensive record of all information relating to radiological equipment and should aid the undertaking's ability to keep equipment under strict surveillance.

However, inspectors found that the strict surveillance of medical radiological equipment should be improved by the undertaking, as at the time of inspection records provided to inspectors highlighted eight pieces of radiological equipment that were overdue annual QA. Four of these had agreed dates ranging from two to six months after the due date. One piece of equipment had a proposed, but not yet agreed, date three months after it was due. The remainder of equipment with overdue QA had yet to have dates proposed or agreed at the time of inspection. Also, RSC minutes reviewed as part of this inspection indicated that the QA schedule KPI was not being met consistently and staff spoken with on the day indicated that this was due to staff resources, demanding clinical workloads and access to radiological equipment. In order to provide assurance around the safe delivery of medical exposures the appropriate quality assurance programmes must be maintained by ensuring regular performance testing. The undertaking must prioritise the regular QA of all radiological equipment in line with local KPIs and national guidance as specified in HIQA's *Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy*.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that the undertaking had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with local policies and procedures.

Multilingual posters were observed throughout the department. Inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents in advance of this inspection, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Inspectors were satisfied that St James's Hospital had a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures and that this system had been implemented and maintained. Minutes of the RSC were reviewed by inspectors and detailed that accidental and unintended exposures and significant events were a standing agenda point.

Staff who spoke with inspectors consistently articulated the process used locally for the reporting and recording of accidental and unintended exposures and significant events. Inspectors were assured that the online adverse incident record (AIR) system allowed the undertaking to record and inform all relevant staff of radiation incidents while also ensuring a multidisciplinary approach to the investigation and close out of all incidents. Staff spoken with on the day also articulated the involvement of the QSID in the oversight of all accidental and unintended exposures and significant events. It was clear after document review and speaking with staff that the undertaking took a comprehensive approach to the entire process surrounding accidental and unintended exposures and significant events and utilised well established resources such as the QSID to minimise the likelihood of incidents for patients undergoing medical exposures at this facility.

The undertaking supplied incident trending data which satisfied inspectors that while a relatively low number of incidents had been reported to the Authority, this did not constitute a deficiency in the undertaking's ability to identify, record or report such incidents. Based on the numbers and type of near misses and incidents which did not reach the threshold for reporting to HIQA, inspectors were satisfied that the number of incidents reported to the Authority in this facility was an accurate reflection of the low numbers of incidents occurring in this facility.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	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 St James's Hospital OSV-0007408

Inspection ID: MON-0035038

Date of inspection: 20/07/2022

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 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: St.James's Hospital acknowledges the importance of timely communication to the Regulator of any change in key personnel within the organisation. The hospital has now submitted a NF201B notification detailing the change of undertaking representative details that took place in June 2020. A further NF201B notification was submitted on 22nd August 2022, advising the Regulator of a further change planned for 30th August 2022. This completes the immediate action required. Responsibility for future notifications rests with the undertaking representative. The designated manager and RPA will provide appropriate support to ensure this communication is made in a timely manner. 2. The Terms of Reference of the St. James's Hospital Radiation Safety Committee note that the CEO is a member of the committee. Notwithstanding the fact that there are a number of channels of communication to the CEO and the Board on matters relating to radiation safety, the Hospital regards the inclusion of the CEO on the committee as an important element of the overall governance. Future meetings of the RSC will be scheduled through the CEO's office to facilitate attendance by the CEO.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Radiation safety legislation requires that the radiation dose administered to a patient during a procedure is captured as part of the medical report. One of the reasons that this mandate exists is so that the level of risk to the patient from the exposure can be put into context for the referrer. The original specification for NIMIS had included this functionality and SJH had been actively involved in promoting this feature but to date it has not been incorporated in to NIMIS. The hospital has contacted NIMIS on a number	

of occasions, to highlight the importance of progressing this functionality within NIMIS. SJH have also engaged with the NIMIS team via the NRPC to seek an update and has been advised that it plans to integrate the required functionality into NIMIS. It is hoped that some elements of the national solution will become available in the first half of 2023 but await confirmation on this. Until that time SJH has taken a number of steps to address the requirement. Dose related information is currently included in reports from CT, DXA, Nuclear Medicine, interventional cardiology and PET CT. SJH is now currently looking at methods of capturing dose information from interventional radiology. This is already included within the electronic patient record and so is available for all patients but SJH will now look to include this data into the radiology report. The timeline envisaged for this is end of 2022. In relation to general x-ray there are significant challenges for this modality. SJH has mapped out the various steps that would be required to provide dose information in a meaningful way. For the general x-ray equipment currently in SJH, there is a minimum of eight additional steps that would have to be taken to identify the dose associated with the exam and incorporate it into the report. Pending the introduction of the NIMIS solution, SJH has explored other ways of addressing the underlying intent of the legislative requirement.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
On the day of inspection, it was noted that quality assurance testing was overdue for 8 of the 44 systems that are subject to annual (bi-annual for intra-oral) testing. There are a number of reasons for this including staff resources and challenges in timely access to clinical systems with high patient throughput. System wide pressures as a result of COVID also inevitably impacted on all aspects of service delivery. In order to ensure timely completion of QA within the due period, the MPBE QA scheduler has been extended to now include the SPECT CT systems which were not previously managed through this system and were two of the systems that were overdue. This will ensure high level visibility within MPBE of any potential slippage in target QA dates for these systems. 7 of the 8 systems that were identified as being overdue QA at the time of inspection had now had their annual quality assurance. The remaining system has been subject to routine QA checks which confirm satisfactory performance but as it is being decommissioned at the end of this month, it was decided to defer the annual QA in the interests of optimal use of resources. For these and all other systems, MPBE will continue to work with clinical colleagues to ensure that QA can be carried out on time while taking account of urgent clinical priorities. The observations noted in the HIQA report in relation to target dates will be communicated to all relevant stakeholders to further highlight the importance of facilitating access. While access can be somewhat difficult for certain modalities, there is general acceptance on the part of users and management that QA and maintenance are essential components of the radiation safety framework. In the event of serious difficulties obtaining access, this will be escalated up through existing structures to the CEO's s office. It is not envisaged that this will be required but it remains as an option. Staff losses and changeover in 2021 and 2022 exacerbated the

pressures on physics resources but this has been addressed and recent deficits will be restored within the next two weeks.

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	20/08/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	30/06/2023

	procedure.			
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	01/10/2022
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	31/12/2022
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	31/12/2022