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:	Bon Secours Hospital Galway
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	Renmore Road, Renmore, Galway
Type of inspection:	Announced
Date of inspection:	30 April 2025
Medical Radiological Installation Service ID:	OSV-0007387
Fieldwork ID:	MON-0044910

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

Bon Secours Hospital Galway (BSHG) is a modern, acute general hospital providing high-quality, patient-centred healthcare services in the West of Ireland. Established in 1954, the hospital is part of the Bon Secours Health System CLG, Ireland's largest independent hospital group. The hospital operates in line with the ethos and mission of Bon Secours Mercy Health, combining compassionate care with clinical excellence. BSHG functions as a Model 2 hospital as outlined in the National Acute Medicine Programme (2010) and provides an extensive range of medical and surgical specialties including Cardiology, ENT, Gastroenterology, General Medicine, General Surgery, Neurology, Ophthalmology, Orthopaedics, Pain Management and Plastic Surgery. The hospital comprises 93 inpatient beds distributed over five wards and 30 day-case beds, supporting both elective and emergency clinical activity. Services are delivered in a safe, effective and patient-focused environment, underpinned by strong governance and quality assurance structures. The Radiology Department at BSHG provides a comprehensive range of diagnostic and interventional imaging services to inpatients, outpatients, day-case patients and general practitioners. The department operates with a multidisciplinary team under the governance of the Radiology Services Manager and Consultant Radiologists, supported by Radiation Protection Advisors (RPA), Medical Physics Experts (MPE), Radiation Protection Officers (RPO), Clinical Specialist Radiographers, General Radiographers, Radiology Assistants and Clerical Administration staff. The department operates core hours from 08:30 to 17:15, with emergency out-of-hours services available to support 24/7 hospital operations. Annual imaging volumes have grown significantly, with approximately 35,000 examinations (with 21,250 of these involving ionising radiation) performed in 2024. Services provided include: • General Radiography • Computed Tomography (CT) • Magnetic Resonance Imaging (MRI) • Ultrasound • Mammography • DEXA scanning • Fluoroscopy • Interventional Radiology • Cardiac Catheterisation All imaging services are delivered in accordance with national regulations and best practice standards in radiation protection and safety. The hospital maintains close collaboration with its appointed RPA and MPE to ensure

compliance with dose optimisation, clinical audit, quality assurance and patient safety requirements.

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 30 April 2025	09:15hrs to 14:15hrs	Kay Sugrue	Lead
Wednesday 30 April 2025	09:15hrs to 14:15hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors carried out an inspection at the Bon Secours Hospital Galway on 30 April 2025. Inspectors reviewed documentation, spoke with staff and management and visited the interventional cardiology suite, the computed tomography (CT) department, the dual-energy X-ray absorptiometry (DXA) room and the general radiography department during this inspection. Corrective measures to improve compliance with Regulation 13(2), which were outlined in the compliance plan submitted following the previous HIQA inspection on 25 October 2022, were also reviewed. Inspectors found that the undertaking had improved compliance with this regulation which was achieved through significant investment and upgrade of its radiological information system (RIS). A similar approach was in the pipeline to upgrade the cardiovascular information system to facilitate the automated transfer of information relating to the patient exposure for all interventional cardiology medical radiological procedure reports, to ensure full compliance with this regulation.

Similar to the previous inspection, inspectors found there were established governance, leadership and management arrangements in relation to the radiation protection of service users in place at the hospital, with clear reporting lines up to the undertaking, the Bon Secours Health System. The Chief Executive Officer (CEO) acted as the main conduit for all radiation safety and protection matters via the hospital committee structure up to the CEO of the Bon Secours Hospital Group.

In relation to the allocation of responsibility for the protection of service users undergoing medical exposures, inspectors found 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. The evidence gathered demonstrated there were adequate continuity arrangements in place to ensure there was appropriate medical physics expert (MPE) involvement in the safe delivery of medical exposures, and MPE responsibilities were allocated in line with regulatory requirements.

Notwithstanding the allocation of responsibilities mentioned above, improvements were required to ensure all aspects relating to the allocation of responsibilities along the medical exposure pathway are addressed, to ensure full compliance with Regulation 6(3). For example, further action was needed to allocate the roles and responsibilities for the oversight, management and approval pathway for applications of new types of practice for submission to HIQA, to ensure compliance with Regulation 7. In addition, inconsistencies, and some ambiguity in documentation provided to inspectors and listed under Regulation 6 also require attention, to ensure that day-to-day practices align with documented procedures**.** The findings in this report mainly relate to gaps in documentation and while

impacting regulatory compliance, they did not represent a radiation safety risk to the service.

Regulation 4: Referrers

Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that medical exposures were only accepted from individuals entitled to refer, as per Regulation 4, at Bon Secours Hospital, Galway.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors viewed the allocation of responsibilities in documentation provided before this inspection and spoke with staff members and hospital management with responsibilities for the radiation protection of service users. The hospital committee and reporting arrangements were also reviewed. The lines of communication outlined in a diagram of organisational structures were consistent with those articulated by staff in discussions with inspectors.

It was clear from the evidence gathered that the hospital radiation safety committee (RSC) was responsible for the oversight of regulatory compliance regarding the radiation protection of service users. The RSC reported to the newly formed radiology quality steering committee which reported to the quality, risk and patient safety committee and from there, upwards to the hospital management team, hospital CEO, the Bon Secours Health System Clinical Group and the undertaking, the Bon Secours Health System. The hospital CEO was the designated manager for this facility and attended the RSC meetings. Following a review of the RSC's terms of reference and committee minutes, inspectors noted that there was potential to expand representation from clinicians involved in the delivery of medical exposures in services located outside the radiology department at this forum.

Inspectors were satisfied that the roles and responsibilities for the conduct of medical exposures and the radiation protection of service users were allocated to

persons recognised as referrers and practitioners under the regulations. The undertaking had arrangements in place to ensure the continuity of medical physics expertise contribution and involvement in medical radiological procedures, the level of involvement being proportionate to the radiological risk associated with practices at this facility.

While individuals allocated with responsibility met regulatory requirements as discussed above, some aspects regarding the allocation of responsibility along the medical exposure pathway needed action to fully comply with Regulation 6(3). For example, the allocation of responsibility needs to improve to ensure that:

- there is no ambiguity in relation to the role of the radiographer as a referrer which was noted by inspectors in hospital procedures and policies
- the allocation of responsibilities includes the oversight, management and approval pathway for applications of new types of practice for submission to HIQA.

In addition, oversight of regulatory requirements in addition to the management of documentation needs to be strengthened to ensure that:

- facility DRLs in DXA imaging are compared to the national DRLs and available to staff for reference at the point of care
- any additions to written protocols are formally approved before implementing into day-to-day practices
- information relating to the patient exposure is included on all medical radiological procedure reports
- medical radiological equipment inventory and records are correctly documented to ensure strict surveillance of equipment as per Regulation 14(1)
- pregnancy enquiries for all medical exposures conducted in the theatre department are consistently based on information provided by the service user, in advance of the procedure, to a referrer and or practitioner, and not based on a third party that is not recognised under the regulations
- there is stronger staff awareness to ensure day-to-day practices for recording justification in advance for each medical exposure that aligns with local procedures
- inconsistencies noted in dose thresholds documented in the letter template for issue to general practitioners for patient follow-up following high dose procedures in the policy *Guidelines for High Radiation Dose Skin Injury* are addressed.

Inspectors were assured from discussions with staff and a review of processes and procedures, that the radiation protection of service users was a central focus for all staff involved in delivering medical exposures at this facility. However, the gaps in documentation listed above impacted regulatory compliance with Regulations 6, 13 and 14, and indicated that stronger oversight by the undertaking is required if full compliance is to be achieved.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that the undertaking had ensured that clinical responsibility was allocated to a practitioner as set out under Regulation (5), thereby, complying with the requirements of Regulation 10(1). Inspectors were satisfied from the evidence gathered during this inspection that referrers and practitioners were involved in the justification of individual medical exposures, and a practitioner and MPE were involved in the optimisation of medical exposures at this facility, in line with regulatory requirements.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that appropriate arrangements were in place to ensure the continuity of medical physics expertise at Bon Secours Hospital Galway.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The professional registration certificates of the MPEs providing medical physics expertise at Bon Secours Hospital Galway were reviewed and provided evidence that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors found that MPEs were involved in radiation protection across a range of responsibilities at the hospital, as set out under Regulation 20(2). For example, the records viewed showed that an MPE was involved in the quality assurance (QA) of medical radiological equipment, dosimetry and optimisation including the application and use of diagnostic reference levels (DRLs). Inspectors were satisfied that an MPE provided advice on the technical specifications for the procurement of new medical radiological equipment. Minutes from the RSC meetings showed that there was MPE representation at each meeting. Inspectors were satisfied that an MPE was involved in the analysis and dose calculations of significant events, should they arise, and also contributed to the radiation protection training for staff.

Judgment: Compliant

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

From documentation viewed and discussions with MPEs, inspectors were satisfied that the undertaking met the requirements of this regulation, in that, MPE involvement in medical radiological practices was evident and was commensurate with the radiological risk posed by the medical radiological practices at this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at Bon Secours Hospital Galway. The evidence gathered showed the undertaking was compliant with Regulations 8, 11, 15, 16 and 17, with action required to attain full compliance with Regulations 13 and 14.

Inspectors were satisfied that DRLs were established, used and reviewed in the radiology department. Areas of good practice identified by the inspection team included special practices applied for medical exposures associated with high radiation doses in which the follow up of relevant service users was assured. Good practices were also noted in relation to clinical audit of medical radiological procedures which included a range of topics audited within the medical exposure pathway. Inspectors were informed that a quality and audit manager for the radiology service had responsibility for planning and review of clinical audits of medical radiological procedures and played a key role in monitoring radiation doses and optimisation of medical exposures, in consultation with the medical physics team.

The process for reporting radiation incidents was consistently described by staff which aligned with hospital policy. Records reviewed by inspectors showed that while the levels of actual events reported were relatively low, it was clear there was a positive reporting culture where good catches made by staff prevented the occurrence of radiation incidents. Written protocols for standard procedures were available and staff described how a multidisciplinary approach was applied when optimising and approving protocols.

Since the last inspection in 2022, and as previously mentioned, significant measures had been implemented to improve compliance with Regulation 13(2). The actions taken to address this gap showed the undertaking's commitment to improving regulatory compliance which was further emphasised in the planned upgrade to the

cardiovascular radiology information system due to be implemented in the near future.

While noting the areas of good practice, some improvements were required. For example, while inspectors were satisfied that a quality assurance programme had been implemented and applied at the hospital, further action is required to improve the strict surveillance of medical radiological equipment as required under Regulation 14. To address this gap, the undertaking must ensure that QA for DXA equipment is carried out in line with HIQA guidance, and more attention is required to ensure the consistency of information included on the inventory of medical radiological equipment and some QA reports.

Overall, despite some areas for improvement noted above, inspectors were satisfied that there were effective processes in place to ensure the safe delivery of medical radiological exposures to service users at Bon Secours Hospital Galway.

Regulation 8: Justification of medical exposures

Inspectors found there was good practices in relation to the provision of information to service users. For example, multiple notices were displayed in each area visited to raise awareness about the risks and benefits associated with medical radiological procedures which were modality specific. In addition, staff had developed a poster specifically targeted towards children attending for X-ray.

Inspectors reviewed the document *Policy for the Referral and Justification of Exposure to Ionising Radiation*, spoke with staff and reviewed records of justification recorded on the radiology information system during this inspection. Overall, inspectors were satisfied that a record of justification was evident in records viewed, thereby complying with regulatory requirements. Inspectors found that a check box for verification of patient identification was identified in hospital policy as the 'justification in advance' tick box. However, there was a lack of clarity among staff demonstrated in discussions with inspectors, as to what the record of justification in advance was, which did not always align with the process outlined in local policy. Management informed the inspection team that a fix was imminent to change the name of this tick box to justification in advance, abbreviated to "JIA", to provide greater clarity to staff in relation to this issue.

Although compliant with this regulation, inspectors found that staff awareness on the referrer and practitioner roles in justifying procedures should also be strengthened in the service. For example, inspectors noted from a review of DXA imaging referrals for completed scans, that clinical details included in one referral viewed was not sufficient enough to appropriately inform the justification process. Inspectors were informed that an audit to evaluate whether referrals from external referrers met recognised standard based criteria for bone mineral density scans had found that improvements were required. As a follow up action, a letter was sent to these referrers outlining the criteria to be met in order to justify these referrals which reduced the occurrence of incomplete referrals from 6.9% to 2.2%.

Inspectors found this to be an example of good practice and considered that this approach, if applied more broadly to all referrers in this modality, had the potential to improve the appropriateness of referrals and referral practices.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors found that facility DRLs had been established and were reviewed each year. Facility DRLs were compared to national DRLs, for the most part, with the exception of DXA imaging, which is detailed under Regulation 6.

Inspectors noted that facility DRLs were displayed and accessible to staff in the clinical areas visited. Staff informed inspectors that regular reviews of paediatric doses were undertaken with a view to establishing paediatric facility DRLs, however, there was insufficient data available to achieve this goal due to the low levels of paediatric medical exposures conducted at the hospital.

Judgment: Compliant

Regulation 13: Procedures

A sample of written protocols for standard radiological procedures across a range of modalities were viewed by inspectors which were available in hard copy and electronic format. While meeting the requirements of Regulation 13(1), inspectors noted that a hand written instruction had been included in the hardcopy of the paediatric protocols which had not been reviewed and approved through the normal processes in place. This hard copy was immediately removed by staff from the clinical area.

Inspectors found that the undertaking had improved compliance with Regulation 13(2) which was achieved through the upgrade of its radiological information system (RIS). This resulted in the automated transfer of information relating to the patient exposure on to all medical radiological procedure reports managed on this system. Inspectors noted the time, effort and resources required to implement this fix in order to improve regulatory compliance. Records from interventional cardiology procedures were managed on a separate system which remained the last modality to receive a planned upgrade to the system. Inspectors were informed that this solution was imminent for implementation.

Referral guidelines were available to staff on desk top computers in the control rooms of the radiology department.

Inspectors were satisfied from a review of documentation and discussions with staff that clinical audits in relation to medical radiological procedures were carried out in accordance with the national procedures, thereby, demonstrating compliance with Regulation 13(4). A good example of audits was evident which covered a number of topics across a range of modalities that looked at dose, image quality, justification and turn-around times. Measures implemented following audits carried out in the interventional cardiology service and CT department had resulted in the reduction of the radiation dose to service users in both services which is a good example of how audit can be used to further optimise dose and enhance the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 14: Equipment

An inventory of medical radiological equipment was provided to inspectors as part of the pre-inspection documentation request. Inspectors noted inconsistencies in the names of some equipment units and serial numbers of X-ray tubes documented that made it difficult to align fully with QA reports by the MPE. In addition, records showed that QA of DXA equipment was not performed in line with HIQA guidance which was required to be completed on an annual basis. Inspectors were satisfied that all other units were subject to regular performance testing by radiography staff, by a service engineer and by an MPE as per the required frequencies.

While equipment details were clarified by staff during the inspection, inspectors found overall, that improvement was required in record keeping and documentation, if the strict surveillance of medical radiological equipment is to be assured and to meet requlatory requirements set out under Regulations 14(1), 14(2)(a), and 14(10).

Judgment: Substantially Compliant

Regulation 15: Special practices

Inspectors visited the interventional cardiology suite and spoke with staff involved in carrying out procedures there. The actions to be taken if a defined dose threshold is reached were mapped out in hospital policy, *Guidelines for High Radiation Dose Skin Injury,* which was effective from April 2025. A peak skin dose of 3,000 milligray (mGy) was the trigger for the first action point, with further actions prompted when threshold doses of 4,000 mGy and 5,000 mGy were reached. The actions outlined provide assurance that the cardiologist is notified by the radiographer when dose thresholds have been reached at each trigger point during the procedure. Doses are then recorded in the patient record, and before leaving the department, the patient

is provided with information to observe for possible skin effects. The patient's doctor is informed by letter and the radiation protection officer (RPO) is delegated the responsibility to follow-up with the patient. Records of high doses were viewed and inspectors saw evidence of patient follow-up by the RPO six weeks after the final procedure which confirmed that there were no tissue reactions experienced by the patient, and also showed the process was followed in line with the policy. The presence of a radiographer during procedures provided additional assurance in relation to the optimisation of doses.

Overall, inspectors were satisfied from reviewing the systems in place, and discussions with staff, that special attention was given to optimising medical exposures involving high doses to the patient, as per Regulation 15.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors spoke with staff and discussed the process for determining the pregnancy status of female patients of childbearing age before carrying out a medical exposure. The procedures described by staff aligned with hospital policy. Records reviewed consistently showed that a scanned pregnancy declaration form signed by the practitioner making the enquiry and the service user was maintained under the patient record on the radiology information system. Notices to increase awareness of individuals to whom Regulation 16 applies were observed by the inspectors in service user waiting areas throughout the radiology department.

Although compliant with Regulation 16, greater assurance is required from the undertaking around pregnancy determination for one sub-group of patients, as detailed further under Regulation 6.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors found from discussions with management and staff and a review of documentation, that the undertaking had implemented an appropriate system for the identification and management of radiation incidents that included a process to track and trend all radiation incidents and near misses. Minutes from the RSC and other committees within radiology governance arrangements demonstrated that radiation incidents were discussed at various committees. Information relating to radiation incidents was also shared to other sites within the group via the group

wide radiology forum. The evidence gathered demonstrated the undertaking's compliance with this regulation.
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	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 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Bon Secours Hospital Galway OSV-0007387

Inspection ID: MON-0044910

Date of inspection: 30/04/2025

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:

Expansion of the Clinician Representation on the Radiation Safety Committee (RSC).
Action: The Clinical Director of the hospital has been asked to nominate a representative from the clinicians in the Cardiac Catheterisation Service and Theatre Service to join the RSC. Additionally, the Rheumatologist responsible for reporting DEXA scans has been invited to join the RSC and has accepted the invitation. The terms of reference for the RSC will be updated by the end of July 2025 to reflect the expanded membership. These updated terms will be ratified at the next RSC meeting, which is scheduled for August 2025.

Remove ambiguity in relation to the role of the radiographer as a referrer.
Action: The role of the radiographer as a referrer is given in the Radiation Safety Procedures (RSPs) BSG PP RAD 057. The section defining this role included a statement allowing radiographers to write referrals based on a surgeon's verbal request. Procedures that involve fluoroscopy in theatre will now require the referrer to complete a referral. The RSPs BSG PP RAD 057 are being updated to reflect this requirement. The changes will be completed by the end of July 2025.

Allocation of responsibilities includes the oversight, management and approval pathway for applications of new types of practice for submission to HIQA.
Action: The RSPs BSG PP RAD 057 are being updated to better align with the application process for new types of practice outlined in the "Methods for Generic Justification of New Practices in Ionising Radiation," HIQA 2023. This will be completed by the end of July 2025.

Facility Dose Reference Levels (DRLs) in DXA imaging are compared to the national DRLs.
Action: National DRLs are now available alongside the Local DRLs in the DEXA room. This was completed on May 5th 2025.

Additions to written protocols are formally approved before implementing into day-to-day practices.
Action: Please refer to the response provided for Regulation 13.

Information relating to the patient exposure is included on all medical radiological procedure reports.
Action: Please refer to the details provided under Regulation 13.

Medical radiological equipment inventory and records are correctly documented to ensure strict surveillance of equipment as per Regulation 14(1).
Action: Please refer to Regulation 14 below.

Pregnancy enquiries for all medical exposures conducted in the theatre department are consistently based on information provided by the service user, in advance of the procedure, to a referrer and or practitioner, and not based on a third party that is not recognised under the regulations.
Action: The RSPs and our practice are being changed to ensure that pregnancy enquiries in the theatre department are carried out only by the referrer or practitioner and not based on information obtained by a third party.

Strengthen staff awareness to ensure recording of justification in advance aligns with local procedures.
Action: The Policy for the Referral and Justification of Exposure to Ionising Radiation BSG PP RAD 064 has been changed, and staff education has been carried out to ensure that the method of justification wording recorded by the practitioner matches that described in the policy. This will be completed by June 18th 2025.

Inconsistencies in dose thresholds in the letter template in the policy Guidelines for High Radiation Dose Skin Injury are addressed.
Action: The figure in the letter template is being changed to match that given in the text of the policy. This will be completed by June 6th 2025.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:

Handwritten instruction had been included in the hardcopy of the paediatric protocols. This page was immediately removed from the policy, and all hardcopy protocols within the department were inspected by the Radiation Protection Unit (RPU), this was completed by May 2nd 2025. The BSHG policy BSHS-QA-PP-1, titled "Development, Review, Approval, and Communication of Policies and Procedures," highlights that all protocols are reviewed and approved before publishing.
Action: This policy was shared with radiography staff in the department, and a

discussion about the development, review and approval of controlled documents will take place at the next radiology team meeting on June 18th, 2025.
Action: Compliance with this policy will be monitored by the Quality and Audit Radiology Manager (QARM) through quarterly observational audits of printed protocols within the clinical area.

Automated transfer of information relating to the patient exposure on all medical radiological procedure.
The Bon Secours Hospital System (BSHS) has recently upgraded its Cardiac Vascular Imaging System (CVIS), which allows for the automated transmission of patient data to the cardiologists' reports.
Action: The efficiency and reliability of the patient dose transfer will be subject to a Quality Assurance (QA) program. This QA program will be overseen by the hospital's Radiation Safety Committee (RSC), with the support of a Medical Physics Expert (MPE). The main component of the QA program will be comparing the patient dose stored in the imaging modality with the patient dose included in the reports. The dose management solution currently in place at the BSHS will continue to monitor, evaluate, and report the radiation doses that patients receive within the Catheterisation Laboratory. The CVIS was upgraded on May 19th, 2025, and radiation dose information has begun to transfer to the cardiologist's report. An audit for accuracy will occur every quarter, commencing July 2025.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:

Inconsistencies in identifiers of X-ray tubes made it difficult to align with MPE QA reports.
Action: The inventory now includes both the current tube and equipment identifier and both of these identifiers will be included on all future MPE testing records.

Records showed that QA of DXA equipment was not performed in line with HIQA guidance which was required to be completed on an annual basis.
Action: It has been agreed that the MPE QA for the DEXA equipment will be conducted annually, in accordance with HIQA guidelines. Our policy, titled "Diagnostic Imaging Quality Overview of Equipment" (BS Galway PP-ORG-072), has been updated to reflect this change and was finalised on June 17th, 2025.

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	30/09/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Substantially Compliant	Yellow	30/09/2025

	radiological 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	31/07/2025
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	31/07/2025
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/07/2025