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 Cork
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	College Road, Cork
Type of inspection:	Announced
Date of inspection:	05 November 2024
Medical Radiological Installation Service ID:	OSV-0007384
Fieldwork ID:	MON-0043051

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

The Bon Secours Hospital Cork (BSHC) is part of the Bon Secours Health System CLG. Established in 1915, BSHC is Ireland's largest private hospital with 344 beds, 1200 staff and 90 consultants, most of whom work in full time private practice. It is a modern acute general hospital providing an extensive range of medical and surgical specialities for adults and children. These include cardiology, cardiothoracic surgery, general medicine, orthopaedics, gastroenterology, neurology, paediatrics, bariatric surgery and pain management. BSHC also provides a full range of cancer services on site including surgery, medical oncology and radiotherapy (Joint Venture with UPMC).

The Radiology Department provides a diagnostic and interventional service to inpatients, outpatients, day case patients and general practitioner referrals. Over 90,000 examinations are performed annually. In the last two years the department has expanded with the installation of a second MRI scanner, a second tomosynthesis mammography unit, a new general radiography room and the replacement of CR mobile x-ray units with DR units. Other modalities include computed tomography (80 slice and 160 slice scanners), fluoroscopy, two digital general radiography rooms, interventional Radiology, nuclear medicine, three ultrasound rooms, and DEXA imaging.

Diagnostic and interventional cardiac imaging is performed in the Cardiac Catheterisation Suite, while the Specialist Breast Care Centre is equipped with a digital breast tomosynthesis system for mammography and a dedicated breast ultrasound room. Mobile radiography is performed in the Critical Care Unit and wards throughout the hospital, and three image intensifiers are used for mobile fluoroscopic imaging in the theatre and endoscopy departments.

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
Tuesday 5 November 2024	09:00hrs to 15:30hrs	Kay Sugrue	Lead
Tuesday 5 November 2024	09:00hrs to 15:30hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection at Bon Secours Hospital, Cork on 5 November 2024, to assess compliance with the regulations. Inspectors reviewed documentation, spoke with hospital management and staff involved in delivering medical exposures in the areas visited within the radiology service. In addition, inspectors reviewed the implementation of the corrective actions outlined in the compliance plan submitted in response to the report of the previous inspection on 15 March 2022 and found that further action was needed to fully address the previously identified gaps with Regulations 6, 8, 10 and 13.

The evidence gathered during this inspection showed that the leadership, governance and management structures in place for the radiation protection of service users remained unchanged since the previous inspection and provided an effective communication pathway up to the undertaking, Bon Secours Health System. Inspectors were assured that medical exposures took place under the clinical responsibility of a recognised practitioner and records showed that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per the regulations. Inspectors noted there were contingency arrangements to ensure the appropriate involvement and contribution by a medical physics expert (MPE) in matters relating to the radiation protection of service users within the radiology service at the hospital.

Staff at the hospital had worked to improve the allocation of clinical responsibility in the dual-energy X-ray absorptiometry (DXA) imaging service which was now aligned with the regulations. Inspectors found that the allocation of clinical responsibility for DXA imaging had been addressed since the last inspection but noted that some aspects relating to the allocation of responsibility in other areas needed action by the undertaking to fully comply with Regulation 6(3). For example, the allocation of responsibility for the oversight and management of new types of practice as per Regulation 7 was not clearly defined in documentation viewed. In addition, inspectors identified that local policy and responsibilities to ask and record the pregnancy status of service users attending for scans in the DXA unit must be reviewed to ensure, where relevant, it is consistently carried out by individuals recognised under Regulation 16(1). Finally, greater assurance must be provided by the undertaking to ensure that initial and ongoing training requirements in radiation protection set out by the regulations are completed when allocating responsibilities for medical radiological procedures.

The gaps in regulatory compliance were mainly related to gaps in documentation and did not present a radiation risk to the service user.

Regulation 4: Referrers

Inspectors reviewed the document *Referral and Justification of Ionising Radiation Examinations* and referral practices at the hospital and found that there were systems and processes in place to ensure that only referrals from appropriately recognised referrers were accepted. Referrers were clearly identifiable in each of the referrals viewed by inspectors which aligned with local policy and procedures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that medical exposures in this facility only took place under the clinical responsibility of a practitioner, as recognised under this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Governance arrangements for the radiation protection of service users were reviewed as part of this inspection. Inspectors found that the undertaking had ensured that there was an established governance and management structure in place. The arrangements reviewed demonstrated that an effective communication pathway was implemented to inform the undertaking of relevant issues relating to the radiation protection of service users. Defined structures viewed in hospital procedures aligned with those described by staff. These included a radiation protection compliance group (RPCG) which reported to the radiation safety committee (RSC) and upwards to the hospital's quality and safety committee. The hospital chief executive officer (CEO) attended the RSC which was chaired by the designated manager. The CEO was the direct reporting link up to the undertaking representative and the undertaking, the Bon Secours Health System. Inspectors were informed that the radiation protection officer also reports directly to the undertaking. From the minutes of the RSC reviewed, inspectors noted that RSC membership and attendances by staff involved in the conduct of medical exposures outside the radiology department requires improvement to help promote awareness in relation to the radiation protection of service users.

Following a review of documentation and discussion with staff and management, several areas of improvement were identified in relation to the allocation of responsibilities required under Regulation 6(3). For example, greater assurance and oversight is required by the undertaking to ensure that staff allocated as practitioners and responsible for the conduct of medical exposures in the radiology department comply with initial and continued training requirements set out under Regulation 22. In addition, specific responsibilities for establishing the pregnancy

status of service users in the DXA service should be reviewed to comply with Regulation 16(1). Finally, inspectors were informed that there had been no new practices at the hospital that required generic justification by HIQA since the commencement of the regulations in January 2019, however, there was no formal process in place should a new practice require assessment for submission to HIQA for approval. Therefore, this gap in the allocation of responsibility should be addressed and documentation updated as required to align documented allocation of responsibilities with the regulations.

While improvements were required in the allocation of roles and responsibilities in some areas, and in the documentation to support staff in these roles, inspectors were satisfied that many good practices were evident to ensure that service users in the radiology department received safe exposures of ionising radiation.

Judgment: Not Compliant

Regulation 10: Responsibilities

From the evidence available, inspectors were satisfied that the undertaking had ensured that recognised referrers and practitioners were involved in the justification of medical radiological procedures. There was also evidence to show that recognised individuals as per Regulation 10(2) were involved in the optimisation of radiation doses delivered to service users undergoing medical exposures in this facility.

On the day of inspection, inspectors were satisfied that the undertaking ensured that all medical exposures took place under the clinical responsibility of a practitioner, as defined under Regulation 5. In addition, to ensure the optimisation of medical exposures, a radiographer was present for each procedure performed at the hospital which was viewed by inspectors as good practice. However, to comply fully with Regulation 10(4)(a), the undertaking must ensure that practitioners who have been allocated the responsibility for carrying out medical exposures have completed the required training requirements as set out in Regulation 22(3).

Furthermore, the delegation of the practical aspects in the DXA service must be reviewed to ensure that persons delegated with the responsibility for establishing the pregnancy status of service users is a referrer and or a practitioner to comply with the regulations.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors spoke with the MPE and staff and reviewed arrangements in place to ensure the continuity of MPE advice for medical radiological practices at the hospital and were satisfied that the arrangements viewed were sufficient to comply with the requirements of this regulation.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

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

Responsibilities allocated to the MPE were outlined in local procedures and were consistent with those responsibilities articulated by the MPE in discussions with inspectors. Documentation viewed provided evidence of MPE contribution and involvement in medical radiological practices. For example, an MPE attended the facility's RSC meetings, gave advice on medical radiological equipment, contributed to the definition of the quality assurance (QA) programme and carried out annual QA testing. This included acceptance testing which was evident in records viewed for new equipment commissioned for use in 2023 and 2024. The evidence gathered also confirmed MPE involvement in optimisation including the establishment, application and use of diagnostic reference levels (DRLs) and staff training in radiation protection.

Inspectors noted that MPEs also acted as radiation protection advisers for the facility and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussions with staff including an MPE, inspectors found that there was appropriate involvement of an MPE in all aspects of medical exposure to ionising radiation conducted at the hospital. The evidence gathered demonstrated the undertaking's compliance with this regulation.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the interventional cardiology suite, the DXA unit and the nuclear medicine service at Bon Secours Hospital Cork. The evidence gathered from discussions with staff and management and a review of documentation and records in relation to medical radiological procedures demonstrated there were systems and processes in place to ensure the safe delivery of medical exposures at the hospital. Inspectors found the undertaking compliant with Regulations 9, 11, 14, 15, and 17 with improvements required to achieve full compliance with Regulations 8, 13 and 16.

Several examples of good practices were identified by inspectors during this inspection. For example, medical radiological equipment was kept under strict surveillance through the implementation of an appropriate quality assurance (QA), programme, as per Regulation 14. Facility diagnostic reference levels (DRLs) were established, regularly reviewed and used for each modality at the hospital, thereby, demonstrating compliance with Regulation 11. Inspectors noted that the undertaking had updated its approach to clinical audit for medical radiological practices to align with HIQA's national procedures, published in November 2023. In addition, clinical audit reports showed there was a strong focus on the optimisation of medical exposures and the radiation protection of service users. This culture of radiation protection of service users was also evident in the special attention given for medical exposures involving high radiation doses, more likely to be experienced by service users undergoing interventional cardiology procedures.

In relation to Regulation 17, the evidence showed there was a strong reporting culture within the radiology service where reporting levels for good catches had recently increased due to the introduction of a manual reporting process. This additional process was described to inspectors as an easier and quicker way to report these types of incidents with the electronic system more appropriate for recording and managing notifiable and non-notifiable radiation incidents.

Measures implemented by staff at the hospital since the previous inspection had ensured that justification in advance of a medical exposure was carried out by practitioner which was evident in the records reviewed. In the DXA service, inspectors noted that there was evidence to show that justification in advance was carried out by appropriate practitioners in this service in a sample of records viewed. However, staff informed inspectors that these records were not available to those delegated the practical aspects to confirm that justification had been completed before carrying out the procedure. In addition, the provision of accessible information about the benefits and risks associated with the radiation dose to service users also required improvement in this service.

Inspectors noted that the solution to improve compliance with Regulation 13(2) resulted in the inclusion of information relating to the medical exposure in the majority but not all of the reports of procedures viewed by inspectors, therefore more action was required by the undertaking to fully comply with this regulation. In relation to Regulation 16, inspectors noted the processes for making pregnancy inquiries and promoting awareness of special protection required during pregnancy

for service users undergoing a planned medical exposure required action to meet regulatory requirements.

Despite the gaps in compliance with respect of Regulations 8, 13 and 16, inspectors found sufficient evidence to show that staff and management at Bon Secours Hosptial Cork were committed to the radiation protection of service users and the safe delivery of medical radiological procedures at this facility.

Regulation 8: Justification of medical exposures

The hospital's justification process was outlined in local policy and reviewed by inspectors in conjunction with a review of a sample of medical radiological procedure records from a range of modalities provided within the radiological service. Inspectors noted that the triple identification check, although a separate process, was defined as the record of justification in advance of each medical exposure within this facility. However, staff awareness regarding this process was not consistently evident in discussions with inspectors and therefore requires improvement. In addition, inspectors identified scope to improve the process for confirming that justification in advance had taken place for procedures performed in the DXA service. Inspectors were informed that individuals carrying out the practical aspects of each scan could not verify that justification in advance by a practitioner had been completed as this record was not accessible on the system in use in this service. It is imperative that justification of each medical exposure by a practitioner is confirmed before carrying out the procedure to ensure compliance with this regulation.

While information about the benefits and risks associated with the radiation dose from medical exposures was available to service users and displayed in the format of posters in most areas assessed, inspectors noted that the provision of this information should be improved in the DXA service as it was not clearly available to service users at the time of this inspection.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Inspectors were assured, from documentation viewed and discussions with staff, that doses due to medical exposures were kept as low as reasonably achievable (ALARA) while ensuring the diagnostic outcome of the examination requested. The hospital policy *Optimisation of Medical Exposures in the Radiology Department* detailed standard approaches to be taken by staff when carrying out the practical aspects of medical radiological procedures across all services within the radiology service. Inspectors noted measures implemented to support the process of

optimisation at the hospital. For example, medical radiological equipment was maintained and underwent regular performance testing, protocols for standard procedures were accessible to staff in clinical areas, and there was evidence to show that DRLs were established, reviewed and applied in the areas visited.

In the interventional cardiology service, medical exposures performed occurred in the presence of a radiographer which provided additional assurance regarding the optimisation of each procedure. Inspectors found that radiation doses in this service were recorded manually and closely monitored by staff and noted from data viewed, that radiation doses had fallen each year between 2017 and 2024. A dose monitoring system was also recently implemented at the hospital. Staff described the procedure and alert system in place to quickly identify and notify the consultant cardiologist if dose thresholds had been reached to ensure there was appropriate follow up of the service user by the consultant.

Inspectors reviewed a sample of clinical audit reports and found that optimisation was a strong focus in the audits completed since 2023. For example, audits were carried out on CT brain studies, complete spine examinations, chest, knee, foot, and pelvis X-rays between 2023 and 2024. The reports showed compliance was good overall and where target compliance levels were not met, action plans were devised and implemented. Re-audits showed that increasing staff awareness on the importance of positioning, collimation and compliance with protocols achieved improvements in areas re-audited. The audit reports viewed provided assurance that staff at Bon Secours Hospital Cork were committed to the optimisation of medical exposures conducted and the radiation protection of service users.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Bon Secours Hospital Cork had a document titled *Diagnostic Reference Levels in Medical Imaging* which was effective since May 2023 and outlined the procedure and staff responsibilities for the establishment, review and use of DRLs in practice. Inspectors found that facility DRLs had been established for all modalities and were recently reviewed in October 2024. Facility DRLs were compared to national DRLs and were displayed and accessible to staff in the clinical areas visited.

Judgment: Compliant

Regulation 13: Procedures

A sample of written protocols for standard radiological procedures were viewed by inspectors in each of the areas visited which provided evidence of compliance with Regulation 13(1).

A sample of reports from medical radiological procedures performed in a range of services within the radiology department were viewed by inspectors. In the majority of the reports viewed, information relating to the medical exposure was included with some exceptions. For example, action was needed to ensure the requirements of Regulation 13(2) are consistently adhered to in all medical radiological reports specifically for medical exposures performed in theatre and the interventional cardiology service.

Inspectors reviewed a programme of clinical audit and a sample of audits reports related to radiological practices carried out at the facility. The document *Radiology Department Audit Policy* was reviewed which contained a clinical audit strategy. Inspectors were satisfied that this strategy aligned with HIQA's *National procedures for clinical audit of radiological procedures* published in November 2023 and included the principles and essential criteria that undertakings must apply to ensure compliance with Regulation 13(4). Inspectors noted that while work done to date met regulatory compliance, there was scope to further enhance the clinical audit programme in the future. For example, consideration should be given to broadening multidisciplinary contribution to clinical audit and expanding the range of audits carried out with a focus on high risk areas or services requiring specific attention.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of the medical radiological equipment in use at Bon Secours Hospital Cork which was verified during this inspection. Documentation reviewed demonstrated that a QA programme for this equipment had been established and implemented with evidence to show that acceptance and regular performance testing by an MPE and radiographers and servicing by equipment manufacturers had been completed in line with the documented schedules defined in the QA programme. Evidence of an equipment replacement programme provided assurance to inspectors that equipment past recommended dates for replacement were either upgraded, were in the process of being upgraded, or had passed QA requirements and were deemed safe for continued clinical use.

Inspectors were satisfied from the evidence gathered that all medical radiological equipment was kept under strict surveillance by the undertaking, thereby meeting the requirements of Regulation 14.

Judgment: Compliant

Regulation 15: Special practices

From the evidence available, inspectors were satisfied that special attention was given to the assessment of the radiation dose received by service users subject to interventional cardiology procedures at the hospital. Staff described the alert system in place to monitor and identify when specific dose thresholds had been reached. Inspectors were informed of the initial notification threshold level that alerted radiographers to notify the cardiologist performing the procedure that this dose had been reached. Staff informed inspectors that a lower threshold was used by radiographers to increase vigilance in relation to the doses delivered during a procedure. A specific dose threshold was also set out in the policy to trigger a follow-up by the cardiologist to ensure that service users are advised of possible tissue injury to the skin that may occur due to this threshold being reached. The practices described aligned with those detailed in the document *Management of Patients following High Dose Radiological Procedures* viewed by inspectors which had been recently approved at the end of September 2024.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Bon Secours Hospital Cork had processes in place to establish and record the pregnancy status of relevant service users prior to carrying out a medical exposure. This was evident in records of medical radiological procedures viewed in each of the areas visited. As previously mentioned under Regulation 10, and to ensure compliance with this regulation, the undertaking must ensure that recognised referrers and or practitioners are allocated the responsibility for making the pregnancy enquiry and this is reflected in local procedures.

Inspectors observed multilingual posters in the majority of areas visited in the radiology service to increase awareness of individuals to whom Regulation 16 applies but noted that access to this information could be improved in patient waiting areas in the DXA imaging service.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents that appropriate systems for the recording and analysis of events involving or potentially involving accidental or unintended exposures were

implemented at Bon Secours Hospital Cork. This was evident from a review of notifications submitted to HIQA from this undertaking since commencement of the regulations which demonstrated that Bon Secours Hospital Cork had a good history for reporting significant events within timelines defined by HIQA. The processes in place included an electronic reporting system to record and manage radiation safety incidents and reportable significant events and an additional manual system implemented to log good catches and near misses in each service within the department. The latter was relatively new and described by staff as an easier way to record these types of incidents. Inspectors were informed that since introducing this system, the levels of reporting had increased across the department which was considered by staff who spoke with inspectors to be a truer reflection of the actual number of occurrences. There was evidence to demonstrate that all incidents and near misses had been tracked and trended in the reports and logs viewed. The introduction of an alternative system was viewed by inspectors as an example of good practice to promote a reporting culture at the hospital.

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	Not Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Bon Secours Hospital Cork OSV-0007384

Inspection ID: MON-0043051

Date of inspection: 05/11/2024

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	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: A Consultant Cardiologist and a Consultant from Theatre will be included in the membership of the Radiation Safety Committee and invited to attend RSC meetings going forward. The Radiation Safety Procedures have been updated to reflect this inclusion. The allocated responsibility to ask and record the pregnancy status of service users attending for DXA scans has been reviewed to comply with regulation 16(1). Current DXA staff will complete the NMBI approved training programme to be recognised as referrers which will allow them to make the pregnancy status enquiry. In the interim, a practitioner, as defined in regulation 5, has been allocated this responsibility. The Justification policy has been updated to reflect this. A policy will be developed outlining the responsibilities and process for the assessment of new practices that require generic justification by HIQA within the hospital in compliance with regulation 7.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: In Cardiology, the cardiologist and radiographer have shared responsibility, with the cardiologist having clinical responsibility for the service user and the radiographer having responsibility for the medical exposure. The Justification policy has been updated to reflect this. Staff working in the DXA service will complete the NMBI approved training programme to	

be recognised as referrers to allow them establish service users' pregnancy status. In the interim, a practitioner, as defined in regulation 5, has been allocated this responsibility.

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
The RIS system will be modified to clearly document justification in advance.

DXA staff can now access the system that allows them to verify that each individual exposure has been justified in advance by a practitioner to comply fully with regulation 8.

Patient information posters have been displayed in the DXA waiting area.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
The issue with the system in theatre that was temporarily not sending dose reports is being resolved by the service provider.

The software in the Cardiac Catheterisation Lab is being updated to facilitate the display of dose in the final report.

Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:
Staff working in the DXA service will complete the NMBI approved training programme to be recognised as referrers to allow them establish service users' pregnancy status. In the interim, a practitioner, as defined in regulation 5, has been allocated this responsibility.

Pregnancy information posters have been displayed in the DXA waiting area.

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.	Not Compliant	Orange	04/02/2025
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any	Substantially Compliant	Yellow	31/03/2025

	medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.			
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Substantially Compliant	Yellow	23/12/2024
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is entered in the register	Not Compliant	Orange	23/12/2024

	established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	30/04/2025
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological	Substantially Compliant	Yellow	23/12/2024

	procedure concerned, and			
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	23/12/2024
Regulation 16(4)	Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to increase the awareness of individuals to whom this Regulation applies, through measures such as public notices in appropriate places.	Substantially Compliant	Yellow	23/12/2024