

# 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	Bon Secours Hospital Cork
Radiological Installation:	
Undertaking Name:	Bon Secours Health System
Address of Ionising	College Road,
Radiation Installation:	Cork
Type of inspection:	Announced
Date of inspection:	15 March 2022
Medical Radiological	OSV-0007384
Installation Service ID:	
Fieldwork ID:	MON-0031224

# About the medical radiological installation:

The Bon Secours Hospital Cork is part of the Bon Secours Health System CLG. Established in 1915, BSHC is a modern acute general hospital providing an extensive range of medical and surgical specialities for adults and children. These include cardiology, 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. Almost 80,000 examinations are performed annually.

Imaging services include Cardiac Catheterisation, Computed Tomography, DEXA, Fluoroscopy, General Radiography, Interventional Radiology, Mammography, Magnetic Resonance Imaging, Nuclear Medicine and Ultrasound. A major refurbishment of the department in 2018 - 2019 saw the installation of two new CT scanners (80 slice and 160 slice), a new open bore 70cm MRI scanner and a new Interventional Radiology suite. Other modalities include Nuclear Medicine, three Ultrasound rooms, two digital General Radiography rooms, a Fluoroscopy room 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 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>&</sup>lt;sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018. <sup>4</sup> 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.

Date	Times of Inspection	Inspector	Role
Tuesday 15 March 2022	09:30hrs to 14:45hrs	Kay Sugrue	Lead
Tuesday 15 March 2022	09:30hrs to 14:45hrs	Noelle Neville	Support

This inspection wa	s carried out during	g the following times:
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# Governance and management arrangements for medical exposures

On the day of inspection, inspectors found that there was effective leadership, governance and management arrangements in place at Bon Secours Hospital Cork for the radiation protection of service users.

Oversight for radiation protection was provided by the Radiation Safety Committee (RSC) which was supported in its operational functions by its sub-committee, the Radiation Protection Compliance Group. The RSC reported upwards to the hospital Quality and Patient Safety Committee. There was also a direct reporting line from the Radiation Protection Officer (RPO) to the undertaking. In addition, inspectors were informed that there was a hospital group radiation safety forum with representation by the Radiography Services Manager (RSM) from each hospital in the group at meetings. Inspectors reviewed documentation and spoke with staff and management and were satisfied that there was a strong commitment demonstrated for the radiation protection of persons undergoing medical imaging at the hospital.

Inspectors found from documentation revision and discussions with staff that the allocation of responsibility detailed in local policies was understood by staff. Records reviewed and discussion with staff provided assurance that referrals were only accepted from those entitled to refer service users for medical exposures. Referral rights for radiographers were clearly detailed in the *Referral and Justification Policy* and consistently articulated by staff. In addition, inspectors were assured that medical exposures took place under the clinical responsibility of a practitioner.

From the records reviewed and discussions with staff, inspectors were satisfied that Bons Secours Hospital Cork had ensured contingency arrangements for the continuity of Medical Physics Expert (MPE) expertise in the facility. Inspectors saw strong evidence of MPE involvement in all areas of MPE responsibilities as per regulations and were therefore satisfied that the level of MPE involvement was proportionate to the radiological risk posed by the service.

Inspectors found the undertaking had met regulatory requirements by ensuring that there was appropriate involvement of a practitioner and MPE in the optimisation of medical exposures at the facility. There was also evidence to show that a referrer and practitioner were involved in the justification process for all modalities with the exception of dual-energy X-ray absorptiometry (DEXA) imaging service. Inspectors found that a review of the process for justification of medical exposures conducted in this service was required to ensure a practitioner was appropriately involved as per regulations. Improvement was also required in relation to the documentation of each delegation of the practical aspects of medical radiological procedures conducted in DEXA imaging. For example, the hospital local procedures reviewed by inspectors stated that the delegation of practical aspects should be documented however, this documentation was not evident on the day of the inspection.

While the gaps in documentation did not present a radiation risk to the service user,

it did however, impact compliance with Regulations 6(3), 10(3) and 10(5). Hospital management acknowledged this finding and provided assurance that appropriate action would be taken following this inspection to ensure compliance with regulations.

### Regulation 4: Referrers

Inspectors were satisfied following review of documentation and from speaking with staff that only those entitled to refer as per regulations were authorised to refer at the hospital. Referrers were clearly identifiable in each of the referrals viewed by inspectors.

The hospital *Referral and Justification of Ionising Radiation Examinations Policy* clearly outlined scenarios in which radiographers could act as referrers. These scenarios to adapt referrals or request secondary referrals were also consistently articulated by staff to inspectors.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed a number of professional registration records, professional qualifications and records of radiation safety training. The hospital radiation safety procedures clearly listed the person with clinical responsibility for medical exposures conducted within each modality. These records and discussions with staff provided evidence that medical exposures only took place under the clinical responsibility of a practitioner as per regulations.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation and spoke to a number of staff and found that governance arrangements at the hospital were understood and effective. The hospital had a RSC which reported upwards to the hospital Quality and Safety Committee and from there to the Hospital Chief Executive Officer (CEO) and CEO of the Bon Secours Health System. Terms of reference viewed also stated that the RPO reported directly to the undertaking representative who was also the hospital group CEO.

The RSC had multidisciplinary membership and was responsible for radiation safety

and protection of patients undergoing medical exposures involving ionising radiation at the hospital. This committee met three times a year. The Radiation Protection Compliance Group was a sub-group of the RSC and met on a monthly basis. Its purpose was to support the operational functions of the RSC. Inspectors reviewed minutes from the radiology governance structures and found evidence that these forums met each of the established terms of reference. Inspectors noted from minutes reviewed that issues of concern were escalated upwards to the Quality and Safety Committee by the RSM. In addition, inspectors were informed that there was an additional hospital group radiology forum which met each quarter and was attended by RSMs from each of the hospitals in the group. This forum offered a platform to share knowledge gained from each radiology service and learning from radiation incidents.

Inspectors viewed a number of hospital policies applied in the radiology service and found that the allocation of responsibility for the protection of patients subject to medical exposures involving ionising radiation was for the most part clearly outlined. From speaking with staff, inspectors were assured that staff were aware of their individual roles and responsibilities. However, while the hospital demonstrated a high level of compliance with respect of the allocation of responsibilities, inspectors found some improvement was required in this area in the DEXA imaging service. Local rules for (DEXA) in the hospital Radiation Safety Procedures stated that "*the operator will confirm patient identification, pregnancy status of the patient and the justification process in accordance with the hospital policy.*" However, inspectors found that there was a lack of clarity as to the role of "operator" in policies reviewed. In addition, this term did not align with persons allocated with responsibility for justifying medical exposures defined in hospital policy or regulations. The hospital should review and update relevant processes and documentation to ensure full compliance with this regulation.

#### Judgment: Substantially Compliant

#### Regulation 10: Responsibilities

Inspectors were satisfied from documentation viewed and discussions with staff that all medical exposures took place under the clinical responsibility of a practitioner as per regulations. Consultant radiologists had clinical responsibility for medical radiological procedures undertaken at the hospital.

Medical exposures in the Cardiac Catheterisation Lab and fluoroscopy examinations performed in Theatre or Endoscopy were conducted in the presence of a radiographer. Inspectors were informed by management that a radiographer was present for examinations conducted in DEXA service each Friday. However, documentation viewed and discussions with staff did not provide assurance that medical radiological procedures conducted in the DEXA were justified by a practitioner. In addition, documentation relating to the delegation of practical aspects in DEXA although referenced in the radiation safety procedures, were not available to view. These gaps in compliance should be addressed to ensure full compliance with the requirements of Regulation 10. This finding was acknowledged by hospital management.

Judgment: Substantially Compliant

#### Regulation 19: Recognition of medical physics experts

Inspectors reviewed documentation including service level agreements (SLAs) which demonstrated that there were formalised arrangements in place to ensure continuity of MPE expertise. The evidence seen provided assurance to inspectors that the Bon Secours Health System had appropriate systems in place to ensure the involvement and contribution of MPEs at the Bon Secours Hospital Cork as per regulatory requirements.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

MPE professional registration certificates were reviewed by inspectors on the day of inspection and found to be up-to-date and met regulatory requirements. Inspectors spoke to an MPE who outlined the level of on-site presence and responsibilities with respect of this regulation. Inspectors were informed by the MPE that the hospital had provided remote access to its radiology information systems enabling full access out of hours. In addition, staff informed inspectors that the MPE was readily contactable via the phone if needed.

Inspectors saw evidence in documentation viewed demonstrating involvement of an MPE in quality assurance of medical radiological equipment, patient dosimetry, review and sign off of facility DRLs and advice and dose calculation for radiation incidents. Additionally, records viewed demonstrated that an MPE contributed to the development of protocols and delivered training on radiation protection to staff.

From documentation reviewed and discussion with management and staff, inspectors were satisfied that the hospital had appropriate arrangements in place to ensure the fulfilment of MPE responsibilities as per Regulation 20.

#### Judgment: Compliant

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

Inspectors reviewed documentation and spoke to staff and were satisfied that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was proportional to the level of risk posed at this facility providing numerous imaging services with different levels of complexity.

Judgment: Compliant

# Safe Delivery of Medical Exposures

Systems and processes in place to ensure the protection of service users undergoing medical exposures at the Bon Secours Hospital Cork were reviewed by inspectors. Inspectors found from discussions with staff and management that the hospital demonstrated a strong commitment and local ownership for the radiation protection of the service user.

An up-to-date inventory and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place which was underpinned in hospital policy. The evidence seen by inspectors provided assurance that medical radiological equipment in all modalities was kept under strict surveillance.

Evidence gathered from documentation reviewed and from speaking with staff demonstrated several areas of good practice. For example, inspectors found that there were appropriate systems and processes in place to ensure radiation doses to patients were optimised. A strong culture of clinical audit was noted by inspectors where 31 audits were completed in 2021 across a range of topics including referral, justification, pregnancy status, optimisation and unintended and accidental exposures. Inspectors found evidence of the use of diagnostic reference levels (DRLs) and written protocols for each type of medical radiological procedure in each modality. Information for service users regarding the risks associated with medical exposures including multilingual pregnancy posters was prominently displayed in each of the patient waiting areas visited by inspectors.

Inspectors found from speaking with staff and review of documentation that there was established systems in place for the reporting and analysis of accidental and unintended exposures and significant events. Records reviewed demonstrated that there was a positive reporting culture within the radiology service. A good area of practice noted by inspectors was the sharing of information and learning associated with significant events and incidents via the group radiology forum which has the potential to improve practices and enhance patient safety.

Inspectors found two areas requiring improvement. The first related to justification of medical exposures in DEXA imaging. While inspectors were satisfied that the justification process met regulatory compliance in most services, gaps were identified in relation to the justification of medical exposures conducted in DEXA imaging. Greater assurance was required that a practitioner as per regulations was involved in the justification of examinations in this service. The second 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 the report as required. This was an area of improvement already flagged by management who informed inspectors that a project was underway and due to be completed in the short term to ensure that the requirements of Regulation 13(2) were met.

Overall, inspectors were assured that the Bon Secours Hospital Cork had effective systems and processes in place to support the safe delivery of medical exposures.

# Regulation 8: Justification of medical exposures

Inspectors reviewed the hospital policy on *Referral and Justification of Ionising Radiation Examinations* and spoke with staff involved in the justification of medical exposures. This policy outlined that justification was a shared responsibility between radiologists and radiographers. A number of radiological procedures such as CT procedures were justified in advance by radiologists. Other procedures in general radiology were justified by radiographers using standard protocols approved by the radiologists. Hospital policy stated that any queries identified by radiographers during the justification process of examinations not individually justified by a radiologist must be discussed with a radiologist before proceeding with the examination.

Discrepancies related to the justification processes in DEXA imaging have impacted compliance with this regulation in that a practitioner as per regulations was not consistently involved in the justification of these procedures. Therefore this gap needs to be addressed to achieve full compliance with this regulation.

Judgment: Substantially Compliant

### **Regulation 9: Optimisation**

Inspectors viewed the policy *Optimisation of Medical Exposure in the Radiology Department* which outlined the practical aspects of optimisation for each modality. A sample of protocols for procedures were viewed in CT, interventional radiology and general radiology and inspectors spoke with staff in each of these services. Inspectors found that there was a multidisciplinary approach to the development of protocols for the optimisation of medical exposures. It was also evident to inspectors that there was a strong commitment demonstrated by staff to ensuring the optimisation of each medical radiological procedure undertaken at the facility.

Optimisation audits were performed on a quarterly basis to assess compliance with hospital policy. Inspectors viewed analysis of these four audits completed in 2021 which looked at different aspects relating to the optimisation process. These

included assessment of a scaling tool for orthopaedic imaging, evaluation ratings on clinical image quality in mammography, dose audits in CT and portable chest X-rays. Dose audits conducted demonstrated that the medium value from the samples audited were within 10 % of facility DRLs. Inspectors were informed that dose audits led to a review of the exposure parameters in use in mobile X-ray which subsequently resulted in the standardisation of patient doses for portable chest X-rays. Overall, a high level of compliance was achieved and any areas of improvement identified through audit were addressed. Inspectors noted that a follow up action plan was the acquisition of a dose tracking system which from discussion with staff and management was a priority for the hospital and hospital group in 2022.

From speaking with staff and documentation revision, inspectors were assured that patient doses are kept as low as reasonably achievable during medical radiological procedures.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

Documentation reviewed by inspectors demonstrated that facility DRLs were established, were in use and were reviewed on a regular basis. Local facility DRLs for each service were displayed in clinical area control rooms and were compared to national DRLs. There was evidence of multidisciplinary involvement in the process of establishing facility DRLs with input from an MPE. Staff who spoke with inspectors described scenarios in which DRLs were applied and actions taken if facility DRLs were exceeded.

Judgment: Compliant

#### Regulation 13: Procedures

Inspectors reviewed a sample of protocols for standard radiological procedures undertaken in the services inspected. These protocols were readily accessible to staff in the clinical areas. The protocols reviewed were up-to-date and subject to multidisciplinary review during the development stage prior to approval by the RSC and RSM.

Inspectors found from discussion with staff and management and review of a sample of medical radiological procedure reports that compliance with Regulation 13(2) was an area requiring improvement. Management were aware of this gap in compliance and were in the process of procuring and implementing a system that would allow the inclusion of patient dose into the record of the report in the near

#### future.

Referral guidelines were observed by inspectors in hardcopy and in electronic format in clinical areas inspected.

Documentation viewed demonstrated that 31 audits were conducted between the beginning of January 2021 until the first week in March 2022. The range of audits conducted were focused on patient identification, optimisation, referral and justification, carers and comforters and analysis of radiation incidents. Clinical audit within the radiology services was underpinned by a hospital policy. Following review of documentation and discussion with staff, inspectors were satisfied that there was a positive culture towards clinical audit within the service.

Judgment: Substantially Compliant

#### Regulation 14: Equipment

An up to date inventory was provided by the undertaking. Inspectors spoke with staff and reviewed documentation and were satisfied that medical radiological equipment at the hospital was kept under strict surveillance at this facility.

Documentation viewed defined the medical radiological equipment quality assurance programme outlining individual roles and responsibilities in the management of equipment during its life cycle from installation to replacement. For example, inspectors saw evidence of acceptance testing by an MPE for newly installed equipment. Quality assurance testing by an MPE and regular performance testing by radiology staff was also evident and consistent with the documented QA programme provided to inspectors.

From documentation reviewed and discussion with staff, inspectors found the undertaking to be compliant with the requirements of this regulation.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Regulatory aspects of this regulation assessed by inspectors were found to be compliant. Multilingual pregnancy posters were displayed in procedure rooms and patient safety waiting areas. Pregnancy status audits were undertaken each quarter which demonstrated an overall high level of compliance was achieved with some improvements required in the completion of pregnancy status declaration form and scanning of forms onto the radiology information system. Inspectors saw evidence on the radiology information system that radiographers performed pregnancy status assessments during the justification of requested medical radiological procedures.

#### Judgment: Compliant

# Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with management and staff and documentation viewed that there was an appropriate system in place to ensure that radiation incidents were identified and managed. Documentation viewed showed that there were seven accidental or unintended exposures reported in 2021; one of which was notifiable to HIQA. In addition, a total of 182 near misses were captured, recorded and analysed in the same period.

Data reviewed for January and February 2022 provided assurance that there was a positive reporting culture within the Radiology Department. There were four incidents reported involving accidental or unintended exposures within this period, two of which were notifiable and 47 events, many of which were described as good catches potentially preventing the occurrence of an accidental or unintended exposure. The hospital had a group radiology forum that facilitated the sharing of learning gleaned from radiation incidents across radiology departments in other hospitals within the group and evident in minutes from meetings reviewed by inspectors.

Referral request errors accounted for a high proportion of incidents reported during 2021 and this trend was again seen in data for the January and February 2022. The hospital demonstrated a commitment to improving the efficiency of the referral process to address this issue as a follow-up actionable item.

Overall, inspectors were satisfied that there were appropriate systems in place and where issues were identified that these were escalated and measures were put in place to address any identified deficiencies.

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	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 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# **Compliance Plan for Bon Secours Hospital Cork OSV-0007384**

### **Inspection ID: MON-0031224**

### Date of inspection: 15/03/2022

#### 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 noncompliance 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. Specific 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: The Local Rules for DEXA (Section 7.5 of BSC-RAD0077 Radiation Safety Procedures) have been updated to remove the term "operator", and to clarify the allocation of responsibility for medical exposure.			
The Referral & Justification policy (BSC-RAD0158) has been updated to clarify practitioner responsibility for the justification of all DEXA referrals, the documentation of this process, and the delegation of the practical aspects of medical exposure in DEXA.			
Regulation 10: Responsibilities	Substantially Compliant		
Outline how you are going to come into compliance with Regulation 10: Responsibilities: The Referral & Justification policy (BSC-RAD0158) has been updated to clarify the allocation of responsibility for medical exposure in DEXA, specifically the practitioner responsibility for the justification of all DEXA referrals and the delegation of the practical aspects of medical exposure as applied to DEXA imaging.			
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 Referral & Justification policy (BSC-RAD0158) has been updated to clarify practitioner responsibility for the justification of all DEXA referrals and the documentation of this process.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: A dose management system is being procured and implemented at BSH Group level; this project is due to be completed in the short term.

## 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	07/04/2022
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	07/04/2022

	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 10(3)(a)	An undertaking shall ensure that the justification process of individual medical exposures involves the practitioner, and	Substantially Compliant	Yellow	07/04/2022
Regulation 10(5)	An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.	Not Compliant	Orange	07/04/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/08/2022