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 Tralee
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	Strand Street, Tralee, Kerry
Type of inspection:	Announced
Date of inspection:	30 August 2022
Medical Radiological Installation Service ID:	OSV-0007385
Fieldwork ID:	MON-0037524

About the medical radiological installation:

The Bon Secours Hospital in Tralee (BSHT) is an acute care hospital located in Tralee, Co Kerry providing medical care to patients from Kerry and across Ireland since 1922. BSHT is part of the Bon Secours Health System healthcare group and includes hospitals in Cork, Dublin, Galway, Limerick, a care village in Cork and an outreach clinic in Cavan. The BSHT is very much embedded in the local community of Tralee, Co Kerry. The BSHT received Joint Commission Accreditation (JCI) in 2005. Our hospital in Tralee has grown rapidly over the years and recent advancements include new clean air operating theatres, two new endoscopy suites, a new radiology wing and a rapid access unit. The hospital provides a range of tests, examinations, surgical procedures and medical services on an inpatient, day case and outpatient basis. The hospital has 104 inpatient beds, 37 day-care beds, consulting suites, operating theatres for major and minor surgery, endoscopy, cardiology and diagnostic imaging facilities. The main diagnostic imaging facilities are located on the ground floor in the hospital and provide imaging services to diagnose a wide range of medical conditions to all patients attending the hospital. The Diagnostic Imaging Department typically operates Monday to Friday from 8am-5pm. An emergency out-of-hours service is available outside of these times. BSHT is a busy multidisciplinary department and performs approximately 17,000 studies a year. Services provided by the Diagnostic Imaging Department include: general radiography, DXA scanning, cardiology, mobile fluoroscopy and mobile radiography. The multidisciplinary diagnostic imaging team is made up of two on-site consultant radiologists, a radiology services manager, radiographers, radiation protection advisor & medical physics expert, a radiation protection officer, nursing staff, clerical administration and diagnostic imaging assistants.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 30 August 2022	09:30hrs to 15:50hrs	Kay Sugrue	Lead
Tuesday 30 August 2022	09:30hrs to 15:50hrs	Maeve McGarry	Support

Governance and management arrangements for medical exposures

On this inspection, inspectors reviewed documentation from the radiology department and spoke with staff and management with responsibility for the delivery of medical exposures within the Bon Secours Hospital Tralee (BSHT). The leadership, governance and management arrangements reviewed demonstrated that there were effective reporting arrangements in place to ensure that matters relating to the radiation protection of service users were communicated up to the undertaking. The hospital had a radiation safety committee (RSC) that met twice a year and reported to the Quality Safety and Risk Committee and from there up to the hospital manager, the hospital board and the undertaking. While representation from the radiology department and management was appropriate, inspectors found representation of clinical groups delivering medical exposures within other areas of the hospital could be improved at future RSC meetings.

Inspectors were satisfied through the review of documentation and discussions with staff 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 hospital had also established practices to ensure a radiographer was present for all medical exposures conducted in the hospital.

Inspectors reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. The evidence gathered demonstrated that there were contingency and continuity arrangements of medical physics expertise services in place, although contingency arrangements viewed should be included in contractual agreements for the MPE service when next reviewed. Inspectors were satisfied that MPE responsibilities as per regulations were met and that the hospital had ensured that the level of MPE involvement was proportionate to the medical radiological risk of the service. Inspectors found that the hospital should ensure that all clinical staff involved in the delivery of medical exposures at the hospital should avail of radiation protection training updates offered by the MPE to provide greater assurance in relation to the radiation protection of service users.

While inspectors were satisfied overall, that the right professionals were involved in the conduct of medical exposures delivered by the hospital, some areas for improvement were identified. For example, inspectors found that documentation viewed did not delineate practitioner and radiographer responsibilities for medical radiological procedures undertaken in the interventional cardiology suite and therefore should be reviewed to reflect day-to-day practices as described to inspectors. In addition, the hospital needs to ensure that a referrer and or a practitioner, as per regulatory requirements and local policy, are involved in enquiring and documenting pregnancy status of service users undergoing medical

exposure in all areas of the hospital.

The gaps in documentation outlined in this report did not represent a radiation safety risk to the service user but did impact on compliance with Regulation 6(3) and 10(5). Inspectors found that established governance arrangement for the radiology service could be improved and strengthened to ensure greater oversight of all services providing medical exposures at the hospital.

Regulation 4: Referrers

Inspectors were satisfied that the undertaking met the requirements of this regulation. From discussions with radiology staff and records viewed by inspectors, referrers were clearly identifiable in each of the referrals reviewed and professional registration numbers could be checked and verified by staff if needed. In the cardiology service, inspectors were informed that the consultant cardiologist was the referrer and practitioner for those procedures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures. The clarity regarding the roles and responsibilities of practitioners are discussed under Regulation 10.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation, prior to, and during the inspection and spoke with several members of staff and hospital management. From documentation viewed and discussions with staff and management, inspectors found that local oversight for radiation protection was provided by the RSC. Meetings of the RSC were held twice a year with representation from the hospital management team evident in minutes viewed. Documentation viewed by inspectors showed that there were established lines of communication upwards via the BSHT Quality and Safety Committee to the hospital manager, the hospital board, the undertaking representative and undertaking. Inspectors were informed that there was also a group wide radiology forum with representation from all radiology services within the Bon Secours Hospital Group. This forum facilitated the sharing of information in relation to radiation protection matters across the sites within the hospital group.

However, following a review of the RSC's terms of reference and committee minutes, inspectors found that there was potential to expand the representation on this committee to ensure appropriate representation from all services and clinical groups providing medical radiological procedures in the hospital.

On the day of the inspection, the role of the designated manager was fulfilled by the Radiography Services Manager (RSM) who also acted as the Radiation Protection Officer (RPO). Inspectors found that the undertaking should review the role of the designated manager at the hospital to ensure it aligns with HIQA guidance and is at an appropriate level to ensure the oversight and compliance with regulations of all services providing medical radiological procedures at the hospital.

While staff who spoke with inspectors were very clear on the practitioner roles in this service, this delineation of responsibility was not clearly defined in policy. For example, inspectors were informed that radiographers were the practitioners for general X-ray and dual-energy X-ray absorptiometry (DXA) procedures and that the cardiologist was the practitioner for interventional cardiology. Furthermore, inspectors were informed that the radiographers performed the practical aspects of medical exposures in the interventional cardiology. However, this delegation was not documented by the hospital. In addition, greater assurance was required to ensure that the referrer and or a practitioner as per regulations were responsible for enquiring as to the pregnancy status of service users undergoing medical exposures which is also discussed under Regulation 16.

Overall, inspectors found that in order to achieve full compliance with this regulation, the undertaking needs to review roles and the current documentation to ensure there is clear allocation of responsibility as per Regulation 6(3) to ensure consistency in practices across all radiological services provided by the hospital while also meeting regulatory requirements.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that all medical exposures were performed under the clinical responsibility of a practitioner recognised under regulations. For the majority of medical radiological exposures conducted within this hospital, the radiographer was the recognised practitioner, with the exception of medical exposures undertaken in the interventional cardiology suite. The consultant cardiologist was the practitioner for interventional cardiology procedures conducted there and the radiographer was delegated with the practical aspects. However, documentation viewed by inspectors did not fully align with practices described, and therefore should be reviewed and updated to clearly define practitioner roles and responsibilities to provide clarity to staff working in the service.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The undertaking had arrangements in place to ensure the continuity and access to MPE services and therefore met the requirements of this regulation. Inspectors viewed communication demonstrating that a second MPE was available to provide cover during planned and unplanned leave, however these contingency arrangements were not included in the contractual arrangement viewed by inspectors. Inspectors found that contractual arrangements should be reviewed to reflect the role of the MPE as per regulations and to formally outline contingency arrangements as articulated to inspectors and viewed in correspondence during the inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From discussions and documentation viewed, inspectors were satisfied that the hospital had arrangements in place to ensure there was appropriate MPE involvement and contribution as required by regulations. Inspectors were satisfied that an MPE was involved in all aspects of medical exposures as per the regulations. These aspects included quality assurance of medical radiological equipment, dosimetry and optimisation including the application and use of DRLs. There was evidence to demonstrate that there was MPE representation on the RSC. From documentation viewed and discussions with the MPE and staff, inspectors were assured that an MPE was involved in the analysis of significant events.

Radiation protection training for staff provided by the MPE was also evident in training records viewed by inspectors. These records showed that not all clinical groups attended the training carried out by the MPE. Inspectors were informed that all practitioners were offered training and some groups had yet to avail of this training. Therefore the undertaking should avail of the support of the MPE, such as the radiation protection training offered to staff, to help enhance the radiation protection of service users and to address areas for improvement outlined in this report.

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 was compliant with this regulation. Inspectors found that MPE involvement in medical radiological practices was evident and the level of involvement provided at the hospital was commensurate with the radiological risk posed by the practice.

Judgment: Compliant

Safe Delivery of Medical Exposures

From documentation reviewed and discussions with staff, inspectors found that the hospital had some measures in place to ensure that effective and safe medical exposures were provided to services users in compliance with the regulations. Inspectors were satisfied that the hospital had an appropriate system for incident record keeping and staff demonstrated knowledge and understanding of the incident reporting process within the hospital. Inspectors found examples of good practice evidenced in clinical audits conducted at this facility which were focused on improving the radiation protection of service users attending for X-ray. In addition, dose audits conducted on a monthly basis in the higher dose modality of interventional cardiology provided assurance that radiation doses delivered to service users from each procedure were monitored by radiography staff and the MPE.

Medical radiological equipment within the facility was kept under strict surveillance with an appropriate quality assurance (QA) programme in place. Evidence gathered also demonstrated that regular performance testing was undertaken therefore satisfying inspectors that regulatory requirements set out in Regulation 14 were met. While all equipment was found to be operating within tolerance and fit for clinical use, inspectors identified that prioritisation for the replacement of medical radiological equipment could be improved with a stronger focus placed on the radiological risk posed by the modality and the guidance from the MPE.

Inspectors identified some areas for improvement in relation to Regulation 8, Regulation 11, Regulation 13 and Regulation 16 which were discussed with staff and management on the day of the inspection.

Inspectors reviewed the justification process including a sample of records of medical radiological procedures conducted in various services within the hospital and spoke with a number of radiography staff. From the evidence gathered, inspectors determined that several areas relating to this regulation required improvement. While inspectors identified that justification in advance was documented for most radiological procedures performed in the hospital, this was not the case for interventional cardiology procedures where staff could not identify the record of justification. Improvements were also required to ensure that sufficient clinical data is included in referrals to inform the justification of all medical exposures. Finally,

the hospital had commenced a project to update the consent process for interventional cardiology procedures which once implemented, should provide additional assurance that service users are provided with information relating to the risks posed from exposure to ionising radiation from these procedures.

Evidence gathered demonstrated that DRLs were established for common radiodiagnostic procedures and performance of the service against these DRLs was comprehensively monitored through audit. Inspectors identified an area of improvement with respect of the use of DRLs in practice where the order of system values displayed on the radiology information system differed to those in the facility DRLs. This made comparison between the two sets of values difficult for staff to interpret or compare. Inspectors were informed by the MPE that this issue would be addressed to ensure the values displayed on the system could be easily compared by staff on a daily basis.

Written protocols were established for each type of standard adult medical radiological procedure provided by the facility, a sample of which were viewed by inspectors. However, inspectors were informed that although paediatric X-rays were performed in this facility, paediatric protocols had not been established as required under this regulation. Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to patient exposure as required by the regulations. Management at the hospital informed inspectors that a solution to address this gap in compliance was under development with implementation expected by the end of 2022.

While evidence viewed demonstrated that there was a system in place to determine the pregnancy status of service users who were due to undergo a medical exposure, more assurance was required by the hospital to ensure that this inquiry is carried out for each medical exposure by persons recognised under Regulation 16(1).

Finally, while meeting the requirements of Regulation 15, inspectors identified that the processes and the policy in place to follow up service users who have received higher radiation doses from interventional cardiology procedures and maybe at a potential risk of developing a skin reaction could be improved. The system in place should ensure that any skin reactions are identified, followed up directly by the hospital and reported to HIQA if they occur.

Overall, inspectors determined that while there was scope to improve the effective and safe delivery of medical exposures for service users at the hospital, much of the findings of this inspection related to gaps in documentation where there was a need to strengthen established processes already in place. Therefore, while this section identifies the non-compliances with respect of regulatory requirements, these did not represent a radiological risk to service users.

Regulation 8: Justification of medical exposures

Inspectors viewed records relating to medical radiological procedures conducted at

the hospital in addition to speaking with several staff members. While the process of justification was clearly outlined and documented in the radiology department, non-compliances were found in radiological services provided outside of the main radiology department.

Inspectors reviewed records of medical radiological procedures in the Radiology Department. These records and discussions with staff demonstrated that there was a defined process for documenting justification in advance for medical exposures delivered there. This process was also evident for fluoroscopy procedures undertaken in the theatre department. However, records for justification in advance of medical exposures delivered in the interventional cardiology suite were not clearly evident. Inspectors were informed that there was a different process in place for justifying procedures in this service. Staff informed inspectors that a consultant cardiologist was the referrer and the practitioner for all medical exposures undertaken in this service and the cardiologist was the person justifying the procedures in advance. Inspectors were informed by staff that the process of justification was included in the time out taken in advance of each procedure to confirm the correct identification and information relating to individual service users prior to undergoing each procedure. However, staff could not identify the documented record of justification to inspectors at the time of the inspection.

From review of medical radiological procedures conducted in the theatre department, inspectors were not fully assured that clinical information relating to the patient was documented in the referral in all cases. For example, one referral viewed by inspectors found that the referral did not contain relevant clinical information to inform the process of justification for the procedure.

Inspectors were satisfied that the hospital had posters providing service users with information relating to the radiological risk in all patient waiting areas and changing cubicles. However, improvements on the provision of additional information relating to the risks and benefits associated with medical radiological procedures delivered in the interventional cardiology suite were required. Inspectors were informed that the hospital had already identified this deficiency and work was underway to address this gap by improving information provided during the consent process. Draft consent forms were viewed by inspectors and demonstrated that risks and benefits associated from coronary angiography and coronary angioplasty procedures were outlined. Inspectors were assured that the revisions seen in the draft forms should address gaps identified in the provision of information to service users undergoing procedures at this facility.

These findings from evidence reviewed meant that greater assurance is required to ensure compliance with Regulation 8.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that there was a system and process in place for the establishment of DRLs at Bon Secours Hospital Tralee. Inspectors viewed evidence of good practice where DRLs were monitored on a monthly basis and any anomalies from the baseline were reviewed. These audits were displayed in the general X-ray control room. Inspectors observed that paediatric X-rays were being performed on the day of the inspection. Staff informed inspectors that paediatric DRLs had not been established due to the low levels of paediatric procedures performed overall which had reduced considerably since the closure of the paediatric ward.

One area of improvement noted by inspectors related to the use of DRLs in daily practice. The order of system values displayed on the radiological information system differed from those displayed in established DRLs. This made the comparison of DRLs to system displayed values difficult and staff could not articulate how to make the comparion. While, inspectors were satisfied that facility DRLs had been established and that these DRLs were monitored against national DRLs, inspectors were not assured that facility DRLs were used by staff as staff were not clear on the application of DRLS in daily practice.

Judgment: Substantially Compliant

Regulation 13: Procedures

While written protocols for most procedures were available and accessible to staff, staff informed inspectors that paediatric protocols had not been developed as very few X-rays were provided for this cohort of service users. However, protocols relevant to this category of service users should be developed and made available to radiology staff as per regulations.

Referral guidelines were available to referrers and staff on desktop computers.

Inspectors viewed patient records and found that information relating to the patient exposure did not form part of the report of medical radiological procedure as required under Regulation 13(2). Management informed inspectors that there was a plan to address this gap through the application of a new software programme due to be implemented towards the end of 2022.

There was evidence to show that the hospital had a system and process in place for clinical audit. Inspectors saw evidence of good practice in clinical audits conducted such as the monthly monitoring of DRLs as previously mentioned, regular dose audits undertaken in the interventional cardiology service and radiographic technique audits.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by inspectors showed that appropriate quality assurance programmes, including regular performance testing had been implemented for medial radiological equipment at the facility.

Inspectors reviewed the inventory of medical radiological equipment and noted that a significant proportion of equipment in clinical use were past nominal replacement dates. All equipment was subject to regular performance checks and annual QA and was deemed to be performing within tolerance and fit for clinical use. Notably, the nominal replacement date for fixed fluorsocopy equipment in use in the high dose modality of interventional cardiology was 2018. Inspectors were informed by the MPE that while facility DRLs for this service remained below national levels, an upward trend in these DRLs had been identified. Recent servicing and an X-ray tube change had not succeeded in lowering the doses and therefore the increasing trend was determined to be related to ageing equipment. Further discussions with hospital management indicated that replacement of this equipment had not been prioritised as the number of procedures performed each year were considered to be relatively low. Inspectors were also informed that equipment replacement for this high dose modality had not been placed on the hospital risk register. Inspectors were satisfied that while there was a procurement process in place for the replacement of ageing equipment, the undertaking should ensure that prioritisation for replacement is based on risk and the advice provided by the MPE.

Judgment: Compliant

Regulation 15: Special practices

From discussions with staff and documentation reviewed, patient doses were routinely monitored by a radiographer during each procedure conducted in the interventional cardiology suite. The presence of a radiographer during interventional cardiology procedures provided additional assurance of the optimisation of each medical radiological procedure performed there. Inspectors were informed that comprehensive reports of radiation doses from each medical radiological procedure conducted in this service were provided to the MPE on a monthly basis. The MPE was also informed when dose thresholds were exceeded during complex interventional radiology procedures. Dose audits reviewed by inspectors for this service demonstrated strong oversight by the MPE and radiographer for this high dose modality. This demonstrated that there was an assurance mechanism for the hospital of the radiation protection for service users undergoing these procedures.

The hospital had a policy on the management of patients following high dose procedures approved for use in March 2022 and was viewed by inspectors. The

policy outlined the procedure to be followed by the radiographer to verbally alert the practitioner when dose thresholds had been reached. Inspectors were informed that the system did not have an automated alert system in place for this purpose. There was also a process included to inform service users and their doctors of the possibility of a delayed skin reaction due to the procedure they had undergone. Inspectors identified that the requirement to report tissue reactions (deterministic effects) as a result of interventional cardiology to HIQA was not included in this policy and not strongly evident in discussions with staff. Although compliant with this regulation, the hospital should review its policies and procedures to ensure that all service users at risk of developing a tissue reaction following a high dose procedure are proactively identified and managed appropriately and these incidents are captured and reported to HIQA as appropriate.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were visible in service user waiting areas. From the documents reviewed and speaking with staff, inspectors were informed of the process for enquiring about and recording pregnancy status. While staff were familiar with this process, an assessment of the pregnancy status of a service user who underwent a medical exposure conducted in the operating theatre did not align with processes outlined. Inspectors were informed that a pregnancy status enquiry on a record reviewed was made by a practitioner but based on third party information documented and provided by a person not recognised as a practitioner or a referrer under Regulation 16(1). Inspectors were therefore not satisfied, based on discussions with staff and the management, that the process for enquiring and documenting pregnancy status in the theatre department for anaesthetised service users either fully aligned with local policy or complied with regulatory requirements. Following on from this inspection, the undertaking must ensure that the appropriate personnel as defined by regulations are involved in establishing pregnancy status as per regulations.

Judgment: Not 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. Incident reports viewed demonstrated that all radiation incidents and near misses were tracked and trended and communicated to the appropriate undertaking via established reporting

structures. Information relating to radiation incidents was also shared to other sites within the group via the group wide radiology forum.
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	Not Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Bon Secours Hospital Tralee OSV-0007385

Inspection ID: MON-0037524

Date of inspection: 30/08/2022

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The hospital manager will fulfil the role of Designated manager at the hospital and this will be updated on the HIQA portal. The hospital has updated the Justification policy to provide clear allocation of responsibility for the practitioner and radiographer roles within Cardiology as required in Regulation 6(3). It also includes the delegation of practical aspects of medical exposure within this service. The updated policy will be approved at the next RSC meeting and circulated to staff. A Consultant Cardiologist will sit on the Radiation Safety Committee to ensure appropriate representation from this service. The hospital will hold an additional two meetings annually to provide greater oversight of operational aspects of radiation protection within the hospital. This will provide a quarterly review of compliance within the hospital and assurance to the undertaking. The terms of reference for the RSC will be updated to reflect this quality improvement and will be approved at the next RSC meeting. Date of completion: 30/11/2022	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: The hospital has updated the Justification policy to include the clear documentation of the practitioner role and the delegation of practical aspects of medical exposure within The hospital has updated the Justification policy to include the clear documentation of the practitioner role and the delegation of practical aspects of medical exposure within the Cardiology service. This policy will be approved at the next RSC meeting and circulated to staff. The documented record of the delegation of practical aspects of medical exposure will be retained by the hospital pursuant to Regulation 10(5).	

Date of completion: 30/11/2022

Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
The hospital has updated the Justification policy to reflect that the Cardiologist is the practitioner carrying out the justification process during the time out taken in advance of the procedure in the Cardiology suite. The time out sheet will be updated to include a documented record of justification of each procedure and signed by the Cardiologist. The new process will be implemented by 30/11/2022. The hospital will issue a communication to all internal referrers from the RSC outlining the necessity for the provision of relevant clinical information in all referrals. For theatre procedures, the radiographer will contact the referrer directly in the absence of sufficient clinical information prior to the individual medical exposure. The updated consent forms with additional information on radiation risks and benefits will be approved at the RSC meeting and implemented from 30/11/2022. The radiographer will carry out the pregnancy enquiry with all theatre patients prior to their procedure. Where the patient is anaesthetised, the radiographer will require the Rejustification form to be completed by a referrer in advance of commencing a medical exposure. The relevant policies will be updated accordingly and approved by the RSC before circulation on the 30/11/2022

Date of completion: 30/11/2022

Regulation 11: Diagnostic reference levels	Substantially Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
The MPE has updated the Local DRLs with the units displayed on the modality and this will be communicated to all staff to ensure that they are competent in the application of DRLs in daily practice.

Date of completion: 30/11/2022

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
The hospital has developed written protocols for paediatric service users. A dose management system is being procured and implemented at BSH Group level; this project is due to be completed in the short term.

Date of completion: 30/11/2022; Dose management system: 31/03/2023

Regulation 16: Special protection during pregnancy and breastfeeding	Not Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:
The pregnancy enquiry for patients in theatre will be performed and documented by radiographers as practitioners as per Regulation 16(1). If pregnancy cannot be ruled out, a referrer must complete a re-justification form prior to medical exposure. The pregnancy policy will be updated and approved at the RSC meeting before circulation to all staff.

Date of completion: 30/11/2022

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	30/11/2022
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Not Compliant	Orange	30/11/2022

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	30/11/2022
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	30/11/2022
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical	Not Compliant	Orange	30/11/2022

	exposure, and shall provide such records to the Authority on request.			
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	30/11/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Substantially Compliant	Yellow	30/11/2022
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	30/11/2022

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	31/03/2023
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 procedure concerned, and	Not Compliant	Orange	30/11/2022