



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Bon Secours Hospital Galway
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	Renmore Road, Galway
Type of inspection:	Announced
Date of inspection:	25 October 2022
Medical Radiological Installation Service ID:	OSV-0007387
Fieldwork ID:	MON-0035041

## About the medical radiological installation:

The Bon Secours Hospital, Galway is part of the Bon Secours Health System, Ireland's largest Health Care Group. Established in 1954, the hospital is a modern acute general hospital providing an extensive range of medical and surgical specialities. These include Cardiology, ENT, Gastroenterology, General Medicine, General Surgery, Neurology, Ophthalmology, Orthopaedics, Pain Management and Plastic Surgery. The Radiology Department provides a diagnostic and interventional service to inpatients, outpatients, daycase patients and general practitioner referrals. Approximately 17,000 examinations are performed annually. Imaging services include Cardiac Catheterisation, Computed Tomography, DEXA, Fluoroscopy, General Radiography, Interventional Radiology, Mammography, Magnetic Resonance Imaging and Ultrasound. Core hours for the service are 08:30-17:15 and an emergency out-of-hours service is available outside of these times. The multidisciplinary Diagnostic Imaging team is made up of: Consultant Radiologists, Radiology Services Manager, Clinical Specialist Radiographers, Radiographers, Radiation Protection Advisor & Medical Physics Expert, Radiation Protection Officers, Clerical Administration and Radiology 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<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:**

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

<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.

**This inspection was carried out during the following times:**

Date	Times of Inspection	Inspector	Role
Tuesday 25 October 2022	09:30hrs to 15:30hrs	Lee O'Hora	Lead
Tuesday 25 October 2022	09:30hrs to 15:30hrs	Noelle Neville	Support

## Governance and management arrangements for medical exposures

On this inspection, inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures by the Bon Secours Health System operating at the Bon Secours Hospital Galway. As part of this inspection, inspectors reviewed documentation and visited the interventional cardiology suite, the computed tomography (CT) department and the general radiography department and spoke with staff and management. Overall responsibility for the radiation protection of service users lay with the Bon Secours Health System which operated a wider hospital group. Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. The Bon Secours Hospital Galway incorporated a radiation safety committee (RSC) into the governance system which reported directly to the hospital Chief Operations Officer (CEO) via the hospital Health and Safety Committee and Quality and Patient Safety Committee respectively. The hospital CEO reported directly to the hospital group CEO and the Board. Inspectors were satisfied that all committees and communication pathways provided an effective mechanism to ensure appropriate oversight of medical radiological procedures at this installation.

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

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

Overall, inspectors were satisfied that a clear and effective allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at the Bon Secours Hospital Galway.

## Regulation 4: Referrers

Following review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that the

Bon Secours Hospital Galway only accepted referrals from appropriately recognised referrers. In line with the regulations, radiographers were also considered referrers in this facility and the specific circumstances in which radiographers could act as referrers were clearly outlined in local policies and articulated to inspectors by staff.

Judgment: Compliant

### Regulation 5: Practitioners

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

Judgment: Compliant

### Regulation 6: Undertaking

Documentation reviewed by the inspectors outlined a clear allocation of responsibility for the protection of service users by Bon Secours Health System operating at the Bon Secours Hospital Galway. The Bon Secours Hospital Galway utilised a Radiation Protection Unit (RPU) and a RSC. The RSC reported to the hospital's Health and Safety committee who, in turn, reported to the Quality and Patient Safety Committee and the CEO. The CEO reported directly to the Bon Secours Health System Board and Bon Secours Health System CEO.

Inspectors were also informed that the Bon Secours Hospital Galway employed alternate communication platforms and pathways providing further assurances that any radiation safety issues could be appropriately discussed and communicated as necessary, examples of these were monthly department manager meetings, senior management team meetings and daily heads of department huddles.

The Bon Secours Health System also employed an external Radiology Forum which allowed discussion of radiation safety related issues on a corporate level, and inspectors were told that this forum enhanced the undertaking's commitment to continuous improvement across all facilities.

Terms of reference and minutes from the last three RSC meetings as well as minutes from Health and Safety Committee meetings were provided to inspectors. From reviewing the documents associated with these committees, speaking with staff and visiting clinical areas, inspectors were satisfied that a clear and effective allocation of responsibility for the protection of service users ensured the safe

conduct of medical exposures at the Bon Secours Hospital Galway.

Judgment: Compliant

### Regulation 10: Responsibilities

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that Bon Secours Health System ensured that all medical exposures took place under the clinical responsibility of a practitioner at the Bon Secours Hospital Galway.

Inspectors were assured that the optimisation process involved the practitioner and the medical physics expert (MPE) in all aspects of optimisation as highlighted in the documents *Policy on the Optimisation of Medical Exposure* and *Radiation Safety Procedures*.

Similarly, inspectors were satisfied that the justification process for individual medical exposures involved the practitioner and the referrer at the Bon Secours Hospital Galway following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to inspectors and the details were available in documents and a service level agreements (SLA) reviewed as part of this inspection. In addition, inspectors were informed that Bon Secours Hospital Galway was currently invested in upskilling a staff member to enhance MPE resources and on-site presence in the future. While inspectors were currently assured that the undertaking was satisfying the requirements of Regulation 19, this proactive measure was seen as a positive commitment to improving MPE continuity of expertise in the future.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors

were satisfied that the Bon Secours Health System had arrangements in place to ensure the involvement and contribution of MPEs at the Bon Secours Hospital Galway was in line with the requirements of Regulation 20.

Judgment: Compliant

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

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

Judgment: Compliant

### Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by the Bon Secours Hospital Galway ensured the safe and effective delivery of medical exposures.

Following review of a sample of referrals across a range of modalities including general radiography, CT, interventional cardiology, DXA scanning and mammography inspectors were assured that the Bon Secours Hospital Galway had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Bespoke service user procedure risk benefit information was available throughout the radiology department in both poster and pamphlet format on the day of inspection.

Inspectors were satisfied that diagnostic reference levels (DRLs) were established, used and reviewed. Inspectors noted that local facility DRL comparison in the general radiography department initiated a larger dose review which resulted in equipment upgrade and associated service user dose reductions. This use of local DRL review to closely monitor, and in certain cases, optimise service user radiation doses was seen as a positive use of regulatory required reviews to optimise service user outcomes.

Inspectors reviewed examples of a range of clinical audits used to monitor and improve compliance with regulatory requirements including pregnancy protocol compliance, justification and patient dose audits. Radiation safety audit results and learning outcomes were clearly displayed in the clinical area on the day of



inspection.

One area noted for improvement on inspection was that information relating to patient exposure did not consistently form part of the medical radiological procedure report at the time of inspection. However, inspectors were satisfied that this non-compliance was being addressed and the undertaking was about to implement a solution to ensure regulatory compliance in the future. Inspectors were also satisfied that the Bons Secours Hospital Galway kept all radiology equipment under strict surveillance regarding radiation protection.

Inspectors reviewed extensive documentation and records of accidental and unintended exposures and significant events and near misses. The Bon Secours Hospital Galway demonstrated a comprehensive approach to the investigation and mitigation of risk from such events which was seen as a positive commitment to continuous improvement by the Bon Secours Hospital Galway.

Overall, inspectors were assured that the Bons Secours Health System had comprehensive systems in place to support the safe delivery of medical exposures at the Bon Secours Hospital Galway.

## Regulation 8: Justification of medical exposures

Inspectors spoke to staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded.

In line with Regulation 8, all referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff spoken with on the day consistently informed inspectors that previous diagnostic information was routinely sought to avoid unnecessary exposure. Inspectors were also informed that as a result of recent analysis and investigation of reportable and non-reportable incidents the Bon Secours Hospital Galway had developed a system which automatically informs referrers if a service user had the same scan or X-ray in the previous three months. This was seen as a positive radiation safety initiative reducing the possibility of duplicate referrals.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of these posters were also available to service users throughout the radiology department.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

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

Inspectors were provided with evidence that an extensive general radiography dose review was undertaken after DRL comparison for two different X-ray rooms. This review highlighted the need to consider the upgrade existing radiographic equipment which had the potential to reduce service user radiation dose. At the time of the inspection the equipment upgrades had been agreed by hospital management and had occurred recently and inspectors were informed that initial dose reviews indicated a significant patient dose reduction. This was seen a positive use of information gained through DRL review to reduce patient dose, optimise the service provided and enhance service user outcomes.

Judgment: Compliant

### Regulation 13: Procedures

Written protocols for every type of standard radiological procedure carried out at the Bon Secours Hospital Galway were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff spoken to in the clinical areas clearly articulated how these protocols were made available to them.

Inspectors spoke with staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. Inspectors observed and were informed by staff and management that information relating to patient exposure did not form part of the report for medical imaging procedures. However, hospital staff spoken with on the day informed inspectors that this non-compliance with the regulations had been addressed and that the undertaking was finalising the implementation of a solution developed by the radiology information system supplier.

Inspectors reviewed a number of examples of radiation safety related clinical audits completed by the Bon Secours Hospital Galway. These included audits of chest and horizontal beam lateral hip X-ray techniques, justification in advance audits, catheterisation laboratory referral audit and pregnancy protocol compliance audits. In the clinical area, results and learning from audits were available to all staff. Audit was a standing agenda point of the RSC and evidence that relevant issues relating

to audit were discussed by this committee was reviewed by inspectors.

Judgment: Substantially Compliant

### Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the undertaking had implemented and maintained an extensive quality assurance program. Inspectors were provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

### Regulation 15: Special practices

The Bon Secours Hospital Galway had mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the patient. For example, inspectors reviewed policies and procedures utilised in the interventional cardiology department to identify potential high skin doses in patients undergoing cardiac interventional procedures. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses. Staff spoken with in the interventional cardiology department clearly articulated the practical application of these policies in clinical practice.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that the Bon Secours Hospital Galway had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with local policies and procedures. Multilingual posters were observed throughout the department with bespoke information relating to the patient dose for a range of diagnostic procedures. Inspectors were assured that measures had been

taken to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

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

Extensive records of non-reportable and near miss accidental and unintended exposures were supplied to the inspectors. Inspectors were assured that the Bon Secours Hospital Galway had a comprehensive approach to the analysis and subsequent implementation of corrective actions to reduce the possibility of reoccurrence of incidents. For example, trending data and incident investigation reports supplied to inspectors detailed how the Bon Secours Hospital Galway had implemented a range of corrective actions after a comprehensive and multidisciplinary analysis of a number of events where duplicate referrals for imaging procedures were received. Corrective actions included a pop-up system incorporated into the radiology information system used by referrers within the hospital, focused training for resident medical officers (RMO) specifically addressing this subject and a booklet entitled *Making Radiology Referrals* designed and distributed by the Bon Secours Health System.

Inspectors were also informed that the Bon Secours Hospital Galway had employed an RMO manager who facilitated direct access to all RMOs for such training requirements as necessary and weekly RMO training schedules were being used to address any short term training requirements in relation to radiation safety. The multidisciplinary approach and range of corrective actions used by the Bon Secours Health System for the incidents reviewed over the course of the inspection was seen as a positive approach to the recording, analysis and subsequent minimisation of the probability and magnitude of accidental and unintended exposures and significant events. Inspectors were assured that the Bon Secours Hospital Galway utilised comprehensive processes in relation to accidental and unintended exposures and significant events as an effective part of their commitment to continuous improvement as articulated to inspectors over the course of the inspection.

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
<b>Governance and management arrangements for medical exposures</b>	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	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	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Bon Secours Hospital Galway OSV-0007387

Inspection ID: MON-0035041

Date of inspection: 25/10/2022

## 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 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: The Bon Secours Hospital Group has procured a dose management system. The procured dose management system, once implemented, will enable automated transmission of patient dose to radiological procedure reports.</p> <p>The robustness and quality of the patient dose data system, once implemented, will be subjected to a Quality Assurance (QA) program, the QA program will be governed by the hospitals Radiation Safety Committee (RSC) with oversight from the Medical Physics Expert (MPE). Comparison of patient dose stored on the modality versus patient dose available on the report will be a central component of the QA program.</p> <p>The Bon Secours Hospital Group is currently introducing this program at group level, where a project team of team members with relevant experience will ensure its timely implementation. The implementation project team will be comprised of representatives from local hospital sites, MPE's, RPO's and IT with oversight governance from the RSM's and Chair of the Radiology Forum.</p> <p>A purchase order for the dose management system has been issued and project team identified. The dose management solution selected automatically monitors, evaluates, and reports the radiation dose that patients receive for multi-facility and multi-modality environments. The manufactures of this system adhere to IOS 13485 and ISO 27001 standards.</p> <p>The RIS vendors have indicated an implementation date for February 2023. Allowing for unanticipated delays in integration, we have set the completion date to June 30th, 2023.</p>	





## 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 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	30/06/2023