



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 Killarney Outreach Clinic
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	The Courtyard, Lewis Road, Killarney, Kerry
Type of inspection:	Announced
Date of inspection:	29 May 2024
Medical Radiological Installation Service ID:	OSV-0008577
Fieldwork ID:	MON-0042284

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

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 outreach clinics in Cavan and Killarney. At the Killarney Outreach Clinic, the multidisciplinary radiology team deliver an outpatient service for DEXA and Ultrasound scans. A DEXA scan will give us an overview of your overall bone health. This scan will enable us to assess the risk for developing osteopenia and osteoporosis (bone loss) and fractures (bone breaks). The clinic is located in the heart of Killarney at ground level, it is typically opened five days a week from 8am-4pm.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ 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 doing, we describe the overall effectiveness of an undertaking in ensuring the quality and safe conduct of medical exposures. It examines how the undertaking provides the technical systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential

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.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 29 May 2024	09:55hrs to 11:47hrs	Kay Sugrue	Lead

Summary of findings

An inspection of Bon Secours Killarney Outreach Clinic was undertaken by an inspector on 29 May 2024, the aim of which, was to assess compliance with the regulations. As part of this inspection, governance and management arrangements that outlined the responsibility for overseeing regulatory compliance were reviewed. In addition, evidence was also gathered regarding the processes implemented by the undertaking for the safe delivery of medical exposures in the dual-energy X-ray absorptiometry (DXA) service.

From speaking with staff involved in the provision of DXA scans and a review of available documentation, the inspector was satisfied that the allocation of responsibility for the conduct of medical exposures in this service met the requirements of the regulations. This meant that only practitioners recognised under Regulation 5 took clinical responsibility for individual medical exposures and DXA scans were only carried out on the basis of a referral from a recognised referrer. The undertaking had also ensured that a medical physicist was engaged to provide specialist advice on matters relating to radiation protection at this facility. In documentation viewed, the continuity of the medical physicist advice was assured and roles and responsibilities assigned to the medical physics expert (MPE) met the requirements of the regulations, with appropriate contribution and involvement evident.

The inspector found that there was an effective system in place to record that justification in advance of each examination had taken place. Similarly, the pregnancy status for relevant service users was recorded following an enquiry made by the practitioner who carried out the procedure.

In relation to Regulation 14, documentation viewed demonstrated that annual quality assurance (QA) was performed by the MPE as part of the QA programme to ensure the medical radiological equipment was kept under strict surveillance and fit for continued clinical use. The inspector noted that facility diagnostic reference levels (DRLs) were established and were below national DRLs. Protocols for standard procedures were available and staff were up-to date with relevant training regarding the radiation protection of service users.

The inspector was satisfied that staff were aware of the procedure to be followed to notify HIQA of a significant event should one occur, and how to report and record any radiation incident or potential incident, thereby, demonstrating compliance with Regulation 17.

Overall, the inspector found from the evidence gathered that the undertaking was compliant with the regulations assessed during this inspection. In addition, staff working in this facility were focused on the radiation protection of service users and the safe delivery of DXA scans performed there.

Regulation 4: Referrers

The inspector reviewed referrals for DXA procedures and found that referrals were from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

From the review of records and documentation, and speaking with staff, the inspector was satisfied that only individuals recognised under this regulation took clinical responsibility for each DXA scan carried out at this facility.

Judgment: Compliant

Regulation 6: Undertaking

The Bon Secours Health System is the undertaking for Bon Secours Killarney Outreach Clinic. From speaking with staff and a review of documentation, it was clear that the responsibility for the radiation protection of service users at this facility rested with the chief executive officer (CEO) of the Bon Secours Hospital Tralee, who was also the designated manager for the inspected facility.

The Bon Secours Hospital Tralee Radiation Safety Committee (RSC) was the forum with responsibility for overseeing the implementation of the radiation safety policy and ensuring compliance with the regulations. This committee met twice a year, was multidisciplinary and attended by the CEO. Minutes from meetings held in 2022 and 2023 demonstrated that there was comprehensive oversight of radiation protection matters by this committee. A diagram depicting the organisational structures in place showed there was an established line of communication up to the undertaking at CEO level of the Bon Secours Health System. These reporting arrangements were confirmed by staff in discussions with the inspector.

In relation to the allocation of responsibilities, the evidence gathered satisfied the inspector that only appropriate individuals recognised under the regulations took clinical responsibility and carried out the practical aspects for individual medical exposures. The undertaking had ensured that a medical physicist was engaged to provide specialist advice on matters relating to radiation physics for medical radiological practices at this facility.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector reviewed the document named *Policy on Referral and Justification of Medical Exposure* and found that the procedure outlined for referring and justifying DXA scans aligned with day-to-day practices. Records viewed showed that justification in advance was recorded by a practitioner on the radiological information system thereby providing evidence of compliance with this regulation.

Risks and benefits associated with medical exposure to ionising radiation were presented in poster formats and accessible to service users attending for DXA scans in this facility.

Judgment: Compliant

Regulation 10: Responsibilities

For the DXA procedures carried out at Bon Secours Killarney Clinic, the radiographer was the practitioner with overall clinical responsibility for each medical exposure. In addition, clinical evaluation of the outcome of each procedure was completed by a radiologist in line with the regulations. The evidence viewed in a sample of records, and verified in discussions with staff, demonstrated that the referrer and a practitioner were involved in the justification of all DXA procedures carried out at this facility.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector saw evidence to demonstrate that facility DRLs were established in November 2023 with the next review due to take place in November 2024. Facility DRLs were found to be below national DRLs for common procedures performed in the DXA service and were accessible to staff in the clinical area visited.

Judgment: Compliant

Regulation 13: Procedures

Protocols for standard DXA procedures were found to be in place and available to staff performing DXA scans.

Information relating to the dose associated with each procedure was automatically populated on the scan and also provided by a radiologist in the report of the outcome of the examination.

A programme of clinical audit was in place. Reports from audits conducted in 2024 and viewed by the inspector included justification audits, DXA referrals, compliance audits and pregnancy status audits. The reports demonstrated that there was a high level of compliance achieved in these audits. The inspector was informed that the staff at this facility had commenced work to ensure that audits were carried out in line with the National Procedures published by HIQA in November 2023 and had already incorporated audit report templates contained in the document into their audit process. The inspector was informed that these audit report templates were user friendly for all staff undertaking audits at this facility.

Judgment: Compliant

Regulation 14: Equipment

The inspector found that the undertaking had ensured that a QA programme was in place and records verified that annual QA and acceptance testing by an MPE had been completed. Staff who spoke with the inspector had attended regular training provided by the application specialist for the equipment and also ensured that quality control checks were carried out in line with the frequencies defined in local procedures. From the evidence gathered through speaking with staff and a review of documentation, the inspector concluded that medical radiological equipment was kept under strict surveillance as required under this regulation.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From a sample of records reviewed, the inspector found that an enquiry to determine the pregnancy status of relevant service users undergoing medical exposure to ionising radiation was made by a practitioner and this record was uploaded onto the radiology information system. The evidence viewed demonstrated compliance with the requirements of this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The document named *Guidelines for Reporting Radiation Incidents Involving Patients Radiology Department* was reviewed by the inspector. This guideline described the processes for reporting patient radiation safety incidents and potential incidents within the service and significant events to HIQA. Staff who spoke with the inspector were familiar with the processes outlined in this guideline and informed the inspector that there had been no incident or potential incident reported since the service opened in the summer of 2023. While meeting regulatory requirements, the inspector noted that low doses associated with DXA imaging were unlikely to meet reporting thresholds set by HIQA, however, there was potential to increase the reporting of potential incidents when considered in the context of the activity within the service.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector reviewed documented arrangements to ensure the continuity of medical physics expertise at Bon Secours Killarney Outreach Clinic and was satisfied that a medical physicist was engaged for the service with appropriate contribution and input as required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the documentation that certified that the medical physicist at Bon Secours Killarney Outreach was a medical physicist with expert knowledge on matters relating to radiation physics and was available to provide specialist advice, as appropriate, as required by Regulation 20(1).

Evidence gathered from documentation reviewed and speaking with staff and the medical physicist, demonstrated MPE involvement across a range of responsibilities outlined in Regulation 20(2). For example, the medical physicist attended RSC meetings held twice a year and was responsible for dosimetry, and had reviewed facility DRLs in 2023 and approved these for use. Records showed that the MPE completed quality assurance testing of medical radiological equipment on 2 March 2024 and the inspector was informed that the MPE had provided advice regarding

the procurement and replacement of the DXA scanner installed and commissioned in May 2023.

The medical physicist engaged for this facility had the dual role of radiation protection adviser (RPA) and MPE therefore met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation reviewed and discussion with staff, the inspector was satisfied that the level of involvement of the medical physicist at Bon Secours Killarney Outreach Clinic was proportionate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	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