



**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:	Beacon Limerick
Undertaking Name:	Beacon Hospital Sandyford Limited
Address of Ionising Radiation Installation:	2-3 Barrington Street, Limerick
Type of inspection:	Announced
Date of inspection:	23 August 2023
Medical Radiological Installation Service ID:	OSV-0008253
Fieldwork ID:	MON-0039917

About the medical radiological installation:

Beacon Hospital opened the outpatient clinic in Limerick city in July 2022. Diagnostic imaging using ionising radiation has been provided since then. The clinic is fully digital with the very latest technology. The current practitioners in Beacon Limerick are registered Consultant Radiologists and CORU registered radiographers. Medical Physics Experts are registered with the ICPM and the RPA is listed on the EPA register. Diagnostic referrals come from both GPs and Consultant Clinicians. Beacon Hospital is registered/ licensed with the EPA for multiple practices and the licence extends to include Beacon Limerick. Beacon Limerick radiology specialises in X-ray (fixed), bone densitometry (DEXA) and computed tomography (CT). Beacon Limerick performed 2660 scans, involving ionising radiation, in its first 12 months of operation. Beacon Hospital has Joint Commission International Accreditation since 2007.

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 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 and management 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 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
Wednesday 23 August 2023	09:30hrs to 13:10hrs	Noelle Neville	Lead
Wednesday 23 August 2023	09:30hrs to 13:10hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

An inspection was carried out at Beacon Limerick on 23 August 2023 by inspectors to assess the facility's compliance with the regulations. As part of this inspection, inspectors visited the computed tomography (CT), general X-ray and dual-energy X-ray absorptiometry (DXA) clinical areas, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking at Beacon Limerick demonstrated compliance with Regulations 4, 5, 6, 8, 10, 11, 14, 17, 19, 20 and 21 and substantial compliance with Regulation 13.

The undertaking at Beacon Limerick had a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures. In addition, inspectors noted involvement in, and oversight of, radiation protection by the facility's medical physics expert (MPE) across a range of responsibilities.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Beacon Limerick and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Beacon Limerick.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms (organisational charts that show the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Beacon Limerick.

Beacon Hospital Sandyford Limited was the undertaking for Beacon Limerick and the facility had a radiation safety committee (RSC). Inspectors reviewed the terms of reference for this committee, which were issued in April 2023, and noted that it had a multi-disciplinary membership including the director of the facility who was also the designated manager, a consultant radiologist and a medical physics expert (MPE). The committee was incorporated into local governance structures, reporting to the facility's quality improvement committee and accountable to the chief executive officer.

Overall, inspectors were satisfied that the undertaking at Beacon Limerick had clear and effective governance and management structures in place to ensure the radiation protection of service users.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological procedures were only carried out at Beacon Limerick by individuals entitled to act as practitioners in the regulations. Practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from discussions with staff and a review of documentation that the undertaking at Beacon Limerick had arrangements in place to ensure access

to and continuity of MPE services as required by Regulation 19.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Beacon Limerick and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors noted that the MPE was involved across a range of responsibilities outlined in Regulation 20(2). The MPE was responsible for dosimetry and gave advice on medical radiological equipment. Records reviewed by inspectors demonstrated that the MPE had contributed to quality assurance and acceptance testing of medical radiological equipment and was involved in optimisation including review and sign-off of facility diagnostic reference levels (DRLs). The MPE also provided advice and dose calculations for radiation incidents and attended RSC meetings.

In addition, the MPE had been assigned the role of radiation protection advisor (RPA) at the facility, therefore satisfying 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 the MPE and staff, inspectors were satisfied that the level of MPE involvement at Beacon Limerick was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the CT, general X-ray and DXA clinical areas of the Beacon Limerick, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the facility. While the majority of regulations reviewed were compliant, including Regulations 8, 11, 14, 16 and 17, inspectors noted that there was further work required to bring Regulation 13 into

compliance.

In relation to Regulation 13(2), inspectors found that while information relating to the patient exposure formed part of the report for DXA, it was not available for all general X-ray and CT reports reviewed. The undertaking, Beacon Hospital Sandyford Limited, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Overall, noting that improvement was required to bring Regulation 13 into compliance, inspectors were satisfied that the Beacon Limerick had processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals reviewed were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of posters throughout the facility and information contained on appointment letters that were sent to service users in advance of their medical exposure.

A document titled *Justification of Medical Exposures within Radiology*, the most recent version of which was issued in January 2022, was in place at the facility. This document provided referrers with information to ensure that medical exposures are justified and requested in an appropriate manner. In addition, the radiation safety procedures in place at the facility outlined the roles and responsibilities in relation to justifying a medical exposure including the process of justification in advance and the recording of same. Inspectors reviewed a sample of records in DXA, general X-ray and CT and noted that justification in advance as required by Regulation 8(8) was recorded as required by Regulation 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The undertaking had a document titled *Radiation Safety Procedures - Limerick*, the most recent version of which was issued in July 2023. This document set out the process for establishing and reviewing diagnostic reference levels (DRLs) at the facility. Inspectors noted that DRLs had been established, regularly reviewed and used at Beacon Limerick and were compared to national DRLs. DRL charts were displayed in each clinical area and staff spoken with demonstrated an awareness of

how to use DRLs when carrying out medical exposures to ionising radiation.

Judgment: Compliant

Regulation 13: Procedures

Inspectors noted that written protocols were available for each standard radiological procedure provided at Beacon Limerick as required by Regulation 13(1). Referral guidelines which were available to staff and referrers were adopted by the facility as required by Regulation 13(3). In addition, a range of clinical audit had been completed at the facility including audit of justification, pregnancy status and referrals. Inspectors noted that the facility viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service users.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors reviewed a sample of reports for DXA, general X-ray and CT medical radiological exposures and found that while information relating to the patient exposure formed part of the report for DXA, it was not available for all general X-ray or CT reports reviewed. The undertaking, Beacon Hospital Sandyford Limited, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Beacon Limerick as required by Regulation 14(1). A document titled *Physics QA Programme for Radiology Equipment - Limerick*, which was issued in April 2023, was in place at the facility. This document outlined staff responsibilities in relation to quality assurance and the quality assurance programmes in place at the facility. The radiation safety procedures in place at the facility also outlined the quality assurance programmes in place for each modality and the frequency of testing required. Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). Inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use

for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The undertaking at Beacon Limerick had a document titled *Radiation Safety Procedures - Limerick*, the most recent version of which was issued in July 2023. This document included information on the pregnancy procedures in place in the facility including the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents, that the undertaking at Beacon Limerick had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures. The incident management process at the facility was outlined in a document titled *Procedure for the Reporting of Radiation Incidents*, the most recent version of which was issued in November 2021, and also included information on the requirement to notify HIQA of certain reportable incidents. Inspectors noted that one incident had been reported to HIQA since the commencement of the regulations in 2019 together with the results of the investigation into the incident and associated corrective measures.

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	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Beacon Limerick OSV-0008253

Inspection ID: MON-0039917

Date of inspection: 23/08/2023

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
Outline how you are going to come into compliance with Regulation 13: Procedures: The Lead Consultant Radiologist in Limerick has communicated the requirement to the Consultant Radiologist group of including the dose in reports. The monthly audit programme now includes compliance with this regulation and will form part of the biannual Radiology Radiation Protection Limerick report to the Quality Improvement Committee.	

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	01/09/2023