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:	Beaumont Hospital
Undertaking Name:	Beaumont Hospital
Address of Ionising Radiation Installation:	PO Box 1297, Beaumont Road, Dublin 9
Type of inspection:	Announced
Date of inspection:	07 May 2025
Medical Radiological Installation Service ID:	OSV-0007305
Fieldwork ID:	MON-0044725

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

Beaumont Hospital is a large academic teaching hospital situated north of Dublin City centre with 820 beds. Beaumont Hospital is a voluntary hospital and part of the North East Hospital group. The hospital provides emergency and acute care services across 54 medical specialties to a local community of some 290,000 people. In addition, we are a Designated Cancer Centre and the Regional Treatment Centre for Ear, Nose and Throat, and Gastroenterology. We are also the National Referral Centre for Neurosurgery and Neurology, Renal Transplantation, and Cochlear Implantation. We are the principal teaching hospital for the Royal College of Surgeons in Ireland. We also enjoy close links with Dublin City University, especially in the area of nurse training, and with other academic institutions in respect of training and research. Diagnostic facilities in Beaumont Hospital's Radiology Department include: 3 MRI scanners, 3 CT scanners, 2 SPECT/CT gamma cameras, 1 fluoroscopy room, 3 interventional radiology suites, 3 mammography units housed in a dedicated breast care building and 5 X-ray rooms. Imaging services are provided during core hours, Monday to Friday, and unscheduled care is also provided 24 hours, seven days a week (24/7). 225,043 radiology exams were performed in Beaumont in 2024 (including non-ionising exams).

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 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] 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.

1. Governance and management arrangements for medical exposures:

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 7 May 2025	09:00hrs to 14:00hrs	Lee O'Hora	Lead
Wednesday 7 May 2025	09:00hrs to 14:00hrs	Noelle Neville	Support
Wednesday 7 May 2025	09:00hrs to 14:00hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

As part of this inspection of the radiology services provided at Beaumont Hospital, inspectors reviewed documentation and visited the cardiology interventional suite, the nuclear medicine department and the general radiography department and spoke with staff and management. Inspectors also reviewed imaging records from general radiography, computed tomography (CT), interventional radiology, interventional cardiology, interventional neurology, departmental fluoroscopy, theatre fluoroscopy, theatre interventional vascular procedures and nuclear medicine.

Overall, responsibility for the radiation protection of service users lay with Beaumont Hospital which operated in a wider hospital group but was an independent undertaking within this group. Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. A radiation safety committee (RSC) and a radiation protection unit (RPU) were incorporated into the governance system.

Inspectors and management discussed the compliance plan and associated actions following a previous inspection and the inspectors were satisfied that improvements had been implemented by the undertaking in line with the compliance plan submitted. However, some work was still required by the undertaking in relation to ensuring that information relating to patient exposure consistently formed part of the report.

Following a review of documents and records, and after speaking with staff, the 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 and management 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 evidence reviewed, inspectors were assured that the level of involvement of MPEs was proportionate to the level of radiological risk at the hospital.

Inspectors noted that there was still some work required by the undertaking to ensure a clear allocation of responsibility in relation to the timely communication of changes of relevant staff to HIQA and update of certain documents to reflect day-to-day practice. Overall, despite some areas for improvement and document update, inspectors found effective governance, leadership and management arrangements

with a good allocation of responsibility for the protection of service users undergoing medical exposures at Beaumont Hospital.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that Beaumont Hospital only accepted referrals from appropriately recognised referrers.

The specific circumstances and modalities where referrals were accepted from radiographers and advanced nurse practitioners were detailed in radiation safety documentation reviewed and were well understood by all staff who spoke with inspectors on the day of inspection.

The undertaking required that referrers within the hospital complete in-house developed online radiation safety training before they are granted referral rights at Beaumont Hospital. Inspectors were informed that this initiative increased the quality of referrals received and reduced the likelihood of unnecessary referrals for ionising radiation procedures. This was seen a positive initiative promoting the radiation protection of service users at Beaumont Hospital.

Judgment: Compliant

Regulation 5: Practitioners

Following a 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 Beaumont Hospital had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Overall responsibility for the radiation protection of service users lay with Beaumont Hospital which operated in a wider hospital group but was an independent undertaking within this group. The Hospital Chief Executive Officer (CEO) was identified to inspectors as the individual with overall responsibility for the radiation protection of service users. Inspectors were informed that the CEO communicated directly with the Hospital Board. Staff at Beaumont Hospital used a RSC which was

appointed by the undertaking as the main platform to monitor and oversee the radiation protection of service users in compliance with the relevant regulatory requirements. The CEO or their nominee attended all RSC meetings but also had the facility to communicate with the RSC chair through fortnightly Executive Management Group (EMG) meetings and direct communication pathways as required.

An RPU, which met monthly, was also integrated into the radiation protection structures of the hospital. The RPU was composed of the Radiation Protection Advisor (RPA), MPEs and medical physicists, the Radiation Safety Officer (RSO), and other expert individuals who could be co-opted as required. Radiation safety documentation detailed that the RPU ensured that the action items from the RSC meetings were closed out and that day-to-day radiation safety issues were addressed. Inspectors were informed and observed through reviewing meeting minutes that the RPU reported to the RSC.

Inspectors were assured that the undertaking had systems and processes in place to ensure that all new types of practice involving medical exposures would undergo the appropriate consideration internally and externally via HIQA as required before general adoption by Beaumont Hospital. Beaumont Hospital had also kept open lines of communication with HIQA in relation to generic justification of procedures which demonstrated an awareness of the responsibilities of both the undertaking and the regulator in relation to Regulation 7.

Inspectors noted many improvements in compliance since the last inspection in relation to the presence of staff from the hospital risk management department at the RSC, the allocation of responsibility for the reporting of accidental and unintended medical exposures and significant events and the hospital's approach to document version control. However, inspectors were not assured that the undertaking had ensured full compliance when it came to the consistent inclusion of information relating to patient exposure on the report as discussed in Regulation 13. Also, some improvement in the formal documentation of the allocation of responsibility for the methods used to ask and record pregnancy status for a small subset of patients undergoing surgical procedures was required to ensure full compliance with Regulation 6.

Finally, at the time of inspection the undertaking had failed to inform HIQA of a change to the undertaking representative and documentation relating to the change of a designated manager had only been submitted after the announcement of this inspection. However, notwithstanding the areas noted for the attention of the undertaking, the inspectors were satisfied that the undertaking had implemented measures to ensure the protection of service users at Beaumont Hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspectors reviewed radiation safety procedure documentation, a sample of referrals for medical radiological procedures and spoke with staff and were satisfied that all medical exposures at Beaumont Hospital took place under the clinical responsibility of a practitioner. The inspectors were also assured that the optimisation process involved the practitioner and the MPE and that the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise were described to the inspectors by staff and management. All evidence supplied satisfied the inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at Beaumont Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by the inspectors and was up to date. From reviewing the documentation and associated records and speaking with staff, the inspectors were satisfied that the undertaking had arrangements in place to ensure the involvement and contribution of Beaumont Hospital's MPEs was in line with the requirements of Regulation 20. Namely; the inspectors were assured that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of QA programmes including acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. The inspectors also noted the extensive contributions of medical physics staff in the development and provision of radiation safety training through Beaumont Hospital's locally developed two-tier online radiation safety training system.

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 Beaumont Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this hospital and noted many areas of good practice in relation to this.

Following a review of a sample of referrals for a number of areas, the inspectors were satisfied that Beaumont Hospital had reliable and consistently applied 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.

The inspectors were satisfied that DRLs were established, used and reviewed. Records of acceptance and performance testing for radiological equipment at the hospital satisfied the inspectors that the undertaking had implemented and maintained an appropriate QA programme. Inspectors also noted the use of the bespoke digital information sharing platform which made all relevant equipment surveillance and QA readily available and accessible in a transparent manner for the relevant staff.

The undertaking had employed robust multidisciplinary incident reporting and clinical audit strategies which were consistently articulated by staff who spoke with inspectors. Beaumont Hospital had also ensured that special attention was given in the areas conducting high radiation dose procedures namely interventional suites across the hospital. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may experience tissue reactions following interventional radiology procedures.

The inspectors were assured that this hospital had appropriate systems in place to support the safe delivery of medical exposures and staff demonstrated a commitment to the continual improvement of X-ray services provided by Beaumont Hospital.

Regulation 8: Justification of medical exposures

The inspectors spoke with staff and reviewed a sample of referrals for a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that

processes were in place to ensure that 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 the inspectors 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 who spoke with inspectors consistently articulated that previous diagnostic information was routinely sought to avoid unnecessary exposure. Additional checklists, observed in the cardiology interventional suite, formally ensured that this process was considered and recorded for all interventional cardiology procedures. This checklist also had a section relating to justification providing a further opportunity for practitioners to ensure justification of these potentially high dose procedures before imaging.

Beaumont Hospital had a robust system in place to ensure that all individual medical exposures were justified in advance. In the nuclear medicine department and cardiovascular lab the record of justification was a multilevel process where practitioner justification was considered and recorded at different points along the patient pathway. This was seen as a positive initiative helping to reduce the possibility of unjustified procedures taking place.

The inspector observed multiple posters which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRL documentation, the inspectors were satisfied that DRLs had been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this hospital. Staff consistently articulated knowledge of departmental DRLs and DRL information was displayed in each area visited on the day.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard radiological procedure were available to inspectors on the day of inspection. Inspectors reviewed a sample of these using Beaumont Hospital's document management system. Staff in the clinical areas

clearly articulated how these protocols were made available to them and were able to access them on request.

Inspectors reviewed information relating to clinical audit via documents supplied, by reviewing Beaumont Hospital's intranet and digital information sharing platform and by speaking with staff. Inspectors were assured that Beaumont Hospital's approach to clinical audit was in accordance with national procedures established by HIQA. The Hospital had a well established approach to clinical audit monitored by the Clinical Audit department, this was a central resource which supported and guided clinical audit and associated recommendations in relation to radiological procedures involving medical exposure to ionising radiation. Clinical audits undertaken by the radiology directorate were also shared with radiology staff via clinical audit days held twice a year by the clinical audit department. Inspectors were also informed that staff involved in these audits could share the findings via weekly radiology meetings and informally as required. Inspectors observed a positive culture of clinical audit aided by an inter-departmental collegial approach to the subject at Beaumont Hospital.

Inspectors were satisfied that information relating to patient exposure was routinely transferred to the report for all nuclear medicine and interventional cardiovascular procedures. Since the last inspection, the undertaking had taken steps to ensure that information relating to patient exposure also formed part of the report of medical radiological procedures for all other clinical areas including general radiography, CT and fluoroscopy. However, while the inspectors noted the improvements in relation to the provision of information relating to patient exposure, not all reports viewed on the day included this regulatory required information. Staff informed inspectors that this had been monitored via an audit and the most recent figures suggested that this information was present in 85-90% of reports. Staff also indicated that the reasons for non compliance had recently been identified and would be addressed without delay.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspectors were assured that all medical radiological equipment was kept under strict surveillance by the undertaking at Beaumont Hospital. This included the implementation of a comprehensive QA and performance testing programme. At the time of inspection, the inspectors were assured that all QA was up to date.

All information relating to equipment including policies and procedures, quality assurance records and manufacturer preventative maintenance records were easily accessible through a digital information sharing platform. Inspectors noted that the readily available, comprehensive equipment information accessed through Beaumont Hospital's digital information sharing platform, not only facilitated the inspection

process but made the same information available to all relevant staff improving transparency on all issues related to radiological equipment surveillance.

Judgment: Compliant

Regulation 15: Special practices

The undertaking had mechanisms in place to ensure special attention was given to optimising medical exposures potentially involving high radiation doses to the patient. For example, all departments using interventional radiology (cardiology, neurology, radiology and vascular surgery) used a high dose alert system to prompt practitioners if a procedure was reaching a pre-defined radiation dose threshold. Once reached, these pre-defined radiation dose thresholds were used in conjunction with dose monitoring software to determine potential areas of high skin dose, and guide appropriate patient communication and follow up. Records of communication with patients who reached these radiation dose thresholds further demonstrated Beaumont Hospital's consistent approach to patient follow up and when relevant their ability to identify patients who may have experienced tissue reactions following interventional procedures.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied the inspectors that Beaumont Hospital had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner or a referrer and the answer was recorded. While meeting the requirements of Regulation 16 in this case, some work was required to clearly define the process and associated responsibilities in the associated documentation which is further discussed under Regulation 6.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility.

Evidence was available to show that incidents were discussed at the appropriate committee level within the facility and subsequently reported to the RSC, thus the undertaking had oversight of incidents in this facility. Inspectors were satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by Beaumont Hospital.

Inspectors observed records and were informed by staff how the incident investigation process in conjunction with the use of clinical audit helped to reduce similar incidents occurring. For example, the recommendations associated with an incident investigation in the Nuclear Medicine department suggested a formal and recorded cross-check and validation process before injection of radio-pharmaceuticals. The subsequent auditing of compliance with the newly implemented procedures provided the undertaking with the necessary assurances that radiation incident recommendations had been implemented consistently by staff and therefore gave assurances that the risk of similar occurrences had been reduced if not eliminated. A multidisciplinary approach had been taken to both the investigation of the incident and the subsequent audit of compliance with the new procedures. This example was seen as a practical and positive use of Beaumont Hospital's system of analysis of events involving or potentially involving accidental or unintended medical exposures in conjunction with a comprehensive corporate audit process to improve and monitor service user safety.

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
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially 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 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 Beaumont Hospital OSV-0007305

Inspection ID: MON-0044725

Date of inspection: 07/05/2025

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, as amended.

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 Procedure for Patients of Childbearing Age has been updated to document the existing method and allocation of responsibility for asking and recording the pregnancy status for a small subset of patients undergoing surgical procedures. This will be brought to the next Radiation Safety Committee (RSC) meeting (11/09/2025) for approval by the Chair of the RSC. A record of any changes to the undertaking representative(s) and/or designated manager(s) will be maintained on the RPU minutes. The RPU will be responsible for notifying HIQA of any such changes in a timely manner.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: As indicated in the inspection report and identified in the referenced audits, patient dose information is currently included on the majority of radiology reporting templates. To improve compliance further, the PACS team have reviewed all existing templates to ensure patient dose information is included on all activated templates. Systems and processes have also been updated to include a regular check of those templates in conjunction with the on-going quarterly audits. All new radiologists will have patient dose information added to their report templates as part of the onboarding process.	

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	11/09/2025
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Substantially Compliant	Yellow	12/06/2025

	radiological procedure.			