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:	30 May 2022
Medical Radiological Installation Service ID:	OSV-0007305
Fieldwork ID:	MON-0035043

About the medical radiological installation:

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 RCSI 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 have 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 magnetic resonance imaging (MRI) scanners, 4 computed tomography (CT) scanners, 2 single photon emission computed tomography (SPECT)/CT gamma cameras, 5 ultrasound rooms, 1 fluoroscopy room, 3 interventional radiology suites, 3 dedicated procedure rooms for ultrasound guided procedures, 3 mammography units housed in a dedicated breast care building and 6 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. In 2021 Beaumont Hospital performed 195,012 radiology 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 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

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

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Monday 30 May 2022	09:30hrs to 15:30hrs	Lee O'Hora	Lead
Monday 30 May 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 at Beaumont Hospital. As part of this inspection, inspectors reviewed documentation and visited the cardiology interventional suite, the neurology interventional suites, computed tomography (CT) and general radiography department and spoke with staff and management.

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. The RPU met more frequently and reported directly into the RSC, the RSC reported directly to the Hospital Board via the CEO who was represented on the RSC by a nominee. The RSC also reported to the hospital Board via the Facility Management and Safety Committee who reported into the Governance and Risk Committee establishing a dual reporting pathway for all radiation safety matters.

RSC terms of reference required the presence of the hospital risk manager or nominee, however, minutes provided to inspectors detailed that this stipulation was not satisfied for the last three RSC meetings. Beaumont Hospital should consider ensuring the presence of corporate risk management representation at this forum to further enhance their ability to effectively manage and oversee radiation protection as well as satisfy the terms of reference set out in the document '*BH RAD Terms of Reference Radiation Safety Committee*'. Also the allocation of responsibility for the reporting of accidental and unintended medical exposures and significant events to HIQA could be strengthened. Given the findings in relation to Regulation 17 of this report, allocating responsibility for this task to a single staff member was identified as an area with potential for improvement, and this was discussed with senior management on the day of inspection.

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 senior 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 documentation reviewed, inspectors were assured that the level of involvement of MPEs 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.

Inspectors reviewed digital platforms which delivered bespoke local training for referrers and practitioners as well as Beaumont Hospital's information sharing platform which made all relevant radiation safety information, policies, procedures and guidance readily available to all staff. Both resources were considered positive information and training resources, however, some documents reviewed lacked approval and review dates, document owners and reviewers. This was discussed with management as an area for improvement which would ensure all radiation safety documentation is up to date and subsequently reviewed by the appropriately allocated staff as necessary.

Overall, despite some areas for potential improvement and document update, 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 Beaumont Hospital.

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 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 the document '*BH RAD Procedure for Referrers of Medical Radiation Exposures*' and were well understood by all staff spoken with on the day of inspection.

The undertaking employed a Beaumont Online Resource for Interactive Study (BORIS) system to enhance the basic radiation safety training for referrers and practitioners. This system was used to deliver radiation safety training for all internal referrers and included a mandatory multiple choice question section which required a 90% pass rate for successful completion. Inspectors were informed that Beaumont Hospital required that all internal referrers complete this training before they were granted access to the hospital radiology information system (RIS) where referrals were generated.

Beaumont Hospital also employed a digital information sharing platform called Rad Central which provided professional registration details of all internal and external referrers to Beaumont Hospital. Inspectors reviewed this information and were informed that this acted as a resource for staff information and an up-to-date record of accepted referrers.

Judgment: Compliant

Regulation 5: Practitioners

Following review of the 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

Documentation reviewed by the inspectors outlined a clear allocation of responsibility for the protection of service users at Beaumont Hospital. The allocation of responsibility and associated communication pathways were clearly articulated to inspectors over the course of the inspection by staff and management. Beaumont Hospital used a RSC which met four times a year and a RPU which met 12 times a year to ensure effective oversight, management and communication of all issues relating to the radiation protection of service users. The CEO and undertaking representative was represented by a nominee at the RSC. The RSC reported to the Hospital Board via the CEO but also reported to the same Board via the Facility Management and Safety Committee representing a dual reporting pathway for radiation protection information.

The RPU consisted of the radiology services manager (RSM), the radiation safety officer (RSO), the radiation protection advisor (RPA), MPEs and clinical specialist radiographers. Inspectors reviewed a sample of minutes and were informed that this forum allowed operational radiation safety issues to be addressed and escalated on a regular basis.

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 Beaumont Hospital. The RPU also allowed an effective supplementary platform for the consideration and communication of any radiation safety issues. However, it was noted that as specified in the RSC terms of reference, a risk manager or their nominee were not present at the last three meetings for which minutes were supplied. Beaumont Hospital should consider ensuring the presence of corporate risk management representation at this forum to further enhance their ability to effectively manage and oversee radiation protection.

It was also noted that the allocation of responsibility for reporting accidental and unintended exposures to the Authority could be improved to ensure a more robust approach to guarantee that all such events are reported to HIQA within the specified

time frames and this is discussed further under Regulation 17.

A review of the provided documents and an on-site review of radiation safety documentation using the digital information sharing platform highlighted that approval dates, review dates, document owners and document reviewer records were not routinely available. This was discussed with management as an area for improvement which would ensure all radiation safety documentation and associated allocation of responsibility for the protection of service users is maintained, up to date and regularly reviewed by the appropriate staff.

Judgment: Substantially 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 Beaumont Hospital ensured that all medical exposures took place under the clinical responsibility of a practitioner.

Inspectors were assured that the optimisation process involved the practitioner and the MPE in all aspects of optimisation. Similarly, inspectors were satisfied that the justification process for individual medical exposures involved the practitioner and the referrer following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff.

The delegation of responsibility for practical aspects of medical radiological procedures to non-practitioners was detailed in documents reviewed and discussed with management and staff during the inspection and satisfied all requirements of Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from communication with staff and a review of relevant policies and other records, that Beaumont Hospital had adequate processes in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed documentation and spoke with staff at the hospital and were satisfied that Beaumont Hospital had arrangements in place to ensure that the involvement and contribution of MPEs was in line with the requirements of Regulation 20. For example, after document review and speaking with staff inspectors were satisfied that MPEs at Beaumont Hospital took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to a range of activities including the establishment and review of diagnostic reference levels (DRLs), the definition and performance of medical equipment quality assurance (QA) and acceptance testing and the training of practitioners.

Judgment: Compliant

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

Mechanisms were in place to ensure that MPEs were appropriately involved in medical radiological procedures in this facility and this was in line with the level of radiological risk. MPEs were found to be appropriately involved in all aspects of medical exposure to ionising radiation conducted at Beaumont Hospital.

Judgment: Compliant

Regulation 22: Education, information and training in field of medical exposure

The undertaking employed a Beaumont Online Resource for Interactive Study (BORIS) system to enhance the basic radiation safety training for referrers and practitioners. This system was used to deliver radiation safety training for all internal staff.

Beaumont Hospital used a locally developed two-tier system to deliver radiation safety training. Tier one was considered basic and delivered using the BORIS system, Tier 2 was delivered across the wider hospital group and involved large in-person training sessions delivered by physics and radiology staff.

Inspectors also reviewed a staff information handbook, titled *'FAQ - A practitioner guide in a regulatory inspection'.* This training resource highlighted pertinent information in relation to individual regulations, gave bespoke local information about these regulations and was considered a very useful resource for staff acting as practitioners. Inspectors were informed that this resource was made available to all staff to aid in regulatory compliance as well as provide a source of regulatory information for practitioners operating at Beaumont Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

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

Following a review of a sample of referrals from a range of departments, inspectors were assured that the undertaking 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 information was available throughout the radiology department on the day of inspection. This information was specific to procedures delivered by the facility as well as the different modalities and risk benefit information was available for the computed tomography (CT), general radiography, mammography, fluoroscopy and interventional radiology departments on the day of inspection.

Diagnostic reference levels (DRLs) were established, used and reviewed. Inspectors reviewed examples of a range of clinical audits including the review of pre-procedure radiation safety checklists. These checklists were considered a positive addition to the imaging process and helped ensure that regulatory requirements such as justification in advance and previous diagnostic information were considered and completed before patient exposures to ionising radiation. 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. Beaumont Hospital had developed and implemented measures to ensure that information relating to patient exposure formed part of the report in some areas and should consider a new or similar approach, or the national solution suggested for facilities using the NIMIS system, to ensure compliance with Regulation 13(2).

Inspectors were satisfied that Beaumont Hospital kept equipment under strict surveillance regarding radiation protection and a QA programme was implemented and maintained and all quality assurance testing was up to date at the time of inspection. Inspectors also noted the use of the bespoke digital information sharing platform which made all equipment information including radiographer and MPE QA, manufacturer preventative maintenance records and fault logs readily available and accessible.

Beaumont Hospital had ensured that special attention was given in the areas conducting high radiation dose procedures namely interventional radiology and cardiology. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses. Beaumont Hospital also proactively reduced patient dose through procedure protocol audits and review for a particular procedure as discussed in Regulation 15. This was also seen as a positive use of radiation safety audit to ensure compliance with Regulation

15.

Inspectors were satisfied that Beaumont Hospital had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility and implemented and maintained a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures. However, areas for potential improvement were highlighted to senior management and staff by inspectors. These included the consistent reporting of incidents within the time frames specified by the Authority and the strengthening of the allocation of responsibility for the reporting of accidental and unintended medical exposures and significant events to HIQA.

Overall, inspectors were assured that Beaumont Hospital had comprehensive systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

Inspectors spoke with 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. This process was further enhanced in theatre, fluoroscopy, interventional radiology and cardiology by the use of radiation safety checklists which were completed in advance of all procedures. A sample of radiation safety checklists were reviewed on site by inspectors, and included a tick box where the review of previous examinations was recorded.

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 in the radiology department.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of DRL documentation, 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 general X-ray department, Neurology interventional suite, cardiac catheterisation suite and the CT department.

In the area of interventional neurology where national DRLs are not yet available Beaumont Hospital had developed a system to compare local facility DRLs to international data, ensuring the review and optimisation of patient doses in this area.

After document review, DRL record review and speaking with staff inspectors were satisfied that in all cases where local facility DRLs exceeded nationally established DRLs the appropriate multidisciplinary investigations had taken place satisfying all requirements of Regulation 11.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard radiological procedure were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff spoken with in the clinical areas clearly articulated how these protocols were made available to them and were able to access them on request.

Inspectors saw evidence that information relating to patient exposure formed part of the report for all nuclear medicine reports reviewed and observed the process for the transfer of information relating to patient exposure to the clinical report in the cardiology interventional suite. On the day of inspection, based on a sample of records reviewed and after speaking with staff, inspectors noted that information relating to patient exposure did not consistently form part of the report of medical radiological procedures. Inspectors were informed that although measures had been put in place for facilities using the national integrated medical imaging system (NIMIS) to come into compliance with Regulation 13(2), these measures were not yet implemented in this hospital. However, Beaumont Hospital had developed and implemented measures to ensure that information relating to patient exposure formed part of the report in the nuclear medicine and the interventional cardiology departments and should consider a new or similar approach, or the national solution suggested for facilities using the NIMIS system, to ensure compliance with Regulation 13(2).

The specific referral guidelines used in this facility were documented in the document '*BH RAD Procedure for Referrers of Medical Radiation Exposures*'.

Inspectors were informed and observed that these referral guidelines were made available digitally for the relevant staff on the associated digital platforms.

The undertaking supplied a list of completed and ongoing clinical audits on medical exposure to ionising radiation. Beaumont Hospital systematically audited local compliance with pregnancy policy and completion of a locally employed radiation safety checklist. Audit results were routinely communicated to staff using departmental notice boards and were available on Beaumont Hospital's local data sharing platform for all staff.

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. This had included the implementation of a comprehensive QA and performance testing programme. From the inventory of equipment provided to inspectors, further documentation reviewed on site and after speaking with staff, inspectors were assured that all QA was up to date at the time of inspection.

All information relating to equipment including policies and procedures, MPE quality assurance records, manufacturer preventative maintenance records, radiographer QA and daily checks and all equipment fault logs were easily accessible through the digital information sharing platform called Rad Central. Inspectors also reviewed records detailing that all faults recorded and identified as part of equipment service and QA had been followed up in a timely manner.

The readily available, comprehensive equipment information 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 involving high doses to the patient. For example, the interventional neurology and interventional cardiology departments 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 follow up.

Inspectors reviewed a neuroradiology dose audit titled '*Dose Comparision in Neuro Interventional Radiology- Neuro DSA v Neuro DSA Care'* which investigated dose optimisation through the modification of manufacturer pre-set imaging protocols. The modification resulted in a dose reduction of 30% for the diagnostic cerebral angiogram procedure with no adverse effect on image quality and as a result the modified settings were subsequently used as the default imaging protocol for all diagnostic cerebral angiograms.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that Beaumont Hospital had processes in place to ensure that all relevant 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 and 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 and speaking with staff, 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 Beaumont Hospital 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.

Staff who spoke with inspectors consistently demonstrated a clear knowledge of the process by which the undertaking records and escalates all accidental and unintended exposures and significant events. Bespoke information on the radiation incident and near miss reporting process was widely available in poster format displayed throughout the radiology department as well as available electronically on the the local data sharing platform employed by Beaumont Hospital.

Inspectors reviewed accidental and unintended exposures and significant events reported to HIQA by the undertaking. Inspectors found that the initial notification of a number of accidental and unintended exposures and significant events relating to high patient skin doses were not reported to HIQA within three working days as required by the Authority. Documents reviewed as part of the inspection also noted that a single staff member was responsible for the reporting of all incidents to HIQA, and this was highlighted on the day of inspection as an area for potential improvement as this system created a single point of failure for the timely reporting of incidents to the Authority.

Despite these regulatory issues, further communications with the undertaking and their representatives as well as information gained through the inspection process assured inspectors that these issues did not represent a current safety concern. There is, however, a need to ensure consistent regulatory compliance in the future reporting and investigation of all accidental and unintended exposures and significant events as defined by HIQA under Regulation 17 and this was brought to the attention of senior hospital management.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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
Regulation 22: Education, information and training in field of medical exposure	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	Substantially Compliant

Compliance Plan for Beaumont Hospital OSV-0007305

Inspection ID: MON-0035043

Date of inspection: 30/05/2022

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: Beaumont Hospital will: • Ensure that corporate risk management is represented at the RSC and that their presence is recorded in the minutes. • That all radiation safety documentation is maintained, up to date and regularly reviewed by the appropriate staff. This includes providing a clear allocation of responsibility and that approval dates, review dates, document owners and document reviewer records are available for each relevant document relating to the safety of service users • Eliminate the single point of failure identified by the inspectors by redeveloping the current hospital electronic incident reporting forms to include a "radiation safety" incident. Once this is raised this report will be emailed to the hospital RSO, RPA and the two designated managers (RSM/Radiology clinical director). Also the RPU will include follow up of these incidents in the agenda.	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Beaumont Hospital is in regular communication with NIMIS, HSE and other national stakeholders with a view to ensuring that information relating to patient exposure forms part of the report of the medical radiological procedure. The RSM will engage with the HSE national team on a regular basis to establish a timeline for when a national practical solution will be in place and thus ensure compliance to this regulation. An automated patient specific dose report within the NIMIS /PACS system is felt to be the optimal	

solution to this problem.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
In order to eliminate the single point of failure identified by the inspectors, we have engaged with risk to redevelop the current hospital electronic incident reporting forms to include a "radiation safety" incident and once this is raised this report will be emailed to the following key members of the Radiation Safety Committee (RSC);

- Radiation Safety Officer
- Radiation Protection Advisor
- Radiology Services and Business Manager (designated manager)
- Radiology clinical director (designated manager)

The above will allow all incidents to be closed out and/or reported to the relevant bodies in an appropriate and timely fashion.

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	31/08/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	01/01/2023

	procedure.			
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and	Not Compliant	Orange	31/08/2022