



**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 Hospital
Undertaking Name:	Beacon Hospital Sandyford Limited
Address of Ionising Radiation Installation:	Beacon Court, Sandyford, Dublin 18
Type of inspection:	Announced
Date of inspection:	04 May 2023
Medical Radiological Installation Service ID:	OSV-0007304
Fieldwork ID:	MON-0039487

About the medical radiological installation:

Beacon Hospital is a private hospital that opened in November 2006 and which provides a radiology and radiotherapy service. The Beacon Hospital has the following medical radiological equipment:

- Radiography (X-ray)
- Fluoroscopy
- Bone Densitometry (DXA)
- Interventional systems
- Mammography
- Computed Tomography (CT)
- Nuclear Medicine
- Positron Emission Tomography Computed Tomography (PET CT)
- Linear Accelerators and
- CT Simulator.

Diagnostic medical exposure referrals come from both general practitioners (GPs) and consultant clinicians. The radiology department at the Beacon Hospital provides a broad range of diagnostic medical radiological procedures incorporating orthopaedics, cardiology and oncology.

The Radiotherapy department provides treatment techniques including 3D Conformal Radiotherapy (3D CRT), Intensity Modulated Radiotherapy (IMRT), Stereotactic Radiosurgery (SRS) and Stereotactic Ablative Body Radiotherapy (SABR), while respiratory gating and surface guided treatment delivery is also available.

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
Thursday 4 May 2023	09:00hrs to 16:45hrs	Kirsten O'Brien	Lead
Thursday 4 May 2023	09:00hrs to 16:45hrs	Agnella Craig	Support
Thursday 4 May 2023	09:00hrs to 16:45hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the radiotherapy and radiology departments at the Beacon Hospital was carried out on the 4 May 2023 to assess compliance against the regulations. On the day of inspection, inspectors reviewed documentation and records and spoke with staff working in both of these departments.

Overall, inspectors found appropriate governance and management arrangements were in place at the Beacon Hospital to oversee the provision of medical radiological procedures. A radiation safety committee (RSC) was established as a forum to provide oversight of medical exposures. Membership of the RSC included the designated managers and staff from areas where medical exposures to ionising radiation were conducted. The RSC was accountable to the Chief Executive Officer (CEO) who was the named undertaking representative.

On the day of inspection in both the radiotherapy and radiology departments, systems and processes were in place to ensure that medical exposures were only carried out at the Beacon Hospital when referred by a person entitled to refer as per Regulation 4. Similarly, inspectors were assured that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. Management at the Beacon Hospital also had measures in place to ensure the appropriate involvement of a medical physics expert (MPE) proportionate to the level of radiological risk at the hospital and that the MPEs took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

However, from the documents and records reviewed as part of this inspection, inspectors were not satisfied that the allocation of responsibility for the radiation protection of service users was clearly documented on the day of inspection. Local policies, such as the *Radiation Safety Procedures* did not always clearly and consistently document the roles and responsibilities of personnel involved in the day-to-day aspects of medical radiological procedures at the Beacon Hospital. In particular, the allocation of clinical responsibility for justifying medical radiological procedures in the radiology department was not clearly defined in documentation reviewed by inspectors.

Overall, notwithstanding the areas for improvement identified over the course of the inspection, inspectors were assured that the Beacon Hospital Sandyford Ltd had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at the Beacon Hospital.

Regulation 4: Referrers

On the day of inspection, inspectors found that in both the radiotherapy and radiology departments processes were in place to ensure that medical exposures were only carried out when referred by an individual entitled to refer as per the regulations. An example of good practice was found in the radiology department where staff and management communicated the process by which general practitioners (GPs) referring patients for medical radiological procedures were reviewed and validated to ensure compliance with Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

In both the radiotherapy and radiology departments, only those defined in the regulations as practitioners took clinical responsibility for individual medical exposures carried out at the Beacon Hospital.

Judgment: Compliant

Regulation 6: Undertaking

From the evidence reviewed over the course of the inspection, inspectors were satisfied that the Beacon Hospital Sandyford Ltd, as the undertaking, had governance and management arrangements in place to provide oversight of medical exposures to ionising radiation conducted in both the radiotherapy and radiology departments at the Beacon Hospital. The RSC was accountable to the CEO, who was the undertaking representative, and reported to the Quality Improvement Committee twice a year. Membership of the RSC also included the designated managers, a consultant radiation oncologist, a consultant radiologist, MPEs and representation from areas outside of the main departments, such as theatre. Radiotherapy and radiology representatives also attended the hospital's Patient Safety Committee and the Health and Safety Committee. A line management structure was in place with both designated managers reporting directly to the CEO. Inspectors were also informed that weekly hospital management meetings were attended by all department leads, including the designated managers, and this provided a further assurance to inspectors that the undertaking had oversight of the provision of medical exposures at the Beacon Hospital.

In the radiology department inspectors reviewed documentation and spoke with staff regarding their responsibilities and roles in the day-to-day conduct of medical exposures. While inspectors were satisfied that only those entitled to act as practitioners as per Regulation 5 took clinical responsibility for individual medical radiological procedures, the allocation of this practitioner role was not clearly or consistently documented and did not align with practice in the radiology

department. Similarly, inspectors found that documentation of who was delegated the practical aspects of medical exposures, was not consistent with day-to day practice. For example, the *Radiation Safety Procedures* documented that the practical aspects of medical imaging were only allocated to a radiographer and did not reflect the role of the MPE in the preparation of radio-pharmaceuticals. Similarly, the hospital's documentation did not accurately reflect the good practice of retaining a radiographer which had been implemented in areas outside the radiology departments.

In the radiotherapy department, an overarching allocation of responsibility for the delivery of medical exposures was provided in the documentation reviewed. A number of policies to guide and support radiation therapists in completing their roles and responsibilities at each stage of a patient's radiotherapy pathway had been developed. For example, there were procedures available for completing specific tasks, such as weekly chart checks. However, inspectors also found that some aspects of this allocation of responsibility required additional clarification and expansion from staff. In particular, as an area for improvement, the hospital should ensure that responsibility for the oversight of equipment issues and corrective actions while in place, is clearly documented.

Inspectors did note as a positive finding in both radiotherapy and radiology departments, that management at the Beacon Hospital had documented the overarching involvement of different professional groups in all aspects of radiation protection as per the regulations. For example, for low dose procedures in the radiology department, radiologists, MPEs and radiographers were involved in optimisation which was aligned with the requirements of Regulation 10.

Overall, although inspectors were satisfied that day-to-day practice was aligned with the requirements of the regulations, in order to achieve full compliance with this regulation, the allocation of responsibility for the radiation protection of patients and other service users attending Beacon Hospital must be clearly documented.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, inspectors found that all medical exposures in both the radiotherapy and radiology departments took place under the clinical responsibility of an individual entitled to act as a practitioner as per the regulations. Similarly, the referrer and a practitioner were involved in the justification process for individual medical radiological procedures. Inspectors noted that documentation reviewed detailed the specific role of both the referrer and practitioner in the justification process for medical exposures conducted at the Beacon Hospital.

In the radiotherapy department inspectors found that radiation therapists, who were recognised as practitioners, carried out the practical aspects of radiotherapy

procedures. From the evidence reviewed the optimisation process in radiotherapy was found to include radiation oncologists, radiation therapists and MPEs.

In the radiology department optimisation included radiologists, radiographers, cardiologists and MPEs. Inspectors noted that as an additional assurance the Beacon Hospital had retained the presence of a radiographer for the practical aspects of all medical radiological procedures conducted outside the radiology and radiotherapy departments, typically in theatre and interventional cardiology suites. In the absence of new training requirements being implemented, as per Regulation 22, this was viewed as a positive additional radiation protection mechanism for service users at the hospital.

However, documentation reviewed by inspectors indicated that only radiographers were delegated the practical aspects of medical exposures in the radiology department. While on the day of inspection inspectors were satisfied that only those entitled to carry out the practical aspects of medical exposure did so, the documentation of this delegation was not consistent with day-to-day practice. For example, the role of the MPE in the preparation of radio-pharmaceuticals was not clearly documented.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that the undertaking, Beacon Hospital Sandyford Ltd, had appropriate measures in place to ensure the continuity of medical physics expertise in both the radiology and radiotherapy departments at the Beacon Hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, inspectors spoke with staff and management, including members of the medical physics team, involved in the delivery of the radiology and radiotherapy services at the Beacon Hospital. Inspectors also reviewed documentation and records relating to the responsibilities of the MPEs at the hospital.

Inspectors were satisfied that, in both departments at the Beacon Hospital, MPEs took responsibility for dosimetry and gave advice on medical radiological equipment. MPEs were also found to contribute to optimisation, QA and acceptance testing, the analysis of events involving or potentially involving accidental or unintended medical exposures, and the training of practitioners and other staff as relevant. For example,

inspectors noted that regular radiation safety training was delivered to radiation therapists by the medical physics team. Inspectors also found that arrangements were in place for an MPE to liaise with the hospital's radiation protection advisers, where necessary.

Judgment: Compliant

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

Inspectors were also satisfied that MPEs were available to act and give specialist advice and were appropriately involved in all aspects of medical exposure to ionising radiation conducted at the hospital, in line with the level of radiological risk in both the radiotherapy and radiology departments at the Beacon Hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors were assured from speaking with staff and from the review of a sample of referrals in both the radiology and radiotherapy departments that all referrals were in writing and contained the reason for the requests. Inspectors were also satisfied that medical radiological procedures in both departments were justified in advance by a person entitled in the regulations to take clinical responsibility for justification. On the day of inspection, only radiologists, radiographers, radiation oncologists, radiation therapists, and, where appropriate, specialist consultant medical practitioners such as cardiologists, were found to take clinical responsibility for justifying medical radiological procedures.

Staff demonstrated a strong multidisciplinary approach to optimisation of medical radiological procedures in both the radiotherapy and radiology departments. Inspectors found examples of good practices in radiology department, in particular, in the delivery of fluoroscopically-guided interventions (FGIs) and computed tomography (CT) procedures. In the radiotherapy department an example of good practice was a quality improvement study which showed that technology was used during radiotherapy treatment delivery to reduce the need for repeat imaging and the treatment time for the patient.

However, inspectors found that processes in place regarding the inquiring and recording of patients' pregnancy and breastfeeding statuses must be reviewed at the hospital. In particular, in the radiology department, a mechanism to ensure that patients' breastfeeding statuses in nuclear medicine are recorded must be implemented as discussed under Regulation 16.

Inspectors found that medical radiological equipment was kept under strict surveillance at the Beacon Hospital. A quality assurance (QA) programme was in place in both the radiology and radiotherapy departments. Similarly, a system was in place for recording and reviewing incidents involving, or potentially involving, accidental or unintended exposures to ionising radiation in both departments. Inspectors noted that incidents and potential incidents were reported to the RSC and also were discussed at the weekly hospital Patient Safety Committee.

Overall, inspectors were satisfied that systems were in place to support the safe delivery of medical exposures at the Beacon Hospital, although some areas for improvement to ensure full compliance with the regulations were identified as part of this inspection.

Regulation 8: Justification of medical exposures

On the day of the inspection, inspectors reviewed a sample of referrals in both the radiology and radiotherapy departments and saw that they were available in writing and stated the reason for the request. From a review of this sample, inspectors were also assured that sufficient medical data, including diagnostic imaging and histology reports, were available to enable the practitioner to adequately consider if the referral was justified. Inspectors spoke to members of staff working at the hospital, such as radiation oncologists, radiologists, radiographers and radiation therapists. From these discussions inspectors were assured that staff were aware of their responsibility regarding the justification of medical exposures in advance.

Prior to the inspection, inspectors reviewed the *Radiation Safety Procedures - Radiotherapy Department* which outlined the patient's pathway and the staff assigned the specific responsibilities of justification in the radiotherapy department. For example, how the radiation oncologist justified the treatment course in advance was documented. In addition, staff involved in the planning and delivery of treatment were found to have considered the risks and benefits of each medical exposure in advance of delivering it. However, staff were less clear of the specific steps in the process when justification by a practitioner was recorded. From speaking with staff and reviewing patient records inspectors found that justification in advance was recorded by means of the processes in place for radiation therapists to complete tasks and checklists on the electronic system. A New Patient Meeting, which involved a multidisciplinary team of radiotherapy staff met weekly to discuss all new referrals for radiotherapy. The team included radiation oncologists, radiation therapists and MPEs and justification in advance for each referral was also completed and recorded at this meeting. This multidisciplinary approach and discussion of justification in advance was acknowledged as an area of good practice in the facility.

In the radiology department inspectors found evidence that all medical radiological procedures were justified in advance by an individual entitled to act as a practitioner. As part of the inspection a sample of patient records were reviewed and

inspectors found that a record of this justification was available for review.

Inspectors were also assured that the Beacon Hospital had measures in place to provide patients attending the hospital with adequate information about the risks and benefits relevant to the level of radiological risk involved in the procedure. In the radiology department, posters and information leaflets were available in the waiting areas and patient information leaflets were provided to patients in advance of their nuclear medicine or positron emission tomography computed tomography (PET CT) scans. In the radiotherapy department, inspectors found that patient information leaflets were available to inform patients of the benefits and risks associated with receiving a course of ionising radiation and that a review and update of the information leaflets was almost complete.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, inspectors reviewed the processes and procedures that management and staff at the Beacon Hospital had in place to ensure the optimisation of medical exposures to ionising radiation in both the radiology and radiotherapy departments. Inspectors viewed the multidisciplinary approach to optimisation taken in both departments at the hospital as good practice.

In the radiology department, inspectors spoke with staff members and reviewed records and other documentation to determine how medical radiological procedures were optimised to ensure that doses were kept as low as reasonably achievable. In particular, inspectors noted a good example of optimisation in relating to the optimisation of CT brain examinations through the use of DRLs and staff education and training. Additionally, inspectors reviewed information regarding an optimisation project involving the upgrade of software on the CT scanner which was currently being carried out at the hospital. Staff spoken with in the nuclear medicine department also described how they ensured that administered activities were verified to ensure adequate diagnostic information was obtained from nuclear medicine scans through the timing of the preparation of radio-pharmaceuticals.

In the radiotherapy department, inspectors spoke with radiotherapy staff and reviewed documentation that outlined the processes in place to ensure that all medical radiological procedure doses were kept as low as reasonably achievable. For example, the *Radiation Safety Procedures - Radiotherapy Department* clearly outlined the stages of a patient's radiotherapy pathway where optimisation was considered including who was responsible. Inspectors also reviewed other policies and procedures which outlined how optimisation was achieved at treatment planning and delivery. Staff outlined how individual treatment plans were optimised and how the medical physics team had developed a Patient Quality Script which provided additional assurances that doses to non-target volumes were kept as low as

achievable and that doses to the planned volume were as prescribed.

A Policy and Procedure on Image Acquisition and Tolerances for Specific Treatment Sites had also been developed in the radiotherapy department which outlined the frequency and imaging type to be adhered to when verifying the radiotherapy treatment for different treatment sites, such as for prostate, lung and breast treatment. Inspectors were also informed that a system was in place which directed that the radiation oncologist must be informed if increased imaging during a treatment fraction was required, before the additional imaging was acquired. This system ensured that imaging doses were kept as low as was reasonable. Staff also informed inspectors that they completed and recorded a time-out check before each treatment phase (fraction) was delivered which included confirming the verification imaging modality and breathing pattern required to accurately deliver that fraction, thus increasing image quality and reducing the need for repeat exposures of ionising radiation.

Inspectors were also informed that an additional optimisation process had recently been introduced into the radiotherapy department for one cohort of patients as a result of incident learning, although the incident itself was not clinically significant. This ethos of ongoing improvement of the optimisation process was acknowledged as an area of good practice in the hospital. In particular, over the last six months, staff recorded the dose for radiotherapy planning CT scans as part of a dose optimisation project in the department to further refine CT protocols for patients undergoing CT treatment planning, and this project was noted as another example of ongoing improvement and good practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

On the day of inspection, inspectors found evidence that DRLs had been established for common medical radiological procedures conducted in the radiology department. DRLs were reviewed annually and displayed in the control rooms of the modalities visited during the inspection. The radiology department's *Radiation Safety Procedures* included a section called the Establishment & Review of Diagnostic Reference Levels (DRLs) which was reviewed as part of the inspection. DRLs were signed off by a multidisciplinary team which included representation from radiologists, radiographers and medical physics.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written protocols for routine examinations conducted in the radiology and radiotherapy departments.

From a review of patient records in the radiotherapy department, inspectors saw that the radiation treatment dose received was generated for each patient and included in a summary letter after patients finished their treatment. However, in the radiology department, inspectors found that while some reports of medical radiological procedure contained information about the dose, other reports reviewed did not. Staff spoken with on the day of inspection also communicated that compliance with Regulation 13(2) was not consistently adhered to at the Beacon Hospital.

A sample of clinical audits conducted in the both the radiology and radiotherapy department were reviewed by inspectors. Inspectors saw that clinical audit results from both departments were included in a report submitted to the RSC. For example, an audit of pregnancy status forms had been completed in both the radiotherapy and radiology departments. Additionally, inspectors were informed that all radiation therapists had completed clinical audit training and were involved in auditing policies and procedures in the radiotherapy department.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at the Beacon Hospital was provided to HIQA in advance of this inspection. Inspectors were satisfied that staff and management at the Beacon Hospital had ensured that a QA programme had been implemented to ensure that all medical radiological equipment, in use at the hospital, was kept under strict surveillance.

In the radiotherapy department the MPE team were assigned responsibility for developing and implementing the QA programme, which comprised of weekly, monthly and annual testing for the equipment as outlined in quality procedures submitted prior to the inspection. The role of the radiation therapists in completing daily QA checks was also explained. In the radiology department, an MPE carried out the annual QA testing and radiographers were responsible for carrying out regular performance testing of equipment. On the day of the inspection, inspectors reviewed documentation which demonstrated that all QA testing was up-to-date, and that acceptance and commissioning testing had been completed for equipment in use in both the radiology and radiotherapy departments.

Inspectors spoke with a number of staff on how they raised issues or concerns about the equipment's functionality, and were informed of a reporting pathway and record-keeping process. Additionally, inspectors were also informed by hospital management that proactive planning was underway to replace one piece of equipment that is due for replacement in 2025.

Judgment: Compliant

Regulation 15: Special practices

Inspectors observed that management and staff at the Beacon Hospital had in place a number of measures to ensure that patients receiving high dose medical exposures were appropriately protected. From a review of documentation, inspectors saw that careful consideration was given to optimisation, for example, in the radiotherapy department patients attended the CT scanner for a breathing assessment prior to the actual CT planning scan being acquired. This allowed staff to determine the patient's suitability for this type of treatment. The immobilisation of these patients was also carefully considered, and some underwent specific preparation to reduce organ motion prior to the CT planning scan and each treatment fraction to ensure that the use of imaging was minimised where possible, while also providing assurances of high treatment delivery accuracy.

In the radiotherapy department, staff involved in treatment planning also informed inspectors that specific planning protocols were used for each treatment site to ensure the doses to normal tissue is kept as low as possible while delivering the optimal treatment dose to the target area. The undertaking also had an imaging system that allowed the treatment area to be identified without the need for permanent treatment set-up tattoos. A quality improvement study completed showed that the use of specific technology during radiotherapy treatment delivery had reduced repeat imaging and time for the patients resulting in a safer and more comfortable experience for the patient.

In the radiology department, inspectors were informed about the involvement of the Beacon Hospital's staff in an international study aimed at enhancing the optimisation of FGI procedures carried out in the interventional radiology suite. Management at the hospital also explained how while a threshold for a tissue reaction had not been reached to date at the hospital, a process was in place to identify and follow-up with patients should this ever occur which was noted as an example of good practice. The hospital had also purchased dose tracking software for modalities which had the potential to deliver a high dose, and while not a specific requirement of the regulations, this was identified as an example of a positive measure to ensure the radiation protection of patients at the hospital.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

In the radiotherapy and radiology department inspectors observed that notices were displayed, in patient bathrooms and changing rooms, to raise awareness of the

special protection required during pregnancy in advance of medical exposure to ionising radiation.

In the radiotherapy department, inspectors reviewed the *Radiation Safety Procedures - Radiotherapy Department*, and were informed of the process for enquiring about and recording pregnancy status for relevant patients undergoing radiotherapy treatment. Inspectors also reviewed a number of patient records and found that this enquiry had been documented at the treatment consent stage by the radiation oncologist and prior to the planning CT scan and prior to the first day of treatment by the radiation therapists. Although, inspectors were assured that appropriate measures were in place to ensure the protection of patients that were pregnant while attending the service, some staff spoken with were unclear about the circumstances in which a pregnancy waiver had to be re-signed by a patient.

In the radiology department, inspectors were informed by staff that a proactive review of the process of establishing pregnancy status for patients that are referred from the Beacon Hospital's emergency department to CT was being carried out. This initiative was noted as an example of good practice. Inspectors also spoke with radiography staff and were informed that radiographers inquired about the pregnancy status of patients and recorded the answer in writing on a dedicated pregnancy status declaration form. This form was then scanned up against the individual patient's referral on the radiology information system (RIS). From a sample of records reviewed, inspectors observed an example of where a pregnancy form had been completed in advance of a CT scan. However, inspectors found that while the radiology department's *Radiation Safety Procedures* included a direction that patients of reproductive capacity must be asked if they are pregnant and the answer recorded, information outlining who is specifically responsible for carrying out the inquiry was not clear. For example, responsibility was allocated the referrer or cardiologist and the radiographer, but depending on the type of procedure, the specific detail was ambiguous. In addition, information about how and when this inquiry takes place was not clearly documented.

Inspectors were informed in the radiology department that radiographers inquire as to the breastfeeding status of patients attending for nuclear medicine and PET CT procedures however, inspectors were informed that the answer was not recorded. From a review of the documentation, inspectors found that the hospital had not documented a formal process for inquiring about and recording the breastfeeding status of a patient in nuclear medicine or PET CT. Consequently, inspectors were not satisfied that the answer to this inquiry about a patient's breastfeeding status was recorded in writing as required by the regulations.

Inspectors did observe that information about how to advise patients who were breastfeeding following a nuclear medicine examination was included in the radiology department's *Radiation Safety Procedures*, including the time lines for interruption to breastfeeding following administration of a radio-pharmaceutical. Staff also communicated that they were aware of this information on the day of inspection. Additionally, information to raise awareness about breastfeeding in nuclear medicine was included on the patient information leaflet issued to patients in advance of a nuclear medicine procedure. However, in order to achieve

compliance with this regulation, management at the Beacon Hospital must ensure that clear and formal processes for inquiring about, and recording a patients pregnancy and breastfeeding statuses, are implemented at the hospital.

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

The undertaking had a system in place in the radiotherapy and radiology department for the recording and review of any incidents, including potential incidents, involving accidental or unintended exposures to ionising radiation. Incidents and potential incidents were recorded on an electronic system. Staff spoken with in both departments on the day of inspection could explain to inspectors the process for reporting a radiation incident, or a potential radiation incident. Incidents from both the radiotherapy and radiology departments were also discussed at the hospital's Patient Safety Committee which was held weekly. Inspectors also saw evidence that incidents and potential incidents were discussed at the RSC.

In the radiotherapy department, a *quality moment report* was generated and discussed at a weekly patient safety meeting. Inspectors were also informed that a staff-led radiotherapy quality team met weekly to discuss incidents and identify corrective actions. The suggested corrective actions arising from this meeting were then feedback to the radiotherapy management team.

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	Substantially Compliant
Regulation 10: Responsibilities	Substantially 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 9: Optimisation	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	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Beacon Hospital OSV-0007304

Inspection ID: MON-0039487

Date of inspection: 04/05/2023

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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <p>Radiology: The Radiation Safety Procedures (RSP) have been amended to clearly state the allocation of responsibility to trained and competent radiographers as practitioner for justification of specifically named modalities; Cardiologists and surgeons have been named as practitioners for justification of relevant procedures under their specialty only. The updated RSPs will be uploaded to QPulse on 27th June 2023.</p> <p>Radiotherapy: Policy on responsibility of oversight of radiotherapy equipment issues has been developed. Completed</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities:</p> <p>The RSPs have been updated to state that the undertaking has delegated the practical aspects of radiopharmaceutical preparation in the radiopharmacy to Medical Physicists and Radiographers who are competent and trained in nuclear medicine and/or PETCT as appropriate. The updated RSPs will be uploaded to QPulse on 27th June 2023.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p>	

The Clinical Lead in Radiology 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 quarterly report to the QIC as part of Radiology Radiation Protection report. This will be audited by the hospital to help attain compliance.

Regulation 16: Special protection during pregnancy and breastfeeding

Not Compliant

Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:

Radiology: Pregnancy is already asked and recorded. The RSPs have been updated to further clarify who must ask this question. Regarding women who may be breastfeeding, this was being asked but not recorded, as such the RSP document has been updated to include recording the information regarding breastfeeding; both Nuclear Medicine and PETCT acquisition forms have been amended to include this information; all radiographers have been educated to this update; the practice commenced from 5th May in both PETCT and Nuclear Medicine. The monthly audit programme now includes compliance with this regulation and will form part of the quarterly report to the QIC as part of Radiology Radiation Protection report. Completed, audit ongoing as part of overall radiology audit programme. The updated RSPs will be uploaded to QPulse on 27th June 2023.

Radiotherapy: The circumstances in which a pregnancy waiver has to be re-signed by a patient will be discussed and re-iterated to all staff at the next quarterly departmental meeting and also focused upon at the next round of annual radiation safety training.

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	27/06/2023
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more	Substantially Compliant	Yellow	27/06/2023

	<p>individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.</p>			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	31/07/2023
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall	Substantially Compliant	Yellow	05/05/2023

	<p>inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and</p>			
<p>Regulation 16(1)(b)</p>	<p>An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.</p>	<p>Not Compliant</p>	<p>Orange</p>	<p>05/05/2023</p>