



## Health Information and Quality Authority

# Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Department of Radiology, Beaumont Private Clinic
Undertaking Name:	Department of Radiology, Beaumont Private Clinic
Address of Ionising Radiation Installation:	Beaumont Hospital Campus, Dublin 9
Type of inspection:	Announced
Date of inspection:	27 June 2023
Medical Radiological Installation Service ID:	OSV-0006059
Fieldwork ID:	MON-0040173

## About the medical radiological installation:

The Department of Radiology, Beaumont Private Clinic is an outpatient diagnostic facility providing a range of diagnostic studies including computed tomography (CT), ultrasound (US), dual-energy X-ray absorptiometry (DXA), general radiography and mammography. The referral sources for these patients are general practitioners (GPs) and consultants within the private clinic and the associated public hospital. The majority of GP referrals are referred electronically through Healthlink, the national web-based messaging service. The department also has a diagnostic imaging workstation with access to the national integrated medical imaging system (NIMIS) radiology information systems (RIS) in addition to local picture archiving and communication systems (PACS).

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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
Tuesday 27 June 2023	08:30hrs to 13:45hrs	Margaret Keaveney	Lead

## Governance and management arrangements for medical exposures

On 27 June 2023, the inspector completed an inspection of the radiological service at the Department of Radiology, Beaumont Private Clinic, in order to monitor the service's ongoing compliance with S.I. 256 of 2018 as amended. On the day of inspection, the inspector visited each of the service's four ionising radiation units.

The Department of Radiology, Beaumont Private Clinic is the undertaking for the service, and the inspector saw that overall there were appropriate governance and management arrangements in place to ensure good oversight of the radiation protection of service users. However, some action is required by the management of the Department of Radiology, Beaumont Private Clinic to achieve compliance with Regulation 6, which is discussed further in the report.

The radiology department consists of a computerised tomography (CT) unit, a general X-ray unit, a DXA scanning unit and a mammography unit, that provide medical exposures of ionising radiation to out-patients referred by general practitioners (GPs), and medical practitioners working both in Beaumont Private Clinic and the associated hospital. The service is led by a managing partner, who is a Consultant Radiologist, and who is supported by the Radiology Services Manager (RSM), team of radiographers, medical physics experts (MPEs) and a team of partner radiologists.

A number of audits on the clinical service had been completed in 2022 by the RSM, such as adherence to justification of medical exposures in advance, and to checking pregnancy status. The inspector also saw that learning from these audits was shared with staff in the service to ensure that they were aware of any actions required that would enhance the radiation protection of service users. This was identified as an area of good practice within the service.

During the inspection, a sample of patient radiological records were reviewed by the inspector who noted that only appropriate persons as per the regulations were involved in referring and justifying medical exposures completed at the service. The inspector was also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

On the day of the inspection, the inspector met with one of the MPEs involved in the service, and determined that their involvement was proportionate to the radiological risk posed by the service, and that the undertaking had robust arrangements in place to assure the continuity of this service. From a review of documentation, the inspector noted the second MPE's involvement in the service was also proportionate to the radiological risk in the service.

Overall, the inspector was assured that service users were receiving a safe

radiological service at CHI at the Department of Radiology, Beaumont Private Clinic.

#### Regulation 4: Referrers

From a review of a sample of medical exposures records and discussions with staff, the inspector was satisfied that referrals, for medical radiological procedures, were only accepted in the service from persons defined in Regulation 4.

The undertaking had developed a *Policy for the acceptance of referrals, roles and justification of studies* which outlined who can refer for medical radiological procedures in the service.

Judgment: Compliant

#### Regulation 5: Practitioners

The inspector was satisfied, from a review of documents and from speaking with staff, that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures in the service. In the Department of Radiology, Beaumont Private Clinic, only appropriately registered radiologists and radiographers acted as practitioners.

Judgment: Compliant

#### Regulation 6: Undertaking

The inspector reviewed a governance structure organogram (organisation chart) that was submitted prior to the inspection, and saw that overall it provided a clear allocation of the governance and management roles and responsibilities for the radiation protection of service users in the service.

The management team at Department of Radiology, Beaumont Private Clinic had established a radiation safety committee (RSC), which met at a minimum every 6 months, to discuss items such as radiation safety incidents, clinical audit and the radiological equipment quality assurance programme. The inspector saw that this group was attended by a radiologist partner, an MPE and the RSM, and that the meeting minutes were available on a shared drive to the radiologist partners and practitioners working in the service. The managing partner of the Department of Radiology, Beaumont Private Clinic assumed the role of the undertaking's designated manager. Although they did not attend the RSC meetings, the inspector was informed that they accessed the meeting minutes on the shared drive, and received

continuous email and in person updates from the RSM and MPE on all radiation protection issues in the Department of Radiology, Beaumont Private Clinic. Through these pathways, they ensured that the undertaking was adequately informed of any such issues.

Despite these governance and management structures, the inspector was not assured that the undertaking had appropriate document quality management arrangements in place, to ensure that the procedures and protocols, available to staff in the department, were regularly reviewed and, when required, updated by the appropriate personnel. For example, the inspector observed that the general X-ray and DXA protocols did not have a named author, approver, approval date or a next review date. A strong document quality management system is a key part of the radiation protection of service users, as it ensures that staff are clearly aware of their roles and responsibilities in providing a safe radiological service to service users undergoing a medical exposure of ionising.

Also, during the course of the inspection, the inspector reviewed the *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* and saw that it required action so that it accurately outlined who was responsible for discussing and recording the pregnancy status with the patient. For example, the policy stated that the referrer was responsible for this inquiry, however from discussions with staff and a review of patient records, the inspector saw that in practice this inquiry was made and recorded by practitioners.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

From a review of documents and discussions with staff, the inspector was satisfied that practitioners, as defined in the regulations, took clinical responsibility for the medical radiological procedures in the Department of Radiology, Beaumont Private Clinic.

In addition, practitioners and the MPEs were noted to be involved in the optimisation process for all medical exposures to ionising radiation.

The inspector was also satisfied that the justification process for individual medical exposures involved the referrer and practitioner.

Judgment: Compliant

## Regulation 19: Recognition of medical physics experts

The inspector met with one of the MPEs engaged by the undertaking to provide medical physics expertise in the Department of Radiology, Beaumont Private Clinic. They detailed the arrangements in place to ensure the continuity of medical physics expertise, which included an arrangement to utilise the expertise of another MPE, where and when necessary. Staff also reported that they had adequate access to medical physics expertise.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Overall the inspector was satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics in the service. From a review of a range of documents, the inspector noted that the MPE took responsibility for dosimetry, was involved in the analysis of events involving accidental or unintended medical exposures in the service and carried out annual quality assurance and acceptance testing of medical radiological equipment in the service. They were also involved in the optimisation of medical exposures, including contributing to the establishment of diagnostic reference levels (DRLs) for each of the four radiological units in the service.

Judgment: Compliant

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

The inspector was satisfied that MPEs were appropriately involved at the Department of Radiology, Beaumont Private Clinic, and that the level of involvement was commensurate with the level of radiological risk posed by the service.

Judgment: Compliant

## Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, the inspector saw that the management of the Department of Radiology, Beaumont Private Clinic were committed to improving the radiation protection of service users, for example,



through the implementation of a rigorous quality assurance programme for radiological equipment and the use of recently revised DRLs. However, some action was required to ensure that female service users were adequately made aware of the need to inform staff of their pregnancy status, where relevant. This is further discussed under Regulation 16 below.

During the inspection, the inspector reviewed a number of referrals, received from both internal and external medical practitioners, and saw that each was in writing, stated the reason for the request and was accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff explained the processes for the justification of each medical exposure, in advance of the exposure happening, and the recording of this was evident for all medical radiological procedures reviewed by the inspector.

From a review of documentation, the inspector was satisfied that local DRLs had been established by the RSM and MPE for each of the four radiological units in the service. These DRLs had been reviewed in January 2023, and were on display in each console area for use by practitioners.

On the day of inspection, the inspector reviewed records and spoke with staff which provided assurances that the undertaking had implemented a quality assurance programme for all equipment in use in the service, to ensure that they produced quality images with the least possible radiation dose to provide the information required. The MPE stated that they were promptly contacted to provide guidance on any quality control test results if required, and the inspector also saw evidence that equipment manufacturers were involved in ensuring that all equipment was fit for use and provided a safe and reliable service to service users.

The inspector was assured that there was a process in place to determine the pregnancy status of service users, where relevant. From a review of patient records and clinical audits, the inspector were assured that this process was monitored and adhered to by staff. However, a review of the pregnancy policy was required to ensure that it clearly, and accurately, allocated the responsibility of inquiring on pregnancy status to the appropriate persons.

The management of the Department of Radiology, Beaumont Private Clinic had arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. These arrangements included ensuring that the undertaking had oversight of incidents that occurred in the service and that HIQA was notified of any reportable events.

## Regulation 8: Justification of medical exposures

All referrals reviewed by the inspector were in writing, stated the reason for the request and were accompanied by sufficient medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Information about the benefits and risks associated with the radiation dose from

medical exposures was available in leaflet form, and was also displayed in poster format in the CT unit.

On the day of inspection, the inspector spoke with a practitioner who explained how medical exposures are justified in advance of the medical exposure being completed, for all referrals received from both external and internal referrers. The inspector reviewed a sample of service user records and saw that justification in advance, by a practitioner, had been recorded for each. The RSM had also completed a 'Reject analysis and justification audit' in 2022, and the results showed that the required information was included on the majority of referrals received by the service. The audit report also highlighted the information that was missing from a small number of referrals, and the inspector was informed of a feedback mechanism to referrers, to improve the quality of information received in referrals. This audit system provided assurances that the Department of Radiology, Beaumont Private Clinic had arrangements in place to ensure that referrals were appropriately justified in advance, by a person entitled to act as a practitioner as per Regulation 5.

Judgment: Compliant

### Regulation 9: Optimisation

From a review of documentation and discussions with staff, the inspector observed that there were measures in place to ensure that all doses from medical exposures were kept as low as reasonably achievable, while providing the required medical information. A number of measures in place were noted as examples of good practice. For example, the RSM had developed a formalised induction programme for new staff members, which included measures on optimising doses from medical exposures.

Additionally, the management team also had developed and recently reviewed a policy on the exposure of carers and comforters to medical exposures, which was reviewed by the inspector. The inspector was also informed that the individual carer or comforter was given the opportunity to ask questions about the medical exposure before the medical radiological procedure was performed, and the inspector saw that there was a form, to be signed by a care and comforter, which included information about the benefits and risk to them from a medical exposure of ionising radiation.

The inspector also observed that the management team had established and maintained a programme of quality assurance of the radiological equipment in use in the service, including regular performance testing by staff and annual checks of the equipment by the MPE. The inspector also saw that the equipment manufacturer and MPE were promptly informed of any equipment matters that required their consultation. They had also developed a programme of establishing and reviewing DRLs for each imaging modality, which assisted in ensuring that all service users attending the Department of Radiology, Beaumont Private Clinic received an

optimised radiation dose.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

The undertaking had developed a *Diagnostic Reference Level (DRL) Departmental policy*, which outlined the method and frequency by which DRLs were established and reviewed for each imaging modality in use in the service.

The inspector observed that DRLs for each modality had been reviewed, compared to national DRLs and approved by the MPE in January 2023. These DRLs were on display in each console area and staff who spoke with the inspector demonstrated an awareness of how to use them when completing medical exposures of ionising radiation.

Judgment: Compliant

### Regulation 14: Equipment

An inventory of the medical radiological equipment in use in the service was provided to the inspector in advance of this inspection.

From a review of RSC meeting minutes, the inspector noted that equipment QA and equipment replacement were discussed routinely at these meetings. From a review of QA records and other documentation, and from speaking with staff on the day of inspection, the inspector was assured that the undertaking had implemented and maintained a quality assurance programme for each piece of radiological equipment. The inspector was also satisfied that the equipment had undergone acceptance testing before first clinical use and had subsequently undergone regular quality assurance testing. Therefore, the inspector was satisfied that the medical radiological equipment was kept under strict surveillance by the undertaking.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

The inspector was satisfied that there was an established process to determine the pregnancy status of service users in the Department of Radiology, Beaumont Private Clinic. A review of a sample of service user records showed that radiographers took responsibility for inquiring on the pregnancy status of service users, and these

records were uploaded to their electronic health care record. The inspector also spoke with staff who outlined the process to be followed in the justification of a medical exposure where pregnancy could not be ruled out. In this scenario, re-justification would be recorded following review by the referrer and practitioner on a specific re-justification form. The management team had developed a *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* which outlined the steps to be followed in both processes, however as stated under Regulation 6 Undertaking above, the policy required review to ensure that it accurately represented who inquired on service users pregnancy status in practice.

During a tour of the radiology department, the inspector noted that improvements on the provision of information to women, with the aim of increasing their awareness to inform staff of their pregnancy status before undergoing a medical exposure, was required. The inspector observed that although there were multilingual posters in the CT and DXA scanning rooms, there were no posters displayed or information leaflets available in the general X-ray room, or in public waiting areas. This would be useful to raise the awareness of service users of the need for special protection during medical exposures while pregnant.

Judgment: Substantially Compliant

### Regulation 17: Accidental and unintended exposures and significant events

The undertaking had a system in place for the recording and review of any incidents and near misses, involving accidental or unintended exposures to ionising radiation, in the service. The RSM had introduced an electronic system which efficiently facilitated staff to submit any incidents or near misses electronically, and staff spoken with were able to clearly describe how they accessed and used this system.

From a review of documentation, the inspector observed that incidents were discussed at the RSC, which met at a minimum every 6 months. However, from discussions with the management team, the inspector was assured that the managing partner, as the undertaking representative, was made aware of any incidents as they occurred by both email and phone call.

The inspector followed up on a number of incidents that had been reported, as per the regulatory requirements, to HIQA. The inspector noted that each had been well managed and investigated, and where relevant learning and changes from such incidents was implemented to prevent future occurrences to other service users. For example, following one incident, the undertaking had installed a new information and communication technology system which improved the storage of image data. This improvement approach to incident management demonstrated good practice, which promoted the radiation safety of patients attending the service.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

# Compliance Plan for Department of Radiology, Beaumont Private Clinic OSV-0006059

Inspection ID: MON-0040173

Date of inspection: 27/06/2023

## 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:            We acknowledge that the policy documentation is not what it should be.            Firstly the pregnancy policy has been amended to change the responsibility of the referrer to discuss pregnancy with the patient. This has already changed to reflect our actual practise of it being the radiographer.            The protocols in DEXA, and General have now been assigned an author, approver and renewal date            We have had a discussion about improving the management of our documentation system. The decision has been that policies will have a review/renewal at 3 years. The responsibility for this renewal and the monitoring of the renewal dates will be the RSC where it will be a running item at every meeting            Policies that are reaching their expiration will be discussed at the meeting. The terms of reference for RSC has been amended to reflect this role and we will record on soft copy a list of all policies and their current renewal date in order to better plan.</p>	
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:            Pregnancy information posters have already been purchased are hanging in a visible area in the waiting area and General X-Ray</p>	





## 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	30/09/2023
Regulation 16(4)	Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to increase the awareness of individuals to	Substantially Compliant	Yellow	14/07/2023

	whom this Regulation applies, through measures such as public notices in appropriate places.			
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