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:	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:	09 February 2022
Medical Radiological Installation Service ID:	OSV-0006059
Fieldwork ID:	MON-0035036

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[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 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 doing, we describe the overall effectiveness of an undertaking in ensuring the quality and safe conduct of medical exposures. It examines how the undertaking provides the technical systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential

[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.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 9 February 2022	11:00hrs to 02:30hrs	Lee O'Hora	Lead

Summary of findings

An on-site inspection was conducted on the 9 February 2022 to follow up on the outcomes of an inspection on 19 May 2021 and a subsequent compliance plan update which was requested from the undertaking at the Department of Radiology, Beaumont Private Clinic in October 2021. This inspection was focused on regulations deemed substantially compliant or not compliant on the previous inspection to validate information received in the compliance plan update provided by the Department of Radiology, Beaumont Private Clinic.

On the day of inspection, marked improvements were noted in the engagement and involvement of key radiation safety personnel and greater oversight of medical radiological equipment. In addition, records and the documentation related to radiation safety practice had improved significantly since the previous inspection. For the regulations considered on the day of inspection, the inspector was satisfied that the undertaking had implemented the required improvements to ensure regulatory compliance with the delivery of medical exposures at the Department of Radiology, Beaumont Private Clinic.

Regulation 6: Undertaking

Extensive *Radiation Safety Procedures* had been developed and implemented by the undertaking since the first inspection. Governance structures and key radiation safety personnel, their responsibilities and communication pathways were clearly defined in documentation reviewed and articulated to the inspector by staff members spoken with on the day.

As seen on the previous inspection, a radiation safety committee (RSC) was incorporated into the governance structure. Minutes reviewed by the inspector demonstrated that the RSC had met in October and December 2021 and regulatory compliance had been included as a standing agenda point since the inspection in May 2021. For example the RSC had discussed quality assurance (QA) testing, justification record audits, diagnostic reference level (DRL) review, staff training and HIQA communications. The inspector was also informed that the RSC was due to meet in the coming week.

The role of the radiation protection officer (RPO), previously combined with the duties of the radiology services manager (RSM), had now been clearly defined in documents. The associated RPO responsibilities and formal engagement arrangements were well defined in a service level agreement (SLA) reviewed on site by the Inspector. The undertaking had engaged an individual to define, establish and undertake the role of the RPO from October 2021 to January 2022. At the time of inspection a new RPO had already been engaged by the undertaking ensuring the

continuity of this role.

The role of the medical physics expert (MPE) had been well defined and was aligned with regulatory requirements in both updated radiation safety procedure documentation and a SLA provided to the inspector. Improvements in the involvement of the MPE in the safe delivery of medical exposures are further discussed in Regulations 19, 20 and 21.

The inspector was satisfied that measures taken by the undertaking since the last inspection, namely the separation of RSM and RPO duties, introduction of a SLA with the MPE and increased oversight by the RSC ensured that any gaps in continuity of key radiation safety roles would not unduly effect the undertaking's ability to maintain regulatory compliance and demonstrated a clear allocation of responsibility for the protection of service users.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector was satisfied that the Department of Radiology, Beaumont Private Clinic developed and implemented a system to ensure that practitioner justification of all individual referrals was recorded. Staff spoken with on the day informed the inspector that the RPO was involved with the development, education of staff and audit of this system.

A *Justification in advance audit* was completed in January 2022 and supplied to the inspector, this demonstrated a compliance rate of 90% with the new system to ensure practitioner justification records. This audit was a standing agenda point of the RSC and the audit was due to be repeated and reviewed in April 2022.

After document review and speaking with staff the inspector was satisfied that the undertaking had adopted an approach ensuring the consistent recording of individual justification and was auditing its own compliance with the approach adopted addressing previous non-compliances with Regulation 8.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector noted a significant improvement in the undertakings approach to establishing, use and review of DRLs at the Department of Radiology, Beaumont Private Clinic. DRLs for dual-energy X-ray absorptiometry (DXA) scanning and general radiography were established and compared with national DRLs in line with

HIQA guidance.

Documents reviewed by the inspector detailed an audit schedule which included annual DRL reviews with the local facility DRLs being based on a representative sample of patient radiation doses. Responsibility for establishment, review and subsequent investigation, where necessary, was shared between the RPO and MPE. The updated documentation in relation to DRLs clearly reflected the operational processes and individuals involved, to establish, review and use DRLs.

Local facility DRLs for the pelvis and abdomen X-ray had not yet reached sufficient numbers to generate a local facility DRL but the inspector was informed that these procedures would be reassessed periodically until sufficient numbers had been reached. A schedule for DRL review for newly installed equipment, detailed under Regulation 14, was seen by the inspector during the inspection. CT DRLs were scheduled to be reviewed and established on 28 February 2022 and mammography data was scheduled to be reviewed on 7 March 2022 with the subsequent establishment of local facility DRLs.

Judgment: Compliant

Regulation 13: Procedures

Updated written protocols for every type of standard medical radiological procedure were established by the undertaking and reviewed by the inspector. Documents reviewed included protocol approval and review dates for CT, Mammography and DXA. However general radiography protocols, while reviewed and updated since the last inspection, did not include protocol approval or review dates. While this was not considered a non-compliance under Regulation 13(1) the inclusion of review dates would improve the undertakings ability to systematically update protocols as necessary and help to ensure that all medical radiological procedures were optimised. Management spoken with during the inspection acknowledged that this was an area for improvement and that it would be addressed as soon as possible.

Judgment: Compliant

Regulation 14: Equipment

The inspector reviewed the updated *Radiation Safety Procedures* which included a substantial section on equipment management and QA. This new documentation gave clear guidance of equipment fault logging, escalation pathways, escalation to service engineers where needed and associated responsibilities of all staff. This document was seen as a useful resource to facilitate the effective communication of all issues relating to equipment faults, maintenance and QA between relevant

parties. The inspector was informed that all staff working at the Department of Radiology, Beaumont Private Clinic were asked to read and sign the updated *Radiation Safety Procedures* and that this document was available to all staff in the clinical area.

The type and frequency of QA tests and responsible persons were also defined in documentation supplied. Annual QA for DXA and general radiography equipment was completed on the 9 July 2021 and 6 August 2021. Acceptance testing of new CT and mammography equipment installed in December and January respectively was also reviewed on the day of inspection. Provisional dates for future QA in addition to regular preventative maintenance by the manufacturer were supplied to the inspector on the day of inspection.

The inspector noted that RPO QA tests on general radiography equipment documented as 2 monthly tests were last completed on 21 October 2021 and were overdue. Staff informed the inspector that this was due to the recent transition of the RPO role. On the day of inspection the inspector was also informed that the MPE was scheduled to be on site on the 10 February 2022 to provide training for longstanding radiography staff to deliver 2 monthly RPO QA testing as a measure to ensure that this testing could be consistently delivered when the RPO was not available. While overdue RPO QA testing did not constitute a regulatory non-compliance at the time of inspection, the undertaking should ensure that QA testing schedules, as defined by local policy, are maintained.

The improved documentation, defined communication channels, records of MPE testing as well as fixed schedules for upcoming performance testing and preventative maintenance gave assurances that the radiological equipment at the Department of Radiology, Beaumont Private Clinic was kept under strict surveillance regarding radiation protection.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Following document review and after speaking with staff, the inspector was assured that the undertaking had made the necessary arrangements to ensure the continuity of expertise of the MPE. As indicated by the undertaking in a compliance plan provided following previous findings, a SLA formalised the engagement of the MPE until July 2022.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Professional registration of the MPE was reviewed and up to date on the day of inspection. The inspector also reviewed documentation which clearly defined the roles and responsibilities of the MPE. The documentation closely aligned with the responsibilities, advice and contributions required by Regulation 20 and was considered a marked improvement in the definition and formalisation of the role of the MPE at the Department of Radiology, Beaumont Private Clinic.

Staff spoken with on the day of inspection noted increased involvement of the MPE in areas relating to the application and use of DRLs, the definition and performance of QA and acceptance testing of equipment, the preparation of technical specifications for new equipment, and the training of practitioners at the Department of Radiology, Beaumont Private Clinic.

Judgment: Compliant

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

Following document review and after speaking with staff, the inspector was satisfied that the MPE involvement had improved since the last inspection and was now appropriate and commensurate with the radiological risk at the Department of Radiology, Beaumont Private Clinic.

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
Summary of findings	
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Compliant
Regulation 14: Equipment	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

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

Inspection ID: MON-0035036

Date of inspection: 09/02/2022

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**
Outline how you are going to come into compliance with :	

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