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:	Peamount Healthcare
Undertaking Name:	Peamount Healthcare
Address of Ionising Radiation Installation:	Peamount Road, Newcastle, Co. Dublin
Type of inspection:	Announced
Date of inspection:	25 July 2024
Medical Radiological Installation Service ID:	OSV-0008347
Fieldwork ID:	MON-0043748

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

Peamount Healthcare (Peamount) is an independent voluntary organisation based in Newcastle, Co Dublin, operating in partnership with the Health Service Executive (HSE), Community Healthcare Organisation (CHO) 7 and Dublin Midland Hospitals Group. The organisation is a provider of consultant-led in-patient and out-patient specialist rehabilitation services in respiratory, age-related healthcare, neuro-rehabilitation, rheumatology, residential services in intellectual disability, older person, neurological and community services in older person and disability.

The radiology department at Peamount provides a one room general radiology service (mainly chest and extremity examinations) using a direct radiography (DR) system. The service operates Monday to Friday 8.30 to 4.00pm. It supports both in-patient, out-patient and local general practitioner (GP) services. It is staffed by 1.5 working time equivalent (WTE), a Clinical Specialist Radiographer and a Senior Radiographer both sharing the radiation protection officer (RPO) role. Since June 2024 the service is available Monday, Wednesday and until 2.00pm on Fridays providing plain radiology service to inpatients and out-patients.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

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

About the inspection report

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

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

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 25 July 2024	09:30hrs to 13:50hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of Peamount Healthcare was carried out on the 25 July 2024 to assess compliance with the regulations. The X-ray facility consists of one general radiography (X-ray) room which was visited by the inspector.

The governance and management arrangements in place to ensure the safe delivery of medical exposures at Peamount Healthcare were reviewed on the day of inspection. The designated manager with responsibility for the radiation protection of service users was the director of rehabilitation. The designated manager reported to the chief executive officer (CEO), who in turn reported to the board of Peamount Healthcare.

The inspector reviewed a sample of referrals and spoke with staff and management at the facility on the day of inspection. From the evidence reviewed the inspector was satisfied that only referrals for medical radiological procedures from those who were entitled to refer had been carried out. Similarly, only those entitled to act as a practitioner had taken clinical responsibility for medical exposures. The facility was also found to have appropriate medical physics expert (MPE) involvement in line with the level of radiological risk.

However, the policies and procedures reviewed as part of the inspection where not fully aligned with the regulations and day-to-day practice in respect of the allocation of clinical responsibilities to persons entitled to act as practitioners. To ensure compliance with Regulation 6, the undertaking must ensure the the allocation of responsibility for the radiation protection of service users is clearly and consistently documented and reflective of day-to-day practice.

Overall, while some areas of improvement were identified on the day of inspection to achieve full compliance with the requirements of the regulations, the inspector was satisfied that governance and management arrangements were in place to ensure the safe delivery of medical exposures at Peamount Healthcare.

Regulation 4: Referrers

The inspector reviewed a sample of referrals for medical exposures that had been carried out and spoke with staff working at Peamount Healthcare. On the day of inspection, only referrals from registered medical practitioners for Peamount Healthcare service users were carried out at the facility.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed. The inspector also spoke with staff working at the facility and found that only persons entitled to act as a practitioner had taken clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The inspector spoke with staff and management working at Peamount Healthcare, and reviewed documentation and other records to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures.

The designated manger was the director of rehabilitation who reported to the CEO. The CEO reported in turn to the board of Peamount Healthcare. A Radiation Safety Committee (RSC) was in place which the inspector was informed reported into the Quality and Risk Committee. However, the diagram outlining the committee reporting structure (organogram) for Peamount Healthcare showed the RSC reporting to the clinical incident management committee. In order to ensure that reporting structures for radiation protection are clear for those working at the facility, the undertaking should ensure that documentation is consistent and accurately reflects the arrangements in place.

The inspector was satisfied that the allocation of responsibility to individuals in day-to-day practice was in line with the requirements of the regulations. For example, the different aspects of clinical responsibility were carried out by radiographers and radiologists. However, in some policies, the documentation of the allocation of responsibility was not in line with regulatory requirements and actual practice in the facility. For example, in the *Pregnancy status and the procedure to prevent and inadvertent ionising radiation exposure of the unborn child arising from medical diagnostic examination* and *Justification of Radiology Referrals Policy* the role of the practitioner was allocated to individuals not recognised as practitioners in the regulations.

In addition, allocation of responsibility for oversight of the conduct of clinical audit at Peamount Healthcare was not clearly documented in the clinical audit strategy provided to the inspector. This is discussed under Regulation 13:Procedures.

Overall, while areas for improvement to come fully into compliance with the requirements of the regulations were identified, the inspector was satisfied that sufficient governance and management arrangements were in place to ensure the

safe delivery of medical radiological procedures at the X-ray facility at Peamount Healthcare on the day of inspection.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and an MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that the referrer and practitioners were involved in the justification process for individual medical exposures. The practical aspects of medical radiological procedures were also found to be only carried out by radiographers at the facility, therefore meeting the requirements of the regulations.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was satisfied from communicating with staff, and a review of documentation, that adequate processes were in place to ensure the continuity of medical physics expertise at the facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and spoke with staff at the hospital and was satisfied that arrangements were in place to ensure that the involvement and contribution of an MPE was in line with the requirements of Regulation 20. For example, medical physicists were found to be involved in the quality assurance (QA) programme, dosimetry and the selection of equipment required to perform radiation protection measurements. In addition, the inspector found evidence of recent training provided by the MPE to practitioners at the facility, however the formalisation of training was identified as an area for improvement to ensure ongoing compliance.

Judgment: Compliant

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

On the day of inspection, the inspector was satisfied from the evidence reviewed that an MPE was appropriately involved at the X-ray facility in line with the radiological risk.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Peamount Healthcare.

Signage in the form of posters containing information about the benefits and risks associated with medical exposure to ionising radiation and to raise awareness of pregnancy were observed in the waiting area. The inspector was satisfied that a practitioner carried out an inquiry as to the pregnancy status of service users, where appropriate, and this inquiry was recorded in writing.

Written protocols were available for standard medical radiological procedures and diagnostic reference levels (DRLs) were found to be established for medical radiological procedures and were available for use by radiographers in the control area. The written procedures included exposure factors which was identified as good practice to facilitate the consistent acquisition of diagnostic information. All referrals reviewed as part of the inspection were in writing and accompanied by sufficient information. Staff working at the facility informed the inspector that a practitioner justified all medical exposures in advance and a record of justification in advance by a practitioner was found on all records reviewed on the day of inspection. Arrangements were found to be in place regarding recording incidents involving, or potentially involving accidental and unintended exposures to ionising radiation.

However, information relating to patient exposure was not included on all of the reports of medical radiological procedures reviewed on the day of inspection. Some gaps in compliance were also found regarding the implementation of the *National Procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* which were published by HIQA in November 2023.

The inspector reviewed documentation and records relating to the X-ray equipment at the facility and found that while a quality assurance (QA) programme was implemented, some gaps in regular performance testing were identified as testing equipment was not available due to annual calibration requirements as discussed in

Regulation 14: Equipment. An up-to-date inventory was provided in advance of the inspection as required by the regulations.

Subject to addressing the areas for improvement noted in this section to come into full compliance with the regulations, the inspector was satisfied that Peamount Healthcare had systems in place to help ensure the safe delivery of medical exposures to ionising radiation.

Regulation 8: Justification of medical exposures

The inspector observed information about the benefits and risks associated with the radiation dose from medical exposures in the form of posters and information leaflets in the X-ray waiting area.

Five referrals and relevant records were reviewed by the inspector who found that these were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. The inspector spoke with practitioners who explained how medical exposures were justified in advance and how this justification was recorded. A record of justification in advance by a practitioner was in place for all records reviewed. The facility's policy for referring and justifying medical exposures was also reviewed by the inspector as part of this inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation submitted in advance of the inspection and also spoke with staff and management, to determine how DRLs were established, used and reviewed at the X-ray facility at Peamount Healthcare. Peamount Healthcare's local facility DRLs were available for use in the control area of the X-ray room on the day of inspection.

Judgment: Compliant

Regulation 13: Procedures

The inspector found that written protocols were established for standard medical radiological procedures. These written protocols also included information about the exposure factors for standard medical exposures which was seen as an area of good

practice to facilitate the consistent production of diagnostic information, especially where new staff or where locum staff may be conducting medical exposures.

On the day of inspection, a sample of medical radiological procedures were reviewed and the inspector found that information relating to patient exposure did not form part of the report of these medical radiological procedures as required by Regulation 13(2).

The inspector reviewed Peamount Healthcare's implementation of HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*, which was published in November 2023, and found some gaps in compliance with Regulation 13(4). The undertaking's clinical audit strategy for medical radiological procedures was requested in advance of the inspection and Peamount Healthcare's *Clinical Audit Policy* was provided to the inspector. The *Clinical Audit Policy* states that it applies to the whole organisation and was the policy was last reviewed in May 2024. However, while this policy included most of the essential criteria as required by HIQA's national procedures, some elements specific to medical radiological procedures, such as focus and coverage, were not included.

Peamount Healthcare's *Clinical Audit Policy* placed oversight and responsibility for the clinical audits with the Clinical Audit and Research Oversight Committee. However, on the day of inspection, the inspector spoke with staff and management at the facility who communicated that clinical audits completed by the radiology department were not included in this committee but instead reported to the RSC. Management at Peamount Healthcare did describe the oversight and assurance arrangements in place for clinical audit to the inspector and these arrangements were not consistent with those included in the *Clinical Audit Policy*.

A schedule of clinical audits for 2024 was available for review in the radiographer's control area. However, this schedule should be reviewed to incorporate the essential elements of prioritisation to ensure oversight across the full clinical pathway in line with the requirements of the national procedures. Examples of clinical audits completed to date were also reviewed and the inspector noted that these used Peamount Healthcare's audit template from the *Clinical Audit Policy* which aligns with the requirements of the clinical audit cycle outlined in the national procedures.

In order to come into compliance with Regulation 13(4), Peamount Healthcare, as the undertaking, must have arrangements in place to assure themselves that the national procedures are implemented and maintained and that the oversight arrangements for clinical audit at the facility are clearly documented in Peamount Healthcare's clinical audit strategy document. In addition, Peamount Healthcare must ensure that the clinical audit strategy fully encompasses all essential elements.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory of medical radiological equipment was provided in advance of the inspection. The inspector was satisfied that a QA programme had been established which included an annual QA assessment by an MPE and regular maintenance by the equipment's manufacturer.

However, records reviewed as part of the inspection demonstrated that there were gaps in the conduct of routine performance testing by a radiographer in line with the frequency requirements as specified in the undertaking's QA programme. The inspector found that lack of availability of testing equipment due to calibration had resulted in weekly testing not being carried out for a period of time in 2024, with a gap also identified in 2023.

The testing equipment has recently been replaced which was seen as a positive step by Peamount Healthcare, however, the inspector was informed that future gaps in routine performance testing would still occur due to the need for the equipment to undergo annual calibration. As a result the undertaking should review its QA programme to ensure that contingency arrangements are put in place to prevent gaps in the conduct of routine performance testing to ensure that the QA programme is adequately maintained.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the X-ray waiting area at the facility. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations. The inspector reviewed a sample of referral records and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Peamount Healthcare was found to have a system in place to facilitate the reporting and recording of actual or potential accidental or unintentional exposures. The inspector spoke with staff and management about the process for reporting and oversight arrangements in place. On the day of inspection the inspector was

informed that no actual or potential accidental of unintended exposures have been reported recently at the facility.
Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Peamount Healthcare OSV-0008347

Inspection ID: MON-0043748

Date of inspection: 25/07/2024

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

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The Committee Reporting Structure; The Radiology organograms for governance and committee reporting within the organisation have been amended to reflect current practice. The Radiation Safety Committee reports directly to the organisations Quality and Risk Committee on all radiation safety events and incidents. The Radiology Department at Peamount Healthcare are aware of the changes in both organograms.	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The recording of x-ray exposures by radiologists on the x-ray reports is to be discussed at the next Radiation Safety Committee meeting on the 01/09/2024. The Clinical Director of Radiology has been informed of the non-compliance of standard 13 and a response is awaited to ensure compliance. The x-ray department is included in the organisational Clinical Audit policy following a review, aligned to the National Guidelines for Clinical Audits 2023. Clinical Audits for the department will be timetabled over 2024 and 2025.	

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The timing of the annual calibration of the dosimeter will be aligned to facilitate for any delays in the return of the dosimeter.

All locum staff will receive training in QA to avoid gaps in the testing procedures.

This has also been updated on the training policy for all radiography staff.

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	02/09/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Not Compliant	Orange	30/10/2024

	radiological procedure.			
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	02/09/2024
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	02/09/2024