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:	Portiuncula University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Dunlo, Ballinasloe, Galway
Type of inspection:	Announced
Date of inspection:	15 November 2023
Medical Radiological Installation Service ID:	OSV-0007371
Fieldwork ID:	MON-0040399

About the medical radiological installation:

Portiuncula University Hospital (PUH) is a Model 3 hospital providing 24/7 acute surgery, acute medicine, oncology and critical care along with Emergency Department and maternity services to adults and children in the catchment areas of East Galway, Westmeath, North Tipperary, Roscommon and Offaly. Portiuncula University Hospital, Ballinasloe, Co. Galway is part of the Saolta University Hospital Group and Galway University Hospital (GUH) is its main territorial referral hospital. The hospital has natural referral pathways to the Midlands, and the hospital's paediatric service has linkages with Crumlin Children's Hospital for shared care arrangements in relation to oncology. The hospital has 194 beds – 118 adult inpatient beds, 30 Maternity beds, 23 Paediatric inpatient beds, 17 adult day care beds and 6 oncology day care beds.

The PUH Radiology Department provides a multidisciplinary service including general X-ray from various referral sources. There are two general X-ray rooms, mobile radiography in ICU/CCU, SCBU, general theatre, ED Resus, and other wards. There are three mobile radiography machines. There are two computerised tomography (CT) units. MRI is provided by Alliance Medical. There is a day services theatre. There is two ultrasound machines. There is a multi-functional fluoroscopy/ interventional radiology suite for the following common procedures: barium studies, video fluoroscopy, IR procedures for e.g. palliative care, surgical, arthography and others. The hospital uses the National Integrated Medical Imaging System, (NIMIS) and Picture Archiving Communication System (PACS), linking all participating health facilities nationwide. There is evening and weekend on call services to inpatients and Accident and Emergency offering general radiography, mobile radiography, CT and ultrasound. PUH utilises a teleradiology company for CT emergencies each day from 20:00 until 08:00 and at weekends 17:00 to 09:00. A multi-disciplinary team of radiologists, radiographers, nurses, administrative staff, radiography assistants and portering provide these services. There are approximately 49,974 imaging exams undertaken per annum.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

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

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 15 November 2023	09:30hrs to 14:40hrs	Noelle Neville	Lead
Wednesday 15 November 2023	09:30hrs to 14:40hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

An inspection of Portiuncula University Hospital was carried out on 15 November 2023 by inspectors to assess compliance with the regulations at the facility. As part of this inspection, inspectors visited the general X-ray and computed tomography (CT) units, spoke with staff and management and reviewed documentation. Inspectors noted that the undertaking, the Health Service Executive (HSE), demonstrated compliance during this inspection with Regulations 4, 5, 6, 8, 10, 11, 14, 16, 19 and 21, substantial compliance with Regulations 17 and 20 and were not compliant with Regulation 13. Inspectors also followed up on the compliance plan from the previous inspection carried out in February 2020 and noted that the majority of actions identified had been completed.

Inspectors noted that there was a clear allocation of responsibilities for the protection of service users from medical exposures to ionising radiation at Portiuncula University Hospital. Inspectors noted involvement in, and oversight of, radiation protection by the hospital's medical physics expert (MPE) across a range of responsibilities. Inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer and only individuals entitled to act as practitioner took clinical responsibility for medical radiological exposures.

Overall, inspectors were satisfied that a culture of radiation protection was embedded at Portiuncula University Hospital and clear and effective management structures were in place to ensure the radiation protection of service users.

Regulation 4: Referrers

A document titled *Guideline on Justification, Optimisation and Patient Protocols*, the most recent version of which was published in November 2021, was in place at Portiuncula University Hospital. This document outlined who was entitled to make a referral for a medical radiological exposure at the hospital. Inspectors were satisfied from discussions with staff and management and from reviewing a sample of referrals that medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at Portiuncula University Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms (organisational charts that show the structure and relationships of departments in an organisation) and spoke with staff and management in relation to governance arrangements in place at Portiuncula University Hospital.

Portiuncula University Hospital had a radiology directorate quality and safety committee. This committee was incorporated into local governance structures, reporting to the hospital's general manager who in turn reported to the Saolta University Health Care Group. This committee incorporated a radiation safety committee (RSC), radiation protection unit (RPU) and radiology directorate incident review group. Inspectors reviewed the terms of reference for the quality and safety committee and noted that the RSC sub-group meets four times a year and had a multi-disciplinary membership including radiologists, a radiation protection advisor, a radiation safety officer, a medical physics expert and a radiography services manager. The RPU sub-group met monthly and was responsible for operational issues relating to radiation protection and its membership included a radiation protection adviser, medical physics expert, radiography services manager and radiation safety officer.

Overall, inspectors were satisfied that the undertaking, the Health Service Executive, had clear and effective governance and management structures in place to ensure the radiation protection of service users and a culture of radiation protection was embedded at the hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors noted that all medical exposures were found to take place under the clinical responsibility of a practitioner, as defined in the regulations. The practical aspects of medical radiological exposures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations. Practitioners and the

MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Since the previous inspection in 2020, a formal arrangement had been put in place and documented in the form of a service level agreement in relation to the continuity of medical physics expertise at Portiuncula University Hospital. Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Portiuncula University Hospital and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). Inspectors noted MPE involvement in radiation protection across a range of responsibilities outlined in Regulation 20(2) at the hospital. The MPE was a member of the hospital's radiation safety committee and radiation protection unit. The MPE gave advice on medical radiological equipment, contributed to the definition and performance of a quality assurance programme and acceptance testing of equipment. The MPE was involved in optimisation, including the application and use of diagnostic reference levels (DRLs). In addition, the MPE carried out dose calculations for any incidents relating to ionising radiation. While inspectors found that the MPE contributed to the training of some staff members in relevant aspects of radiation protection, not all practitioners had not been included in this training and so did not fully meet the requirements of Regulation 20(2)(c). Inspectors noted that the MPE liaised with the hospital's radiation protection adviser and so met the requirements of Regulation 20(3).

Judgment: Substantially Compliant

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

Despite the improvement required in training noted in Regulation 20, inspectors were satisfied that the level of MPE involvement at the hospital was commensurate with the radiological risk posed by the facility as required by Regulation 21.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors visited the general X-ray and CT units at Portiuncula University Hospital, spoke with staff and management and reviewed documentation to assess the safe delivery of medical exposures at the hospital. While Regulations 8, 11, 14 and 16 were compliant, inspectors noted that there was further work required to bring Regulations 13 and 17 into compliance.

In relation to Regulation 13(1), inspectors found that there was scope for improvement in relation to having written protocols for each standard procedure in theatre. In relation to Regulation 13(2), inspectors found that information relating to the patient exposure formed part of the report for approximately half of the records reviewed. The undertaking, the Health Service Executive, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

In relation to Regulation 17, inspectors noted that improvements were required in meeting the three day timeline to notify HIQA of reportable incidents to meet the requirements of Regulation 17(1)(e). In addition, inspectors determined that there was potential scope for improvement in relation to the identification and reporting of potential incidents, analysis and learning in the context of the relatively high number of procedures taking place at the hospital each year and the low levels of incidents and near misses being reported.

Overall, noting that improvements were required to bring Regulations 13 and 17 into compliance, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors were satisfied that all referrals were in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the benefits and risks of the medical exposure. Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users and displayed on posters throughout the facility. Information leaflets were also available to service users and

included a quick response (QR) code which linked to an online video with information explaining radiation dose.

A document titled *Guideline on Justification, Optimisation and Patient Protocols*, the most recent version of which was published in November 2021, was in place at the hospital. While this document included some detail on the justification process in place at the hospital, inspectors determined that there was scope to include further detail of the steps taken to justify a medical radiological procedure for each modality used at the hospital. Since the previous inspection in 2020, inspectors found that staff at the hospital had implemented measures to comply with Regulations 8(8) and 8(15). Inspectors reviewed a sample of records in general X-ray and CT and noted that justification in advance was recorded for all exams reviewed as required by Regulation 8(8) and Regulation 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

A document titled *Guideline for the Establishment and the use of Diagnostic Reference Levels in the Radiology Department*, the most recent version of which was published in February 2022, was in place at Portiuncula University Hospital. This document set out the responsibilities of staff in respect of diagnostic reference levels (DRLs) and also the method for establishing and using DRLs. It stated that local DRLs are usually reviewed annually in collaboration with medical physics and may be audited more frequently in cases where new equipment, techniques or procedures are introduced. Inspectors found that local DRLs had been established, regularly reviewed and used, having regard to national DRLs for general X-ray and CT at the hospital as required by Regulation 11(5) and DRLs for fluoroscopy were awaiting sign-off by the hospital's MPE. DRL charts were displayed in each clinical area and staff spoken with demonstrated an awareness of how to use DRLs when carrying out medical exposures to ionising radiation.

Judgment: Compliant

Regulation 13: Procedures

While written protocols were in place at Portiuncula University Hospital for standard general X-ray and CT radiological procedures as required by Regulation 13(1), inspectors found that there was scope for improvement in relation to having written protocols for each standard procedure in theatre.

Referral guidelines were adopted at the hospital and were available to staff and referrers as required by Regulation 13(3). In addition, inspectors noted a range of

clinical audits which were ongoing and complete at Portiuncula University Hospital. These audits included triple identification, public knowledge and perception of ionising radiation and CT pulmonary scan referral appropriateness.

Regulation 13(2) states that an undertaking shall ensure information relating to the patient exposure forms part of the report of the medical radiological procedure. Since the previous inspection in 2020, inspectors noted that some improvements had been made in relation to meeting the requirements of Regulation 13(2). Inspectors reviewed a sample of reports for general X-ray and CT medical radiological exposures and found that information relating to the patient exposure formed part of the report for approximately half of the records reviewed. Inspectors were informed that a technical solution to include information relating to the patient exposure on the report was in the process of being implemented in the hospital at the time of the inspection. The undertaking, the Health Service Executive, should ensure that information relating to the patient exposure forms part of the report of the medical radiological procedure to ensure full compliance with Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at Portiuncula University Hospital as required by Regulation 14(1). Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for equipment as required by Regulation 14(2). There was a policy in place at the hospital titled *Physics Radiology QA Programme for PUH* which set out the quality assurance tests required and the frequency of tests for each modality in use. Inspectors reviewed records of regular performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

A document titled *PPG for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* was in place at Portiuncula University Hospital, the most recent version of which was published in May 2022. This policy included information on the pregnancy procedures in place at the hospital including the practitioner and referrer role in ensuring that all

reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age. From a sample of records reviewed, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in the waiting areas of the facility to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents that an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures was implemented at Portiuncula University Hospital. The incident management process in place at the hospital was outlined in a document titled *Guideline for Accidental and unintended exposures and significant events in the Radiology Department*, the most recent version of which was published in November 2021. This document included information on the requirement to notify HIQA of certain reportable incidents and the timeframe for completing same. Inspectors noted that of the five incidents reported to HIQA since the commencement of the regulations, three of these were outside of the required timeline of three working days and as a result did not meet the requirements of Regulation 17(1)(e). In addition, inspectors determined that there was potential scope for improvement in relation to the identification and reporting of potential incidents, analysis and learning in the context of the relatively high number of procedures taking place at the hospital each year and the low levels of incidents and near misses being reported.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially 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	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Portiuncula University Hospital OSV-0007371

Inspection ID: MON-0040399

Date of inspection: 15/11/2023

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 20: Responsibilities of medical physics experts	Substantially Compliant
Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: The Medical Physics department has established and is actively providing an on-line training programme for Radiologists. Notifications have been sent to practitioners to adhere with the requirements as outlined in Regulation 20. This will ensure our compliance with Regulation 20(2)(c).	
Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Regulation: 13(1). Updated PPPG has been developed, finalised and operationalised in relation to written protocols for each procedure in theatre. These have been disseminated to all stakeholders and supporting audits will be undertaken to ensure compliance with same. Regulation: 13(2). At time of inspection, the site was actively updating and implementing the information relating to patient exposure as part of the medical radiological procedure report. On the date of inspection, 50% of reports reviewed by the inspectors noted compliance. Since this date of inspection, the site has undertaken measure the ensure 100% compliance with this specific regulation.	

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

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
In order to ensure full compliance by the site in adherence with the set timeframe to notify HIQA (3 days) of an adverse patient exposure event, an education programme has been developed. This programme outlines the procedures to be undertaken once the practitioner is aware that an adverse event has occurred. This programme will be presented on a cyclic basis to all practitioners.

In order to improve compliance with the "identification and reporting of potential incidents, analysis and learnings", the site have collaborated with medical physics to develop a program to support same. A QR code repository have been developed to support practitioners in reporting incidents and near miss events. The program allows for all data to be extrapolated to support trend analysis and review.

All incidents and near miss events will also be submitted on the National Incident Management System as per the sites requirement. Incident review meetings will be conducted regularly and supported by the Quality and Patient Department to review all submissions. Local quality improvement plans will be initiated and implemented by the radiology department as required.

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 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	09/01/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Red	09/01/2024
Regulation 17(1)(e)	An undertaking shall ensure that the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose,	Not Compliant	Orange	16/01/2024

	and			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially	Substantially Compliant	Yellow	30/01/2024

	involving, accidental or unintended medical exposures; (vii) the selection of equipment required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			