



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	UPMC Whitfield Hospital Limited
Undertaking Name:	UPMC Whitfield Hospital Limited
Address of Ionising Radiation Installation:	Cork Road, Waterford
Type of inspection:	Announced
Date of inspection:	12 November 2024
Medical Radiological Installation Service ID:	OSV-0007190
Fieldwork ID:	MON-0040996

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

UPMC is an international, not for profit healthcare organisation, which operates 40 hospitals across the world. The UPMC Ireland Group also operates UPMC Aut Even, UPMC Kildare, UPMC Sports Surgery Clinic Santry, UPMC Outreach Centre Carlow and Hillman Cancer Centre Cork in joint venture with Bons Secours Hospital Cork. UPMC are committed to providing excellent cancer care close to home for our patients.

UPMC Whitfield Hospital has 88 inpatient beds with over 50 expert consultants working across a range of specialities including cardiology, orthopaedics, oncology, radiology, gynaecology, urology and general surgery.

UPMC Whitfield Hospital Radiology Department offers state-of-the-art diagnostic imaging services that include MRI, X-ray, ultrasound, and CT/ PET-CT, DEXA and Fluoroscopy imaging to both inpatients and outpatients. The outpatient department operates Monday to Friday 8am-7pm (MRI) and all other Departments 8am-5pm with an On call service in place from 5pm for Xray and theatre emergencies.

UPMC Whitfield Hospital Ltd trading as UPMC Hillman Cancer Centre is located in Co. Waterford on the campus of UPMC Whitfield Hospital. The UPMC Hillman Cancer Centre provides radiotherapy services to both public and private patients in the South East under a service level agreement with the HSE. The UPMC Hillman Cancer Centre which opened in 2006, operates Monday to Friday 8am-8pm. There is an out of hours service available at the weekend for emergency patients. The department has two Varian linear accelerators, while brachytherapy is provided in a theatre within the hospital. The department provides radiotherapy services including CT simulation, treatment planning and treatment delivery for patients undergoing external beam radiotherapy. Advanced modalities such as VMAT/IMRT, IGRT and respiratory gating are provided within the centre. Brachytherapy treatments are also provided. The department continues to grow with the replacement of the our linear accelerators completed during the past 12 months. The department achieved Ambulatory Care JCI Accreditation again in November 2023.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

¹ 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
Tuesday 12 November 2024	09:15hrs to 16:50hrs	Emma O'Brien	Lead
Tuesday 12 November 2024	09:15hrs to 16:50hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the radiotherapy and radiology departments at UPMC Whitfield Hospital Limited was completed on 12 November 2024 to follow up on the compliance plan actions from the previous inspection of the radiotherapy service on the 11 May 2021 and to also assess the undertaking's ongoing compliance with the regulations. As part of this inspection, the inspectors reviewed documentation, spoke with staff and management, and visited the clinical areas in the radiotherapy and radiology departments.

The radiology department at UPMC Whitfield Hospital Limited consists of two general X-ray units, one mobile X-ray unit, three mobile fluoroscopy units, an interventional cardiology unit and one computerised tomography (CT) unit. The department also has a PET/CT scanner which is in the process of being replaced and at the time of this inspection there were no PET/CT procedures being conducted at this facility. In the radiotherapy department there were two linear accelerators and shared access to the radiology CT scanner for CT planning scans.

During the previous inspection of the radiotherapy service in May 2021 inspectors found that radiation safety documentation required updating to reflect practice. While inspectors saw evidence that some documentation had been updated, further improvements are required in both the radiotherapy and radiology services to ensure that documentation clearly defines the allocated roles and responsibilities of staff, and is aligned with day-to-day practice in the services and current regulatory language.

From a review of documents and from speaking with staff on the day of the inspection, inspectors were satisfied that the undertaking, UPMC Whitfield Hospital Limited, had appropriate forums in place for the oversight of the radiation protection of service users, with effective pathways established to communicate any issues from the day-to-day operations in the facility up to the undertaking.

Inspectors were satisfied that appropriate persons, as per the regulations, were involved in referring for medical exposures completed in both the radiotherapy and radiology services. Inspectors were also satisfied that only those entitled to act as practitioner, as defined in Regulation 5, were taking clinical responsibility for medical exposures. Although many of the roles and responsibilities relating to radiation protection had been allocated within the service, inspectors identified some gaps in the allocation of responsibilities that should be addressed by the undertaking. This is further discussed under Regulations 6 and 10 within this report.

After speaking with staff and reviewing radiation safety related documentation and records, the inspectors were assured that the responsibilities, advice and contributions of the medical physics experts (MPE) were commensurate with the

services provided by UPMC Whitfield Hospital Limited and satisfied the requirements of the regulations.

Overall, despite a few areas noted for improvement to meet regulatory compliance the inspectors were satisfied that the undertaking had implemented and maintained effective governance and management arrangements for the radiation protection of service users at UPMC Whitfield Hospital Limited.

Regulation 4: Referrers

Inspectors found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at UPMC Whitfield Hospital Limited. In the radiotherapy department, referrals were only accepted from appropriately registered medical practitioners, and from radiation therapists for adapted and modified referrals. While in the radiology department, referrals were only accepted from appropriately registered medical practitioners, and from radiographers for adapted and modified referrals.

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 UPMC Whitfield Hospital Limited. In the radiotherapy department, radiation oncologists and radiation therapists acted as practitioners, while in the radiology department this role was allocated to radiologists, cardiologists and radiographers.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that the undertaking had established governance and management arrangements, which provided oversight of the radiotherapy and radiology services at UPMC Whitfield Hospital Limited. While separate governance arrangements were established for each of the services, the inspectors were satisfied that these arrangements provided effective oversight and support. Within each service there were regular staff huddle meetings and multidisciplinary forums responsible for the day-to-day operations of the service, and any issues arising from these meetings were escalated to the radiation safety committees (RSC). Each

service had their own RSC and both were chaired by the chief operating officer, who reported directly to the undertaking representative. From a review of meeting minutes inspectors were satisfied that the required multidisciplinary personnel attended each meeting and items such as equipment quality assurance (QA), incidents, clinical audit and radiation protection training were discussed at both meetings. The MPEs for both services attended both RSC meetings, as well as the general manager for the hospital who was the designated manager for the radiology service, and the director of oncology services who was the designated manager for the radiotherapy service.

As discussed under Regulations 4, 5 and 20 in this report, individuals allocated with roles and responsibilities met the regulatory requirements. However despite these arrangements, inspectors noted that further action was required to ensure that all aspects regarding the allocation of responsibility aligned with the regulations, and were documented in the relevant documentation. For example; from a review of service users' records inspectors noted that for a sub-set of fluoroscopy exposures the undertaking had not allocated responsibility for the clinical evaluation of the outcome of the exposure to a practitioner. This is further discussed under Regulation 10. Also, in the radiology service there was no allocation of responsibility for the justification of new practices.

From a review of documentation, inspectors also noted that a number of documents in both the radiotherapy and radiology services required review and update to ensure that radiation safety documentation reflects day-to-day practice and regulatory language. For example, on the day of the inspection the inspectors viewed a range of patient records, including a sample from each of the different modalities in the radiology department. While the justification process in each modality was different, inspectors were satisfied that each justification process met the requirements of Regulation 8. However, the different justification processes were not outlined in any documentation viewed by the inspectors on the day of the inspection. Also, the radiation safety procedure document for the radiotherapy service states that the referrer, practitioner or others delegated responsibility shall enquire about pregnancy. Regulation 16 requires that only the referrer or practitioner can make this enquiry and while inspectors were satisfied that the day-to-day practice in the facility complied with this regulation, the documentation should be updated to reflect this. On the day of the inspection, the management team informed the inspectors that there was no delegation of practical aspects in either the radiotherapy or radiology services, however, inspectors viewed documentation, including the *Roles and Responsibilities of the Referrer, Operator and Practitioner in Radiology* that allocated responsibilities to 'operators', who were defined as radiographers undertaking the practical aspects of a medical exposure. While inspectors were satisfied that staff spoken with on the day of the inspection understood their roles and responsibilities in the radiation protection of service users, the undertaking should ensure that all radiation safety documentation is reviewed and updated to reflect the day-to-day practice in both services in order to assist and support staff in carrying out their duties.

While improvements are required in the allocation of roles and responsibilities in some areas of the service, and in the documentation to support staff in these roles,

inspectors were satisfied that many good processes were in place to ensure that service users received safe exposures of ionising radiation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From discussions with staff and a review of a sample of patient records and other documents, inspectors were satisfied that both referrers and practitioners were involved in the justification of individual medical exposures in both the radiotherapy and radiology departments. Similarly, inspectors found evidence in both departments that practitioners and MPEs were involved in the optimisation process for individual medical exposures as required by Regulation 10.

Inspectors noted that the majority of medical exposures, including radiotherapy treatments, general X-ray, CT, interventional cardiology and some fluoroscopy exposures took place under the clinical responsibility of a practitioner as defined in the regulations. However, from discussions with the management team and a review of radiology reports, inspectors noted that for a sub-set of fluroscopy medical exposures the clinical evaluation of the outcome was not completed by a practitioner. In order to reach full compliance with Regulation 10(1) the undertaking must ensure that all aspects of clinical responsibility for all medical exposures are allocated to a practitioner.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at UPMC Whitfield Hospital Limited. In the radiotherapy department the undertaking had engaged a team of MPEs and inspectors were informed that physics staff, employed in the service, were in a training programme to become MPEs, which positively supported ongoing MPE continuity arrangements and the radiation protection of service users in the service. In addition, one MPE was available in the radiology department and inspectors were informed that a service level agreement (SLA) was in place with an external company to ensure continuity of MPE expertise for the radiology service. The evidence seen by inspectors on the day of the inspection provided assurance that the undertaking had appropriate systems in place to ensure the involvement and contribution of MPEs at UPMC Whitfield Hospital Limited as per regulatory requirements.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of the MPEs engaged by the undertaking to provide specialist advice, as appropriate, on matters relating to radiation physics which met the requirements of Regulation 20(1). Evidence viewed in documentation, and discussions with the undertaking's management team and the medical physicists, demonstrated that the MPEs fulfilled a range of responsibilities as per Regulation 20(2) relevant to the service. For example, inspectors noted that the MPEs were responsible for dosimetry and advising on the dose calculation for radiation incidents in both departments. They were also involved in the quality assurance and acceptance testing of medical radiological equipment, and in the selection of new equipment, for example, the new linear accelerators in the radiotherapy department and the new PET/CT scanner in the radiology department. The MPEs from both departments also outlined their roles in the training of practitioners and other staff in relevant aspects of radiation protection.

Judgment: Compliant

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

Inspectors were satisfied that the level of MPE involvement was commensurate with the radiological risk posed by the medical radiological practices, in both the radiology and radiotherapy departments, at UPMC Whitfield Hospital Limited.

Judgment: Compliant

Safe Delivery of Medical Exposures

During the course of the inspection, inspectors observed that the undertaking had implemented many effective processes and procedures in both the radiology and the radiotherapy departments that ensured the radiation protection of patients and the safe delivery of medical exposures.

During the previous inspection in May 2021 the inspectors found that not all equipment QA checks were up-to-date. During this current inspection inspectors were satisfied that the undertaking had implemented effective improvement actions, as detailed in the previous compliance plan, in response to this finding as all QA

records viewed by inspectors were up-to-date and signed off by the appropriate personnel.

From speaking with staff and a review of a sample of referrals in both the radiotherapy and radiology services, inspectors were assured that all referrals for medical exposures were in writing, contained the reason for the requests and were accompanied by sufficient medical data. From this review, inspectors were also satisfied that procedures were justified in advance, by a person entitled to take clinical responsibility for justification.

Inspectors saw many examples of good optimisation practices in both departments, including the use and regular review of diagnostic reference levels (DRLs), the implementation of appropriate equipment QA programmes and the use of site-specific protocols when conducting medical exposures. Inspectors observed good processes in place regarding the inquiring and recording of patients' pregnancy status and the management team had made good efforts to create a culture of incident awareness and reporting in the service.

Inspectors noted that action was required by the undertaking to achieve full compliance with Regulation 13(2), as dose information was not available on the patient reports for one sub-set of fluoroscopy exposures completed in the service. This is further discussed under Regulation 13 below. Additionally, while paediatric procedures represented a very small percentage of the total procedures carried out in this facility, the undertaking should consider displaying relevant national DRLs in the clinical area, and developing written protocols for these non-standard procedures to assist staff in the radiation protection of this cohort of patients.

Overall, inspectors were satisfied that the undertaking had good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users in UPMC Whitfield Hospital Limited.

Regulation 8: Justification of medical exposures

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

In the radiotherapy department inspectors were informed that, during the initial consultation with the radiation oncologist, enquiries were made to determine if a patient had completed previous radiotherapy treatment. Where relevant, this treatment information was obtained and considered in the treatment planning

process as a key radiation protection measure. Inspectors were also informed that new patient consent forms were being implemented in the radiotherapy department. Inspectors were informed that these new forms were site specific and the aim of their implementation was to ensure that patients are fully informed when consenting to a course of radiotherapy treatment. This initiative was identified by inspectors as an area of good radiation protection within the service.

Prior to the inspection, inspectors reviewed the *Policy and Procedure on Time Out Procedures (Final Active Verification)* which outlined roles and responsibilities of staff involved in the justification process along the different stages of the radiotherapy treatment pathway. Inspectors were informed that the radiation oncologist justifies the patients radiotherapy CT planning scan by electronically signing a treatment request form. Similarly, by reviewing and electronically approving the final treatment plan, the radiation oncologist justified the radiotherapy treatment course in advance. In advance of delivering daily radiotherapy medical exposures, radiation therapists completed a series of checks such as reading updated medical notes and checking the patient's treatment position with verification imaging. Again, these checks were electronically documented on a daily treatment record with the initials of the two radiation therapists who had responsibility for justifying the procedure.

In the radiology department inspectors found evidence that all medical radiological procedures were justified in advance by an individual entitled to act as a practitioner. As part of the inspection a sample of patient records were reviewed and inspectors found that a record of this justification was available for review. Inspectors were also assured that UPMC Whitfield Hospital Limited had measures in place to provide patients attending the radiology department with adequate information about the risks and benefits, relevant to the level of radiological risk involved in the procedure, through the use of posters and information leaflets in the waiting areas. While meeting the requirements of this regulation the undertaking should ensure that policies and procedures are updated to include the justification process for each modality to provide clarity for all staff involved in the justification process, as discussed under Regulation 6.

Judgment: Compliant

Regulation 9: Optimisation

From discussions with staff and a review of documents, inspectors were satisfied that the undertaking had implemented a number of measures to ensure that all doses due to medical exposures are kept as low as reasonably achievable in both the radiotherapy and radiology services in UPMC Whitfield Hospital Limited.

Inspectors were informed that a very small number of diagnostic procedures were performed on paediatric patients per year and that these exposures were individually optimised by using weight and height measurements for this cohort of patients. The undertaking should consider, as an area for improvement, displaying

national DRLs for paediatric procedures in the clinical area and also developing written paediatric protocols for these non-standard procedures, to assist staff in completing these exposures.

Inspectors were assured from the evidence gathered during this inspection that radiotherapy treatments were individually planned, their delivery appropriately verified taking into account that doses to surrounding normal tissues are as low as reasonably achievable and consistent with the intended outcome of the course of treatment. Staff in the planning CT unit described how they optimised each CT exposure through the use of immobilisation equipment, and specific scanning protocols for each treatment site. Staff also informed inspectors that the doses from CT planning scans were recorded for each patient's CT planning scan in order to monitor these doses and ensure that they were kept as low as possible while providing adequate information for treatment planning. Inspectors spoke with staff in the radiotherapy planning department who explained that all treatment plans were individually planned to deliver the prescription dose to the treatment area and to keep doses to surrounding normal tissues as low as possible. Staff explained to inspectors that prior to treatment commencing QA checks were completed on all radiotherapy plans to provide additional assurances that doses to the treatment area would be delivered as prescribed. The processes used to ensure medical exposures are verified before proceeding with treatment were outlined in documentation reviewed by inspectors, with details of the type and frequency of imaging used to guide and verify treatment for each treatment site outlined in the *Verification Imaging for Radiation Therapy* document which was easily accessible by staff on the treatment units.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors viewed the *Dose Reference Level Values Establishment and Review Policy and Procedure* and the *Dose Reference Levels* policy which included information on the development and use of local facility DRLs in both the radiotherapy and radiology departments.

Inspectors found that local DRLs for radiodiagnostic examinations and interventional radiology procedures were established and compared to national levels, and were used in the optimisation of medical radiological procedures as required by Regulation 11(5). In the radiotherapy department inspectors noted that the undertaking had established DRLs for CT planning scans to monitor scan doses to ensure that any high dose scans were identified and investigated. This was identified as an area of good practice in the service.

In both departments, DRL charts were displayed in the clinical areas and staff who spoke with inspectors demonstrated an awareness of how to use DRLs when carrying out medical exposures to ionising radiation. Inspectors were informed that

when a local facility DRL exceeded national values a multidisciplinary team was involved in the associated investigation and the implementation of corrective actions.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at UPMC Whitfield Hospital Limited for standard radiological examinations as required by Regulation 13(1), and were readily available to practitioners in the clinical areas in both the radiotherapy and radiology departments. Additionally, inspectors were satisfied that referral guidelines for medical imaging were available to referrers in both departments.

Inspectors spoke with staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. In the radiotherapy department, inspectors observed that a discharge letter was generated after each patient completed their radiotherapy treatment which included information on the treatment dose received by the patient. In the radiology department inspectors reviewed a sample of reports for general X-ray, CT, interventional cardiology and fluoroscopy procedures and found that information relating to the patient exposure formed part of the report for each modality, with the exception of a small cohort of fluoroscopy procedures. The undertaking should ensure that information relating to the patient exposure forms part of the report of all medical radiological procedures to ensure full compliance with Regulation 13(2).

In advance of this inspection inspectors viewed the *Quality Improvement and Patient Safety Programme* and the *Radiology Clinical Audit Strategy* documents which outlined the clinical audit strategies in both the radiotherapy and radiology departments. While different clinical audit strategies were implemented in the radiotherapy and radiology departments, inspectors were satisfied that they both aligned with the *National Procedures for Clinical Audit of Medical Radiological Procedures* developed by HIQA. Inspectors saw evidence that both strategies considered the nine principles and essential criteria that undertakings must consider when developing their clinical audit strategy. Each strategy also identified appropriate governance and management structures for clinical audit and had allocated specific resources to ensure that the clinical audit programme was implemented and maintained.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at UPMC Whitfield Hospital Limited was provided to HIQA in advance of this inspection. Inspectors noted that a number of improvements in relation to equipment QA had been implemented since the previous inspection and were satisfied that medical radiological equipment was kept under strict surveillance as required by Regulation 14(1). A number of documents including the *Radiotherapy Equipment Quality Assurance Programme* and the *Radiology Quality Assurance Program* outlined the QA programme in place in both the radiotherapy and radiology departments. These documents outlined the checks involved and the frequency of testing for each piece of equipment and also assigned responsibility to staff for completing these checks. Inspectors viewed a sample of QA records for equipment in the radiotherapy and radiology departments and were satisfied that the QA programmes outlined in documentation was implemented. From discussions with staff and a review of documentation inspectors were assured that there was appropriate oversight by the undertaking of all completed testing.

Judgment: Compliant

Regulation 15: Special practices

In the radiotherapy department inspectors were informed that a multidisciplinary radiotherapy team met weekly to review all treatment plans in advance of treatment commencing. This meeting was attended by radiation oncologists, radiation therapists, MPEs and nursing staff. This forum provided staff with an opportunity to proactively plan for patients starting radiotherapy treatment and to discuss any complex cases, and was identified by inspectors as one of many examples of good multidisciplinary collaboration in the radiotherapy department. Inspectors observed that the multidisciplinary team had also implemented a number of appropriate measures to ensure that patients receiving high dose medical exposures were appropriately protected. For example, staff in the planning CT unit informed inspectors how, for some cohorts of patients, they completed a short scan in order to assess that preparation was optimal, before proceeding with a more comprehensive CT scan. This initiative was seen as an example of good practice in the radiation protection of service users in the department. Inspectors were also informed that 'time-out' processes were in place at CT and at the treatment units prior to treatment delivery. These time-outs prompted staff to check that key radiation protection measures were in place before they completed a medical exposure. Staff in the radiotherapy treatment planning department informed inspectors that specific planning protocols were used for each treatment site to ensure the doses to normal tissues are kept as low as possible while delivering the prescribed dose to the treatment area. Also, inspectors were informed that additional patient specific quality assurance (PSQA) checks were used to verify dose delivery for complex cases in advance of the first treatment.

Inspectors reviewed policies and procedures used in the interventional radiology department to identify potential high skin doses in patients undergoing cardiac

interventional procedures. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses as part of their procedure. Staff spoken with clearly articulated the practical application of these policies in clinical practice.

Inspectors were satisfied that UPMC Whitfield Hospital Limited had given special attention to appropriate radiation protection practices for patients receiving high dose procedures.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, inspectors observed multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation in public areas of the radiotherapy and radiology departments.

In the radiotherapy department radiation therapists, as practitioners, had been allocated responsibility for carrying out the inquiry of patients' pregnancy or breastfeeding status, where relevant, in line with the regulations. Inspectors reviewed a sample of records for medical exposures and found that an inquiry regarding the pregnancy and breastfeeding status of the patient took place, where relevant, prior to CT scanning and again on the first day of treatment prior to the medical exposure being completed. All enquires were recorded in writing in the patients electronic healthcare chart.

From a sample of records reviewed in the radiology department, inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users, where applicable, and recorded the answer to this inquiry in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident summary reports, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility.

Inspectors spoke with a number of staff who clearly described the incident reporting processes in the radiotherapy and radiology departments which aligned with the processes outlined in the *Policy and Procedure on Incident Reporting* and *Radiation Safety Procedure Manual* documents. Staff also commented that they regularly

received feedback on emerging trends and the outcome of incident investigations through quarterly quality reports and electronic staff dashboards.

Inspectors noted that both the radiotherapy and radiology departments at UPMC Whitfield Hospital Limited had systems for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, which were appropriate in meeting the requirements of Regulation 17(1)(c). The management team informed inspectors that year-on-year there has been an improvement in incident reporting which they attributed to a change in personnel and leadership, a review of incident reporting processes and education sessions for staff aimed at empowering staff to report incidents and near misses. Inspectors were also informed of a number of quality improvement projects that had been instigated as a result of investigations into trends identified through the analysis of incidents and near misses. For example, in the radiotherapy department, imaging policies and procedures had been reviewed and updated to ensure a clear, concise and standardised approach to imaging following a number of issues due to imaging. From discussions with staff and a review of documentation, inspectors were satisfied that there was a good culture of reporting of both incidents and near misses and that arrangements were in place to ensure that HIQA is notified of the occurrence of a significant event within the time frame, if required.

From a review of documentation inspectors observed that incidents were a standing agenda item at the RSC meetings and had been discussed at recent meetings, thereby providing assurance that the undertaking has comprehensive oversight of radiation incidents in this 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	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for UPMC Whitfield Hospital Limited OSV-0007190

Inspection ID: MON-0040996

Date of inspection: 12/11/2024

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiotherapy specific to Regulation 6: Radiation Safety Procedures and associated documentation will be reviewed and updated to reflect the day-to-day practices as outlined in the HIQA Inspection report, and any amendments highlighted on the day of inspection will be included. The review is actionable with immediate effect. The undertaking shall ensure that the RSP's are ratified at the next RSC scheduled for April 2025 and communicated to all staff following the RSC.</p> <p>Time bound: Radiation safety documentation review to be completed by mid-February and ratified at RSC in April.</p> <p>Diagnostic Radiology Department Regulation 6: Undertaking UPMC Whitfield Hospital Undertaking will ensure full compliance with the Regulations by formalizing and documenting the specific justification processes for each radiological modality including CT, X-ray, fluoroscopy, and interventional radiology and updating role and responsibility documentation for Referrers, Operators, and Practitioners to reflect actual day-to-day practices observed during the inspection. A detailed description of Justification steps specific to each of the modalities has been created and added to Policy WHITRAD016 Roles and Responsibilities of the referrer, operator, and practitioner in Radiology. This has been submitted to Hospital Document Control for review and acceptance at their next meeting.</p> <p>A task force consisting of Clinical Specialist Radiographers and Radiology Services Manager have undertaken the review and documentation update process. Shared learnings regarding documentation to support the staff will be delivered through Modality Staff Huddles.</p> <p>These updates directly address HIQA's findings, ensuring that justification processes are clear, consistent, and in line with regulatory requirements, thereby supporting patient safety and effective medical exposures in the day-to-day services.</p> <p>Completion and updated documentation by 31st January 2025 followed by distribution to staff and collect staff acknowledgement by 28th February 2025.</p>	

Allocation of responsibility for Justification of New Practices. A new SOP has been created to outline the steps to be undertaken by UPMC Whitfield in the Justification of New Practices involving medical exposures in advance before being generally adopted. This SOP will be submitted for acceptance by the RSC scheduled for January 2025. This document was written by the Radiology Services Manager, reviewed by the Director of Quality and Designated Manager prior to submission and acceptance at RSC. Following approval, it will be shared to staff and reviewed at the next Monthly staff meeting scheduled in February for acknowledgement. Approval and acceptance of this new SOP by 31st January 2025 followed by distribution to staff and collect acknowledgement by 28th February 2025. Implement new SOP 1ST March 2025. These steps align with HIQA's findings and ensure compliance with Regulation 7, thereby enhancing patient safety and care quality for justification in advance of any new practices.

Paediatric patients make up a very small cohort of the imaging completed in UPMC Whitfield Radiology Department. In the absence of sufficient paediatric numbers completed to create local DRLs, UPMC Whitfield Hospital will adopt the national DRLs for paediatric procedures and put them on display in the clinical area for reference by the Radiographers. Written paediatric protocols will also be devised and optimised by reviewing best practice guidelines and monitoring dose to assist staff in completing these exposures. Currently, these procedures are optimised by selecting Paediatric settings on the unit and inputting patient height and weight. This action will be completed in January following discussion at RSC and adopted National DRLs for paediatric patients will be put on display in each of the Modalities for reference. This action will be completed by the Radiation Protection Working Group. These steps align with HIQA's findings and ensure compliance with Regulation 7, thereby enhancing patient safety and care quality to paediatric patients.

Regulation 10: Responsibilities	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 10: Responsibilities: Radiation Safety Procedures and associated documentation will be reviewed and updated to reflect the day-to-day practices as outlined in the HIQA Inspection report to ensure full compliance with Regulation 10. The Undertaking shall ensure it has updated all documentation to assign clinical responsibility for medical exposures in fluoroscopy to practitioners. This will enhance oversight and verification of roles and responsibilities of the practitioner involved in justification and clinical evaluation processes of medical exposures during fluoroscopy procedures. The clear allocation of roles and responsibilities for all aspects of the responsibility for clinical outcome for medical exposures for this subset of Fluoroscopy imaging will be

documented.

A task force consisting of Clinical Specialist Radiographers and Radiology Services Manager have undertaken the review and documentation update process. The auto-report step as discussed on the Inspection Day for this imaging subset has been implemented in November 2024 by the PACs provider following agreement of the Radiologists, Radiographers and Hospital Management.

The undertaking shall ensure that this is reviewed, approved and ratified at the next RSC scheduled for January 2025.

Completion and updated documentation by 31st January 2025 followed by distribution to staff and collect staff acknowledgement by 28th February 2025.

These steps align with HIQA's findings and ensure compliance with Regulation 10, by ensuring all medical exposures take place under the responsibility of a practitioner.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:

The Undertaking shall ensure that information relating to the patient exposure forms part of the report of all medical radiological procedures by implementing additional information outlining dose reference values into the report template for the fluoroscopy procedures.

This information includes comprehensive material on average radiation doses for various modalities and examinations, allowing for informed decision-making and enhanced patient education regarding the potential risks and benefits of radiological procedures.

This information will be available on the printed report and on the RIS.

This change will be discussed at the next RSC and if approved, implemented by the PACs provider by 31st January 2025. This change request will be submitted by the Clinical Specialist Radiographer of Theatres and authorised by the RSM.

The associated documentation will also be updated, reviewed and accepted by 31st January 2025 and shared to the staff through the Modality Huddle and monthly staff meeting in February.

This initiative directly addresses HIQA's feedback and ensures patients' radiation safety information is comprehensively documented.

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	30/04/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	28/02/2025

Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	31/01/2025
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