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:	UPMC Hillman Cancer Centre
Undertaking Name:	UPMC Whitfield Hospital Limited
Address of Ionising Radiation Installation:	Cork Road, Waterford
Type of inspection:	Announced
Date of inspection:	11 May 2021
Medical Radiological Installation Service ID:	OSV-0007190
Fieldwork ID:	MON-0031321

About the medical radiological installation:

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 private patients and to public patients in the South East under a service level agreement with the HSE. UPMC Whitfield Hospital has 88 inpatient beds with over 50 consultants working across a range of specialities including cardiology, orthopaedics, oncology, radiology, gynaecology, urology and general surgery.

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 weekends for emergency patients. The department has two linear accelerators, a computed tomography (CT) scanner with positron emission tomography (PET) capabilities and 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 methods to further enhance treatment delivery are available in this centre and these include Intensity Modulated Radiation Therapy, Image Guided Radiation Therapy and respiratory gating. Brachytherapy, which is a procedure where radioactive material is put directly into the cancerous tissue is also a service provided in this centre, along with radiopharmaceuticals.

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
Tuesday 11 May 2021	09:30hrs to 15:15hrs	Agnella Craig	Lead
Tuesday 11 May 2021	09:30hrs to 15:15hrs	Kay Sugrue	Support
Tuesday 11 May 2021	09:30hrs to 15:15hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

The focus of this particular inspection was the leadership, governance and management arrangements in place for the radiation protection of service users at the radiotherapy service at the UPMC Hillman Cancer Centre. The general manager of UPMC Whitfield Hospital was the designated manager of this service and also had responsibility for radiation protection for the radiology department at this site. Having undergone restructuring since making separate initial declarations to HIQA under Regulation 6 in 2019 for the radiology and radiotherapy services and noting that both services are now part of the same governance structures and located on the same site, the undertaking should consider reviewing their initial declarations for these services and align with their updated model.

Inspectors were informed that the general manager reports to the vice president for Health Services UPMC Ireland, who in turn reports to the undertaking via the country manager and vice president of UPMC International. Inspectors met with these key individuals in management on the day of inspection. The hospital's Radiation Safety Committee (RSC), chaired by the radiation oncology medical director reports to the general manager. Based on the terms of reference of the RSC, the membership of the RSC, and the minutes of the RSC meetings along with minutes from other relevant committee meetings, inspectors were satisfied that an effective mechanism was in place to ensure oversight of the radiotherapy department.

Inspectors were informed of the process in place to ensure involvement and continuity of medical physics expertise. From the documentation reviewed, inspectors were assured that the level of involvement of the Medical Physics Experts (MPEs) was proportionate to the level of risk in this installation, and that the MPEs take responsibility for all aspects of medical exposures associated with radiotherapeutic practices, as per the regulations.

From the records reviewed, inspectors were satisfied that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors found that clinical responsibility for medical exposures was taken by personnel entitled to act as practitioners as per the regulations. However, although staff were mostly aware of the roles and responsibilities, documentation and local policies should be updated to reflect the day-to-day practice and clearly detail the allocation of responsibility, and this allocation of responsibilities should be communicated to staff. These documents should clearly specify the personnel involved in the day-to-day aspects of medical exposures with the specific roles and responsibilities detailed. In addition, the organisation of personnel records of those involved in conducting medical exposures should be organised efficiently in order to provide the undertaking with assurance that a quality and safe service is provided for service users.

However, notwithstanding some deficits in the organisation of documents and lack

of clarity in some of the documentation, inspectors were assured that the undertaking had oversight of this medical radiological facility.

Regulation 4: Referrers

Although not documented clearly, from speaking with staff and reviewing patients' records, inspectors found that referrals for medical exposures were only accepted from those entitled to refer as per the regulations.

Inspectors were informed on the day of inspection that a recent update had been made to the *Radiation Safety Procedures Manual* and that this was in the process of being signed off by the appropriate committees in the hospital. However, senior management acknowledged during the course of this inspection that further revision was necessary to reflect individual roles and responsibilities and align with current practice in this department.

Judgment: Compliant

Regulation 5: Practitioners

From speaking with staff and reviewing patients' records, inspectors found that only those who are entitled to act as practitioners took clinical responsibility for medical exposures in this facility, although the documentation of this role could be more clearly outlined as referenced previously in Regulation 4.

Judgment: Compliant

Regulation 6: Undertaking

From reviewing the documents for this inspection and speaking with management staff on the day of inspection, inspectors were informed of the governance structures in place for the radiation safety of those using this service. The day-to-day operations were overseen by the operations manager who reports to both the Radiation Safety Committee and the general manager of the hospital. The terms of reference for the Radiation Safety Committee were provided to inspectors along with minutes of the last three meetings. From these documents, inspectors were assured that the appropriate personnel were represented on this committee and that aspects such as incidents, quality assurance and replacement of equipment were discussed at these meetings with specific actions, and personnel charged with following up on these actions, documented in the minutes.

Continuous Quality Improvement (CQI) meetings were held weekly with representation from management, radiation therapists (RTs) and MPEs. Inspectors were informed that this is the forum used to discuss any day-to-day operational issues such as scheduling issues, incidents or potential incidents with outcomes from these meetings reported to the Managers Meetings and to the Radiation Oncology Clinical Governance Board. Learnings from the CQI meetings were provided to staff through various means including newsletters, huddle boards, education sessions and posters.

Although inspectors found that the undertaking had good oversight at this facility, documentation about the roles and responsibilities of personnel requires some updating to reflect the current practices. This lack of clarity was also evident in discussions with staff, some of whom were very clear on the role of the radiation therapist as a referrer within the department who perform adapted and or secondary referrals, while others were not clear. In addition, the *Radiation Safety Procedures Manual* applied to both general radiology and radiotherapy services provided on site but was weighted toward general radiology services. This meant that specific roles and responsibilities of personnel involved in the justification and optimisation of radiotherapy treatments were not clearly outlined in this document to reflect day-to-day practices. These findings were discussed with management staff who accepted this feedback and identified that further updates to the *Radiation Safety Procedures Manual* should be prioritised.

Similarly, documentation regarding personnel records for those involved in all aspects of medical radiological exposures should be organised efficiently to provide the undertaking with assurance of the radiation safety of service users by those allocated responsibilities associated with medical exposures.

Notwithstanding the issues identified above, inspectors were assured by the structures in place that this undertaking had oversight of this facility and senior management accepted the findings and identified that the gaps in the alignment between practice and documentation should be addressed.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From the information gathered over the course of this inspection, and the documents reviewed as part of this inspection, it was evident that practitioners and the MPEs were involved in ensuring the optimisation of all medical exposures, including those used in both imaging and treatment delivery. The protocols reviewed as part of inspection identified the specific work processes for procedures carried out in this facility which included how imaging is used to ensure the treatment dose is optimised.

Patients' records viewed on the day of inspection identified that both the referrer

and the practitioner were involved in justifying all medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

A number of MPEs were working in this department and inspectors were informed of the system in place to ensure the continuity of medical physics expertise in this radiotherapy department.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the MPEs were involved in all aspects of medical exposures as per the regulations. These aspects included training, quality assurance, dosimetry and optimisation. Evidence that MPEs were involved in the CQI meetings and acted on issues identified at these meetings was also provided to inspectors for review, and the MPEs were represented on the RSC and had previously reported significant events to HIQA. An MPE had been involved in the investigations of these events and had also taken responsibility for following up and implementing some of the actions identified in these investigations.

Judgment: Compliant

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

From speaking with staff and reviewing the records and documents available, inspectors were assured that the MPEs were closely involved in all medical radiological practices, and their level of involvement in all radiotherapeutic practices was, as per the regulations, in line with the level of risk posed by this service.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors found evidence that the radiotherapy department had appropriate

systems and processes in place to ensure the safe and effective delivery of medical exposures to service users within the radiotherapy department in this hospital. This included evidence of appropriate processes to ensure the justification of radiotherapy procedures, written protocols for different types of procedures, and the use of peer review and multidisciplinary meetings throughout the patient journey. Evidence that exposures were justified in advance and a record kept of justification was also seen, and inspectors were satisfied with the processes in place for reporting accidental and unintended exposures in the radiotherapy department. In particular, the audit conducted to evaluate the processes implemented after an incident was a good example of how clinical audit and evaluation can be used to provide the undertaking with assurance of the safe delivery of medical exposures. The education sessions associated with the learnings from this incident were also an example of how services can and should learn from accidental and unintended exposures.

Documentation on the quality assurance (QA) programme that was implemented was also provided to inspectors, and although some quality assurance testing had not been completed within the specified time frame due to resources and lack of access to the equipment during a busy time, inspectors were satisfied that this testing had subsequently been completed. However, a contingency should be planned to prevent this from occurring in the future.

Notwithstanding the issue associated with the quality assurance testing, inspectors were assured by the procedures in place that this service was providing safe medical exposures to ionising radiation in the radiotherapy department. This included the appropriate technical arrangements to ensure that medical exposures to ionising radiation are carried out safely and having specific systems and processes in place to track and trend any issues, with the learnings associated with these issues made accessible to all staff.

Regulation 8: Justification of medical exposures

The process of justifying medical exposures before conducting the CT scan for planning the radiotherapy treatment in this facility was explained to inspectors. This involved the use of a number of checklists that needed to be completed by the RT for each patient before imaging the patient. These checklists included checking the medical records along with the previous relevant imaging and pathology results to confirm the diagnosis. All referrals viewed on the day of inspection were in writing, stated the reason for the medical exposure and contained the relevant information to allow the practitioner determine if the referral was justified. A record of this justification was also evident in the electronic system for all records viewed on the day of inspection. Information relating to the risks and benefits of treatment were also reviewed by inspectors, and inspectors were informed that notes of the specific information leaflets made available to patients can also be entered into the patient record in the electronic system.

The process of justifying the radiation treatment before the patients' first treatment was also outlined. Again this involved a number of checks carried out by one practitioner and cross-checked by a second practitioner. Information about the weekly on-treatment and planning review meetings was provided to inspectors and a number of records of these meetings were also reviewed by inspectors. These meetings allowed the team to discuss any treatment issues for individual patients and ensure that the benefits of treatment outweighed the risks.

From the documentation and records reviewed, inspectors were satisfied that the justification of radiation dose is an ongoing process as patients move through their prescribed treatment pathway.

Judgment: Compliant

Regulation 13: Procedures

Inspectors were satisfied with the procedures in place for the safe delivery of radiation therapy to users of this service. These procedures included having referral guidelines in place for use by referrers.

In addition, protocols were in place for the standard procedures carried out for the patient categories who attend this service. These included protocols for the management of breast cancer and prostate cancer. The protocols for both the pre-treatment imaging and imaging while on treatment for these procedures was also provided to, and reviewed by, inspectors.

Inspectors were satisfied that a culture of audit was evident in this department. For example, inspectors saw evidence of good practice on audit as part of a quality improvement measure following a radiation safety incident. The incident in question had identified the lack of an appropriate skill-mix as a potential contributory factor. This audit evaluated the measures put in place following this incident and demonstrated to inspectors the success of these measures in ensuring the appropriate skill-mix is consistently available for every medical exposure. However, the overall audit programme appeared to lack organisation, with a number of audits collecting similar information at similar time points. Consideration of a more cohesive approach to the audit cycle may be beneficial in this service.

Samples of the summary report sent to the team who initially referred the patient into this service were reviewed and inspectors noted that information about the radiation dose that patients receive was included in this report.

Judgment: Compliant

Regulation 14: Equipment

Although an undertaking is obliged to provide an up-to-date inventory of medical radiological equipment, this inventory was not made available to inspectors in the form and manner as requested before this inspection. Subsequently, the documentation provided on the day of inspection highlighted an issue in documenting the quality assurance testing on the equipment. Inspectors were informed that due to two different systems in place to document QA, the information was not accurate. In order to maintain strict surveillance of the equipment, the undertaking should ensure that processes and systems are in place and fit for purpose to accurately record QA. While discussing this issue with management staff, inspectors were informed of a new system being implemented which will allow all QA to be captured in one system that will provide the undertaking with oversight.

While reviewing the monthly performance testing records for the radiological equipment, inspectors noted the absence of testing on one particular month in early 2021. Inspectors were informed by some staff that this was not completed in the usual time frame as it was a particularly busy time and they encountered issues with accessing the equipment to be tested. Staff informed inspectors that this issue had been escalated to senior management for mitigation and although discussions between the MPEs and management staff had taken place, the specific mechanism to prevent a similar issue in the future had not been decided at the time of inspection. Management staff informed inspectors that this was a resource issue, caused by lack of key personnel. Regardless of the underlying cause, the undertaking should ensure that contingencies are in place for busy periods to facilitate performance testing. Inspectors noted the outstanding testing had been completed at the start of the subsequent month and that all monthly testing was up to date on the day of inspection.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were informed that a paper-based system had previously been used to record incidents and potential incidents but that an electronic system for recording radiation incidents had recently been implemented. Near misses were also recorded in this system. Staff who spoke with inspectors on the day of inspection demonstrated a knowledge and understanding of the incident reporting processes within the hospital. Radiation incidents were an agenda item at the RSC meetings and were also discussed at the weekly CQI committee meetings. Inspectors were informed that staff are notified of the learnings from incidents and potential incidents through different forums including newsletters and education sessions. Inspectors were informed that these education sessions were recorded, which is a

good initiative to increase staff accessibility to this information.

Previous presentations used to discuss the hospital's incident reporting cycle with staff were also provided to inspectors and inspectors noted that an incident reported to HIQA in 2020 had been used as a case study for discussion in an education session. The process improvements that were implemented following this incident were also included in this education session and these changes had been evaluated by an audit as detailed earlier.

The *Accidental and Unintended Exposures Report 2020-2021* and the *CQI Report 2019-2020* were provided to, and reviewed by, inspectors and although some areas for improvement were highlighted including categorisation of issues to reduce ambiguity, inspectors were satisfied that a system to analyse incidents for trending purposes was in place in this hospital.

From the documents reviewed, and meetings with staff, inspectors were satisfied that this undertaking had measures in place to minimise the likelihood of accidental or unintended exposures, with good examples of how learnings from incidents and near misses had been used to education staff and change processes.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
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 13: Procedures	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for UPMC Hillman Cancer Centre OSV-0007190

Inspection ID: MON-0031321

Date of inspection: 11/05/2021

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

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

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

A finding of:

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

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: The undertaking will ensure that the radiation safety manual and associated competency documents will be revised to include the specific roles and responsibilities of personnel involved in the justification and optimisation of radiotherapy treatments under S.I. No. 256 of 2018 in order to more accurately reflect current day-to-day practices. This revision will also provide clarity to roles and responsibilities within both diagnostic radiology and radiation therapy. The undertaking through the chair of the radiation safety committee will ensure that this multidisciplinary review is fully completed, and the updated radiation safety manual and associated competency documents are formally ratified by the radiation safety committee which is due to meet on 23rd July 2021. Following formal ratification of the updated radiation safety manual, the radiation protection officer will provide education sessions which will be mandatory for all grades of staff within the radiotherapy department to update them on the revised version of the manual. This is to be completed by 30th July 2021. The Lead Clinical Specialist Radiation Therapist will oversee completion of the revised competency assessment with all grades of Radiation Therapists. This is to be completed by 30th July 2021. The lead for Quality & Patient Safety will send an update to HIQA on the status of this compliance plan on or before 03rd August 2021.	
Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The radiotherapy unit "Inventory of Radiological Equipment" has been updated in line with the HIQA format and submitted to HIQA. This will be available at any time by request or on inspection by HIQA.

Under the documented responsibilities of the medical physics expert (MPE), this inventory will be kept under review to accurately record and maintain the quality assurance (QA) programme including performance testing on a defined regular basis and after any maintenance procedure liable to affect the equipment's performance as well as a contingency plan for access to equipment during busy periods. The review of the "Responsibilities of the MPE Policy" will be completed by the Chief Physicist and will incorporate a review of resources required to meet those responsibilities.

The undertaking through the chair of the radiation safety committee (RSC) will ensure that the review of this policy is fully completed and formally ratified by the radiation safety committee on 23rd July 2021. Audit on the compliance of the QA programme will be presented by the Chief Physicist or designate at the biannual radiation safety committee meeting and reported to the undertaking through the chair of the radiation safety committee.

The lead for Quality & Patient Safety will send an update to HIQA on the status of this compliance plan on or before 03rd August 2021

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	23/07/2021
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation	Substantially Compliant	Yellow	23/07/2021

	protection.			
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	27/05/2021
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	27/05/2021
Regulation 14(10)	An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation, in such form and manner as may be prescribed by the Authority from time to time.	Not Compliant	Orange	13/05/2021