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 Bon Secours
Undertaking Name:	Cork Radiation Oncology Associates Ltd
Address of Ionising Radiation Installation:	Bon Secours Hospital, College Road, Cork
Type of inspection:	Announced
Date of inspection:	05 September 2024
Medical Radiological Installation Service ID:	OSV-0006849
Fieldwork ID:	MON-0040999

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

The Cork Radiation Oncology Associates is a joint venture company between Bon Secours Hospital System and UPMC Hillman Cancer Centre. The radiotherapy department, Bon Secours Radiotherapy in partnership with UPMC Hillman Cancer centre, is situated within the Bon Secours Hospital on Western Road in Cork City. The department opened in July 2019 and provides radiotherapy services to both public and private patients in the Munster region.

Bon Secours Radiotherapy in partnership with UPMC Hillman Cancer Centre is an outpatient department and operates Monday to Friday 8am-8pm. We provide radiotherapy services to adults and young persons aged 16 and over.

The department has two Varian linear accelerators and a GE CT scanner. The department provides radiotherapy services including CT simulation, treatment planning and treatment delivery for patients undergoing external beam radiotherapy. Advanced modalities such as IMRT, IGRT, respiratory gating, Surface Guided Radiotherapy (Vision RT) and stereotactic radiotherapy treatments are provided within the centre.

Since opening in 2019, over 4000 patients have received external beam radiotherapy in the Cancer Centre. The department has active clinical trials, in conjunction with Cancer Trials Ireland with 49 patients now recruited onto various international trials. The department was recently JCI (Joint Commission International) re-accredited and continues to provide quality and safe treatments to our patients.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

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

1. Governance and management arrangements for medical exposures:

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 5 September 2024	09:30hrs to 15:40hrs	Margaret Keaveney	Lead
Thursday 5 September 2024	09:30hrs to 15:40hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

On 05 September 2024 inspectors completed an inspection of the radiotherapy services at UPMC Bon Secours to assess the undertakings ongoing compliance with the regulations and to follow up on a compliance plan from the previous inspection in August 2021. During the course of this inspection, inspectors were assured that Cork Radiation Oncology Associates Ltd, as the undertaking for radiotherapy services in UPMC Bon Secours, had implemented the compliance plan actions and overall demonstrated good compliance with the regulations. However, inspectors noted that action was required by the undertaking to achieve full compliance with Regulation 17: Accidental and unintended exposures and significant events.

From a review of documentation and discussions with the management team, inspectors were informed that the undertaking, Cork Radiation Oncology Associates Ltd, was a partnership between the Bon Secours Hospital and UPMC, with the undertaking's board of directors consisting of representatives from both groups. Inspectors were assured that the undertaking had established effective governance and management arrangements, which provided oversight of radiation protection in the service. Local oversight was provided by the Continuous Quality improvement (CQI) committee which met weekly and in turn reported to the Quality, Radiation Protection and Patient Safety (QRPPS) committee which met monthly. Both meetings were attended by, among others, the Quality and Regulatory Manager, medical physics expert (MPE), Operations Manager and Lead clinical specialist radiation therapist (CSRT). Radiation protection matters discussed at these meetings included incidents and near misses, the equipment quality assurance (QA) programme, clinical audits and dose reference levels (DRLs).

Summaries of the matters discussed at the CQI and QRPPS meetings were then discussed at the six monthly radiation safety committee (RSC) meetings. The RSC meetings were chaired by the Chief Operations Officer (COO) of UPMC, and were attended by the undertaking's Medical Director, the MPE, Lead CSRT and other members of the undertakings senior management team. The RSC reported to the Radiation Oncology Governance Board, which subsequently reported to the undertaking’s Ireland Oncology Board, which was attended by the designated manager of the service, who is the Director of Oncology Services in UPMC, the undertaking’s representative, who is the Managing Director of UPMC, and the lead radiation oncologist. A review of board meeting minutes by inspectors showed that the undertaking's board of directors were appropriately updated on the radiation protection matters routinely discussed at these forums.

Inspectors reviewed a range of documentation that supported staff in their roles and responsibilities in the radiotherapy department. This review included the service’s *Radiation Safety Procedure*. This document supported the undertaking in meeting their responsibilities under the regulations, however, some minor updates are

suggested to ensure that all staff involved in the planning and delivery of radiotherapy treatment are clearly aware of their responsibilities.

A sample of service user records for medical exposures were reviewed by inspectors and showed that appropriate persons as per the regulations were involved in referring and justifying medical exposures completed in the service. Inspectors were also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

The inspectors reviewed documentation and spoke with the management team regarding MPE involvement in the safe delivery of medical exposures, and were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at UPMC Bon Secours.

Regulation 4: Referrers

Inspectors were assured that the medical exposures carried out in the radiotherapy department of the UPMC Bon Secours were referred only by individuals entitled to refer as per the regulations, namely by appropriately registered medical practitioners and by radiation therapists for adapted and modified referrals.

Judgment: Compliant

Regulation 5: Practitioners

On the day of the inspection, inspectors found that radiation oncologists and radiation therapists acted as practitioners and took clinical responsibility for individual medical exposures carried out in the radiotherapy department of the UPMC Bon Secours, which satisfied the requirements of this regulation.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors observed that the undertaking had effective governance and management arrangements in place, to provide appropriate oversight of radiation protection measures in the radiotherapy department at UPMC Bon Secours.

From a review of documentation and speaking with staff, inspectors were assured that the undertaking had allocated the roles and responsibilities for the radiation protection of service users. Inspectors also noted that many of these responsibilities were fulfilled by good cooperation between the various disciplines involved in the planning and delivery of radiotherapy medical exposures in the radiotherapy service and that there were effective communication pathways in place. For example, a weekly on-treatment review meeting was attended by a multidisciplinary team, and each patient as discussed to ensure that the benefits of their medical exposures continued to outweigh the risks. This multidisciplinary approach and opportunity to discuss radiation protection matters throughout the patient's course of treatment was acknowledged as an area of good practice in the department.

Inspectors also noted that the undertaking's management team had developed and implemented a range of documents to support and guide staff on their responsibilities in the radiation protection of patients undergoing radiotherapy treatment.

Judgment: Compliant

Regulation 10: Responsibilities

From discussions with staff and a review of a sample of patient records and other documents, inspectors were assured that clinical responsibility for medical exposures was allocated to and completed by radiation oncologists and radiation therapists in the radiotherapy department of the UPMC Bon Secours.

Inspectors were also satisfied that both referrers and practitioners were involved in the justification of individual medical exposures in the service.

Similarly, inspectors assessed that practitioners and MPEs were appropriately involved in the optimisation of all aspects of all medical exposures carried out in the service.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors noted that the undertaking had engaged a team of MPEs, which provided assurances that there were arrangements in place to ensure access to and

continuity of medical physicist expertise in the radiotherapy department as required by Regulation 19(9).

Inspectors were also 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.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of MPEs at UPMC Bon Secours and were satisfied that the team gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

During the inspection, inspectors noted MPE involvement in radiation protection in the service which was in line with their allocated responsibilities as outlined in Regulation 20(2) . Inspectors were informed that the MPE team was very accessible to staff to advise on all radiation protection matters, and noted that there was MPE representation on the radiation safety committee, and on other departmental committees tasked with the radiation protection of service users.

From a review of documentation, it was evident that the MPE team gave advice on medical radiological equipment, and contributed to the definition and performance of a quality assurance programme. The team was also involved in optimisation along the patient's radiotherapy pathway, including the application and use of diagnostic reference levels (DRLs) in the CT unit and treatment planning.

Inspectors also noted that the MPE team were involved in the review of all radiation incidents and near misses that occurred in the service and when required carried out dose calculations for any incidents relating to ionising radiation.

Inspectors found that the MPE contributed to the training of practitioners in relevant aspects of radiation protection, and records showed that this training was delivered during staff induction period and annually for all practitioners. Inspectors noted that the MPE liaised with the hospital's radiation protection adviser and so met the requirements of Regulation 20(3).

Judgment: Compliant

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

On the day of inspection, inspectors found that MPE involvement in medical radiological procedures was in line with the level of radiological risk at UPMC Bon Secours.

Judgment: Compliant

Safe Delivery of Medical Exposures

During a tour of the radiotherapy department, inspectors met with staff in the computed tomography (CT) unit and at one of two treatment units to discuss the radiation protection measures in place for patients receiving radiotherapy treatment. These discussions and a review of documentation evidenced that the undertaking's management team was committed to improving the radiation protection of service users, by ensuring that medical radiological procedure doses were kept as low as reasonably achievable. This was achieved through the use of written protocols for all steps of the patient's radiotherapy pathway and evidence based referral guidelines being available to staff, by reviewing diagnostic reference levels (DRLs) in CT and by implementing service improvements as a result of clinical audit.

A sample of referrals reviewed were found to be in writing and contained the reason for referring the patient for radiotherapy. Staff spoken with described how medical exposures along a patient's pathway were justified by a radiation oncologist and or radiation therapists. Inspectors were also informed that patients were provided with information on the benefits and risks of their treatment course at initial consultation, and were then given adequate time at home to consider this information, with family involvement if desired, before providing written consent to radiotherapy medical exposures at their CT appointment. This informed consent process was the result of a quality improvement plan in the service and was identified as an example of good practice.

From a review of QA reports, inspectors were satisfied that an appropriate equipment QA programme had been implemented in the service, with testing responsibilities allocated to radiation therapists and the medical physics team, and also frequent involvement of the equipment manufacturers. Inspectors were also assured that there was a process in place to determine the pregnancy status of service users, where relevant. From a review of service user records and clinical audits of the pregnancy inquiry and recording process, inspectors were assured that this process was safe and effective.

Inspectors also reviewed records that evidenced that there were good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. However, as discussed with the management team on the day of the inspection, improvements were required to ensure that as an incident occurred in the service it was appropriately reviewed to

establish if it met the thresholds for reporting to HIQA. This is further discussed under Regulation 17 below.

Overall, 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

Following the previous inspection in August 2021, the management team in UPMC Bon Secours had developed a document titled *Policy and Procedure on Time Out Procedures (Final Active Verification)*, which provided appropriate staff with guidance on their assigned roles and responsibilities on the justification process along the radiotherapy patients' treatment pathway. From discussion with staff at CT and on the treatment units, inspectors were assured that staff were aware of their responsibilities on recording the justification decision.

Inspectors were informed that by electronically signing a treatment request form, the radiation oncologist justifies the patient's radiotherapy CT planning scan in advance of the scan. Similarly, by reviewing and signing the final treatment plan, the radiation oncologist justifies in advance the medical exposures that are carried out along the radiotherapy treatment course. Inspectors also observed that radiation therapists are responsible for the justification of daily medical exposures of radiotherapy treatment and indicate these justification decisions by electronically completing quality checklists in patient records.

On the day of the inspection, inspectors reviewed a sample of referrals for radiotherapy medical exposures and saw that they were available in writing and stated the reason for the request. From this review, inspectors were assured that practitioners had access to sufficient medical data to consider the risks and benefits of the medical exposure during the justification process. Inspectors were also informed of the two-step process prior to the CT planning scan, whereby enquiries were made to determine if a patient had completed previous radiotherapy treatment in another facility. Where relevant, this treatment information was obtained and considered in the treatment planning process as a key radiation protection measure. This two-step check had been implemented by means of an electronic task and was identified as an area of good practice within the service.

Inspectors observed that treatment site-specific information leaflets, about the benefits and risks associated with medical exposures, had been developed for patients in line with national and international evidence, and staff who spoke with inspectors explained the process of providing this information to patients. Inspectors were also informed that a *Patient Informed Consent* quality improvement plan (QIP) had recently been completed in the service, which reviewed the overall treatment consent process to ensure that patients were provided with adequate information on the risks and benefits of the medical exposures on their radiotherapy pathway, and were provided with adequate time to consider this information before consenting to the medical exposures. As a result of this QIP, the consent process had been revised

in line with the objectives, and this initiative was identified by inspectors as an area of good radiation protection within the service.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff about the measures in place to ensure that the medical radiological procedures in the radiotherapy department at UPMC Bon Secours were optimised.

A multidisciplinary team had developed a number of policies and procedures, such as *Policy and Procedure on Verify and Treatment Procedure for All Sites* and *Image Acquisition and Online IGRT Policy and Procedure* to outline the optimisation processes in place for medical exposures along the patient's radiotherapy pathway, and to ensure that staff were aware of their responsibilities in these processes. These documents guided staff on optimising patient preparation and positioning at CT and during radiotherapy treatment delivery, and on the acceptable parameters for different medical exposures.

On the day of inspection, inspectors spoke to staff in CT about the protocols developed and used to set appropriate scan limits for each patient. Inspectors were also informed that all treatment plans were individually planned and evidence based constraints were applied to keep doses to non-target areas as low as achievable. Inspectors were also informed that prior to treatment commencing a Patient Specific Quality Assurance (PSQA) check was completed on each plan to provide additional assurances that doses to the target area would be delivered as prescribed.

The multidisciplinary team had also completed an audit on optimisation of medical exposures during CT planning scans with the aim of monitoring the doses delivered, and ensuring that they were comparable with international data on similar exposures. The results of this audit were on display in the CT console area for use by staff. A follow-up audit was planned for later in 2024 with information provided by a dose monitoring system and by CT staff where deviations from expected values were encountered. This proactive approach to radiation protection of radiotherapy patients was identified as an area of good practice in the service.

A quality assurance programme for the medial radiological equipment in use in the service was also established and implemented, which also contributed to optimisation. It included regular performance testing by radiation therapists and by the medical physics team. The medical physics team were also noted to review and sign off all quality control results, which was seen as an additional assurance that any issues with equipment performance could be identified and actioned promptly.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written protocols for the range of radiotherapy medical exposures completed in the department. These protocols were specific to the treatment sites commonly treated in the service. Inspectors were also informed that national and international referral guidelines were in use in the service, and were accessed online to ensure use of the most recent version. Inspectors were also informed that a weekly meeting was held and attended by all radiation oncologists working in the department, an MPE and a radiation therapist representative, at which all new radiotherapy treatment plans were peer reviewed. This radiation protection measure was noted as an area of good practice within the service.

Inspectors observed that a discharge letter was generated after each patient completed their radiotherapy treatment, and included the total treatment radiation dose received by the patient and potential side effects associated with the medical exposures delivered during the radiotherapy treatment course.

The undertaking had developed a *Quality Improvement and Patient Safety Programme* document, and inspectors noted that clinical audit was a key element in this programme. The governance roles and responsibilities for clinical audit were outlined in the document, with oversight responsibility allocated to the Clinical Governance Meeting and responsibility for implementation of the clinical audit strategy allocated to the Quality and Regulatory Affairs Manager. Inspectors also noted that a Clinical Audit Lead was assigned in the service, with responsibility for ensuring clinical audit opportunities were met in line with the clinical audit schedule. The results of clinical audits were included in quarterly *Quality, Radiation and Risk Management Report*, which was discussed at the undertaking's quarterly board meetings. Inspectors noted that a range of clinical audits had been completed in the service in the last 12 months, and were provided with assurances that future audit topics were being considered from incident and near miss learning and other quality measures.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment at the UPMC Bon Secours was provided to HIQA in advance of this inspection. Inspectors were satisfied that medical radiological equipment in use in the service was kept under strict surveillance as required by Regulation 14(1).

A number of documents including *Radiotherapy Equipment Quality Assurance Programme and Policy* and *Procedure on Preventative Maintenance of Radiotherapy*

Equipment outlined the quality assurance (QA) programme in place in the radiotherapy department. The programme included daily, weekly, monthly and annual testing for the CT scanner, treatment units and ancillary equipment by the undertakings' staff, and quarterly testing by the equipment manufacturer. Inspectors were also informed that the treatment planning system was included in the QA programme. From a review of records, inspectors noted that the programme was implemented by UPMC Bon Secours staff and the equipment manufacturer's engineers as planned, and were assured that there was appropriate oversight by the undertaking of all testing completed.

Judgment: Compliant

Regulation 15: Special practices

On the day of the inspection, inspectors observed that there was good cooperation and collaboration between the various disciplines involved in the planning and delivery of radiotherapy medical exposures at UPMC Bon Secours. 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 and by medical physics experts. This multidisciplinary approach and opportunity to discuss radiation protection matters was acknowledged as an area of good practice in the 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, at the CT patient immobilisation stage**,** position and scanning margins were carefully considered to ensure that only relevant areas were scanned. Inspectors were also informed that the dose delivered to the patient during CT was recorded, audited and compared to internationally published data, to ensure that it was optimal. In addition, some patients underwent specific preparation to reduce organ motion during the CT planning scan and treatment exposures, to ensure that target doses to target organs were achieved and doses to non-target organs minimised.

Inspectors were also informed that 'time-out' processes had been introduced at CT and at the treatment units since the previous inspections had been developed. These time-outs reminded staff to check that key radiation protection measures were in place before they completed a medical exposure. Inspectors also observed that the undertaking had implemented an electronic patient record system that ensured key tasks on the patient's radiotherapy pathway were completed before the next key task became available to complete. This system also ensured that the tasks were completed by appropriate personnel, and therefore ensured that patients were receiving high quality and safe courses of radiotherapy treatments.

During the course of the inspection, inspectors also spoke with physics staff in the radiotherapy treatment planning department, who informed inspectors that specific

planning protocols were used for each treatment site to ensure the doses to normal tissue is kept as low as possible while delivering the optimal treatment dose to the target area. Inspectors were also informed of a contouring software system in the planning department, which automatically outlined the non-target structures located close to the treatment target to avoid or limit the dose to these structures. This system was used to optimise contouring of these structures, and improve radiation protection in treatment planning.

Inspectors also observed that ancillary equipment was in use in the department, which detected the patient's position on the treatment couch, compared it to their position during CT planning and subsequently corrected any variations, thereby reducing the number of verification images, and the associated dose to patients.

During the course of the inspection, inspectors were satisfied that the undertaking had given special attention to appropriate radiation protection practices for patients receiving radiotherapy treatment.

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 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.

The *Policy and Procedure for Determining Pregnancy Status of Women Receiving Radiotherapy* had been developed to support and guide staff on their roles and responsibilities in this radiation protection measure. Minor refinements of this policy were required to ensure that all roles reflected the current regulations, however this did not impact on the undertaking's compliance with this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors noted that there was a good culture of incident reporting in UPMC Bon Secours. From discussions with staff and a review of incident records, inspectors were assured that the undertaking had systems in place for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures, with this process outlined in a document titled *Policy and Procedure on Incident Reporting*.

A review of meeting minutes evidenced that incidents were discussed at the weekly CQI meetings, and subsequently at the monthly Quality, Radiation Protection and Patient Safety Committee meetings and biannually at the RSC. All matters discussed at RSC were subsequently discussed at the Radiation Oncology Clinical Governance Board, which was attended by the undertaking representative and thereby provided the undertaking with oversight of incidents in this service. The undertaking also had arrangements in place to feedback to staff in the radiotherapy department on incidents and near misses, by means of a weekly 'huddle' meeting.

Inspectors noted that the management team in UPMC Bon Secours had arrangements in place to notify HIQA of the occurrence of a significant event, as required by the regulations. However, a review of records showed that one incident that had occurred in the service was deemed by the local investigation team to not meet the thresholds for reporting to HIQA, and was therefore not reported. On the day of the inspection, inspectors were provided with evidence that the incident had been appropriately investigated and measures implemented to minimise the likelihood of a similar incident reoccurring. However, inspectors spoke with the management team on this incident who subsequently agreed that it met the thresholds for reporting to HIQA.

Notwithstanding this gap in compliance under Regulation 17(1)(e), inspectors were satisfied that overall the undertaking had implemented measures to minimise the likelihood of incidents occurring for patients in the service.

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, 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	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 9: Optimisation	Compliant
Regulation 13: Procedures	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	Substantially Compliant

Compliance Plan for UPMC Bon Secours OSV-0006849

Inspection ID: MON-0040999

Date of inspection: 05/09/2024

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 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: Specific to Regulation 17: Accidental unintended exposures and significant events will continue to be measured and monitored and reported through internal weekly Continuous Quality Improvement (CQI) meetings. The undertaking shall ensure that CROAL will notify, promptly, and as soon as possible of the occurrence if there is any uncertainty of the breaching of a certain threshold (as defined by HIQA guidelines). This is actionable with immediate effect and will be communicated to all attendees at the next CQI meeting (17th October 2024) and the next Radiation Safety Committee Meeting on 25th October 2024.	

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 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, and	Substantially Compliant	Yellow	17/10/2024