



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:	23 August 2021
Medical Radiological Installation Service ID:	OSV-0006849
Fieldwork ID:	MON-0033181

About the medical radiological installation:

The Cork Radiation Oncology Associates Limited is a joint venture company between Bon Secours Hospital 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 to 8pm. The department provides radiotherapy services to adults and young persons aged 16 and over. The department has two linear accelerators and a computed tomography (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 intensity modulated radiotherapy, image-guided radiotherapy, respiratory gating and stereotactic treatments are provided within the centre.

Since opening in 2019, 1200 patients have received their radiotherapy treatment in this facility. In 2020, 512 patients received external beam radiotherapy in the Cancer Centre. The department continues to grow with clinical trials, in conjunction with Cancer Trials Ireland, being initiated in the last few months.

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 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. 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
Monday 23 August 2021	10:00hrs to 16:45hrs	Agnella Craig	Lead
Monday 23 August 2021	10:00hrs to 16:45hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

From the evidence gathered as part of this inspection, inspectors were satisfied with the leadership, governance and management arrangements in place for the radiation protection of service users of the radiotherapy department at UPMC Bon Secours. The documentation reviewed detailed the specific systems and processes in place for radiation protection along with the allocation of responsibility in this facility. The operations manager was the designated manager in this facility and was a member of the Radiation Safety Committee (RSC). The lines of reporting from this committee up to the undertaking were clearly identified and from the evidence available, inspectors were assured that the undertaking had oversight of this facility.

Appropriate measures were in place to ensure that all referrals were from those entitled to act as referrer. Similarly, inspectors were assured that clinical responsibility for medical exposures was taken by personnel entitled to act as practitioners as per the regulations. The reviewed documentation detailed the responsibilities of referrers and practitioners and the medical physics experts (MPE).

Inspectors were satisfied of the mechanism currently in place to ensure continuity of MPE services. This mechanism availed of the expertise from another facility to ensure the presence of an MPE on-site at all times during the working day. The recruitment of a second MPE locally was also progressing. From the documentation reviewed and from speaking with staff, inspectors were satisfied that the MPE was involved in all aspects of radiation protection, as per the regulations, and that the level of involvement was proportionate to the level of risk posed in this facility.

Overall, inspectors were assured of the governance and management arrangements in place to ensure that the undertaking has appropriate oversight of this relatively new radiotherapy facility.

Regulation 4: Referrers

The policy documents reviewed for this inspection outlined the personnel entitled to act as referrers. As per the regulations, this included radiation oncologists and radiation therapists (RTs) and the records reviewed on the day of inspection was evidence that the local practice was in line with the facility's policies.

The document titled *Roles & Responsibilities of the Radiation Therapist Cork* specified that RTs, working under the regulations, their scope of practice and the local hospital governance structures, could adapt referrals or perform secondary referrals in defined circumstances. Staff who spoke with inspectors on the day of inspection gave examples of these circumstances such as performing additional

verification imaging when warranted in particular situations.

Judgment: Compliant

Regulation 5: Practitioners

The policies reviewed by inspectors in advance of the inspection outlined who is entitled to act as practitioner as per the regulations. From the records viewed in the radiotherapy department on the day of inspection, inspectors were assured that medical exposures were conducted as per these policies.

Judgment: Compliant

Regulation 6: Undertaking

Documentation detailing the organisation structures of this undertaking was provided in advance of this inspection and staff were able to clearly outline these structures on the day of inspection.

A Radiation Safety Committee was in place and the terms of reference for this committee were provided to inspectors along with minutes of the last three meetings. From reviewing these documents, inspectors were informed of the reporting structure from the RSC to the undertaking and that the appropriate personnel were represented on this committee. The RSC which meets twice yearly reported to senior hospital management at the joint venture board of directors meeting and the Clinical Governance Board. Agenda items discussed at the RSC meetings included incidents and near misses, training, radiation safety procedures and their associated documentation.

In addition, management team meetings and continuous quality improvement (CQI) meetings were held weekly and inspectors were informed that both committees provided a forum to discuss aspects of radiation protection. The minutes of recent meetings was evidence of these discussions and inspectors noted that representatives from management, radiation therapy and medical physics attended these meetings.

The policy and procedure documents reviewed provided evidence that a clear allocation of responsibility was in place and from speaking with staff, inspectors were assured that staff were aware of their role and responsibilities. However, the specific details about recording justification, as detailed in Regulation 8, should be clarified for all staff.

The day-to-day operations were overseen by the operations manager who is also the designated manager in this facility and sits on committees including the RSC, the

management committee, and the CQI committee. The *Radiation Safety Procedures Manual* outlined the responsibilities of personnel involved in radiation protection and referred to additional documentation for full details of these roles. Inspectors reviewed these documents which detailed the roles and responsibilities of the undertaking, the MPE and the RTs.

From the evidence available at the time of this inspection, inspectors were satisfied that the governance structures in place provided the undertaking with oversight of this facility.

Judgment: Compliant

Regulation 10: Responsibilities

From the records reviewed, inspectors were satisfied that all medical exposures took place under the clinical responsibility of a practitioner. In addition, individuals recognised as practitioners were responsible for conducting medical exposures in this facility. The records viewed on the day of inspection also identified that both the referrer and the practitioner were involved in justifying all medical exposures however staff were less clear on where the record of justification was recorded. Evidence that practitioners and the MPE were involved in optimisation of all medical exposures in both imaging and treatment delivery was also available over the course of this inspection. This included guidance documents detailing how imaging is used to ensure the treatment dose is optimised.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From speaking with staff on the day of inspection, inspectors were satisfied that a mechanism was in place to provide continuity of medical physics expertise. This involved an arrangement with a separate facility to provide cover for the MPE in this facility when needed, for example during periods of annual leave. In addition, the current MPE supervised the work of two additional physicists and inspectors were also informed by a number of staff that a recent recruitment campaign to appoint a second MPE to provide additional contingency within the service had been successful.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From speaking with staff and reviewing documents it was evident that the MPE took responsibility as detailed in the regulations. These responsibilities included: dosimetry, optimisation, quality assurance and acceptance testing, analysing events involving or potentially involving ionising radiation, and training and education of staff. A recent policy document titled *Roles & Responsibilities of the Medical Physics Expert* provided information on the responsibilities of the MPE, again in line with the requirements of the regulations.

The MPE was the radiation protection officer for this facility and liaised with the radiation protection adviser as appropriate. The MPE was also a member of a number of committees relevant to radiation protection, for example, the RSC.

Judgment: Compliant

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

From the evidence obtained over the course of this inspection, inspectors were assured that the level of involvement of the MPE in radiotherapy practices was in line with the level of risk posed by this installation.

Judgment: Compliant

Safe Delivery of Medical Exposures

The undertaking, Cork Radiation Oncology Associates Ltd. was found to have appropriate systems and processes in place to ensure that safe and effective medical exposures are provided to service users at the UPMC Bon Secours radiotherapy department. This included the implementation of a QA programme which had been maintained as evidenced in the records of quality assurance and performance testing reviewed as part of this inspection. Inspectors were also satisfied that staff enquired about, and recorded the pregnancy status of service users, as appropriate. The comprehensive methods used to optimise all medical exposures was explained to inspectors and included the use of peer review from another facility, the use of advanced techniques to keep the radiation dose delivered to the organs around the tumour as low as reasonably possible while maintaining the required clinical outcome, and the use of international protocols to guide treatment plans. This facility had also used technology to enhance communication with relevant stakeholders. For example, the use of virtual meetings facilitated family members to be present for consultations between the clinician and patients. Similarly, virtual meetings facilitated local staff to interact with their peers in another facility. Inspectors were informed that these facilities had collaborated extensively

while setting up this new facility at the UPMC Bon Secours, and that this collaboration had continued. Technology had also been used to record consultations with patients where the benefits and risks of radiotherapy were explained. These recordings were made available to patients and provided full transparency for patients and their families.

Clinical audit was evident in this facility and the undertaking had also availed of independent external expertise to review doses before using the equipment. Similarly, projects designed to establish dose limits in the CT scanner had been set up to assist in designing and optimising new treatment techniques as they were implemented in this department. Examples of the special attention that was given in radiotherapy are further detailed in Regulation 9 and Regulation 15.

Inspectors were satisfied with the processes in place for locally reporting accidental and unintended exposures however, updating the documentation to reflect the full process would be beneficial. Similarly, although some evidence that exposures were justified was available on the day of inspection, the specific mechanism to record that all exposures are justified in advance needs to be improved and made known to all staff involved in the justification process.

Notwithstanding the minor issues identified in this report, overall inspectors were assured by the arrangements in place that this service was providing safe medical exposures to ionising radiation in this radiotherapy department.

Regulation 8: Justification of medical exposures

All referrals for radiotherapy reviewed by inspectors on the day of inspection were available in the booking form, stated the reason for the request and were accompanied by medical data which allowed the benefit and the risk of exposures to be considered by the practitioner.

Inspectors reviewed information about radiotherapy available for patients and were informed that the radiation oncologist provides information to all patients on the benefits and risks of treatment as part of the consent process. Inspectors were informed that this consultation is recorded and the audio-recording is made available to patients. In addition, family members are permitted to virtually attend these consultations should a patient be interested in this option. Using technology in these ways is an example of good practice as it provides additional opportunities to ensure the patient is informed of the risks and benefits of radiotherapy before consenting to treatment. RTs, as practitioners, also provided information on risks and benefits before patients started treatment.

Practitioners described how previous medical records are sought in advance and how this information is considered when justifying a medical exposure. The task list created for patients was reviewed by inspectors who noted that radiology and pathology review are tasks that should be completed for each patient before their pre-treatment scan. Inspectors noted the option to record the justification if an

additional scan is required as an example of good practice, and the staff explained how this is used.

Although, inspectors noted that the process of justification was documented in the *Roles & Responsibilities of the Radiation Therapist Cork* policy, some staff were not readily able to advise as to where the record of justification or ultimate decision making for the exposure to proceed was documented. The policy documents should be updated to identify the process for recording that justification has taken place and, in line with the policy updates, staff should be made aware of their responsibility, as practitioners, in recording this decision.

Judgment: Substantially Compliant

Regulation 9: Optimisation

The optimisation of medical exposures for patients undergoing radiotherapy was discussed with staff on the day of inspection, and documentation relevant to the optimisation process of radiotherapy procedures was reviewed by inspectors. This included documentation about the QA testing and the process for assessing and verifying patient doses and inspectors noted the use of an independent external audit to verify dose.

Inspectors were assured that treatments were optimised by individually planning all exposures to the required area, verifying the dose to this area and reducing the dose to nearby organs as much as possible while ensuring the dose is consistently delivered to the target. Staff described many processes in place to optimise treatment and these included imaging projects to establish the set-up margin required when initiating new treatment techniques.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors reviewed a number of the written protocols for treatments conducted in the radiotherapy department. A member of staff described the international guidance documents used as the evidence base when deciding on the referrals to radiotherapy and the specific protocols that are followed for patients.

A positive culture towards conducting clinical audit was noted by inspectors, with examples of previous audits made available to inspectors. For example, the audit *Patient identification and timeout* provided an assurance of the process to identify the correct patient for treatment, the correct site, and the correct procedure and this audit showed high levels of compliance. From reviewing additional audit reports,

inspectors were able to ascertain that any issues identified in audits had been addressed and were re-audited.

Inspectors observed that information relating to patient exposure was recorded on the patient reports. On reviewing the patients' charts, inspectors noted that the total prescribed radiation dose received by the patient was included in both the *patient summary sheet* and the *exit letter* produced when patients finish treatment.

From the evidence available and detailed above, inspectors were satisfied that this facility was compliant with Regulation 13.

Judgment: Compliant

Regulation 14: Equipment

A full inventory of equipment was provided by the undertaking. The details of the quality control programme that was implemented for each piece of medical radiological equipment were reviewed and the records of acceptance testing, performance testing and quality assurance reports were also available and provided an assurance that the QA programme had been maintained. The role of the MPE in relation to equipment was also evident in the policies and records reviewed.

From the documentation reviewed and from speaking with staff, inspectors were assured that the undertaking had strict oversight of the surveillance of all medical radiological equipment in this installation.

Judgment: Compliant

Regulation 15: Special practices

This facility had mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the patient. For example, all patients in this department were discussed at an initial peer review meeting. Inspectors were informed that this peer review meeting provides an opportunity for the radiation oncologist to discuss each treatment proposal and specific protocol to be followed before any medical exposure is conducted. A second peer review process is then conducted once the patient's treatment is planned. This was viewed by the inspectors as an example of good practice which provides the undertaking with assurances of the special attention given to radiotherapy patients.

A further example of good practice identified was a project proposal recently initiated in this department. This project, once completed, will allow the department to establish, review and set local dose limits in the CT scanner for radiotherapy planning scans. This should provide a mechanism to review doses delivered to

patient cohorts with the potential to reduce dose without compromising on the efficacy of the planning scan.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From the documents reviewed and speaking with staff, inspectors were informed of the process for enquiring about and recording pregnancy status. The radiation oncologist and the RTs were involved in enquiring and documenting pregnancy status. Details of the process including the point at which the enquiry is first made and when this is re-checked was provided in the documentation and was known by staff. However, a reference to older legislation was included in one section of the pregnancy policy and staff acknowledged that this should be updated. From samples of records reviewed on the day of inspection, inspectors saw evidence that pregnancy status is checked at a number of stages throughout the patient's treatment course, including the initial referral stage and before the pre-treatment planning scan. Notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were visible in public places.

Notwithstanding the minor update required to the policy, inspectors were satisfied that this facility was compliant with Regulation 16.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors found evidence that measures were taken within this facility to minimise the probability of accidental or unintended exposures. Oversight from senior management within this hospital was evident as radiation incidents and potential incidents are a standing item at a number of committee meetings including the RSC meetings.

Documentation provided before this inspection highlighted the approach taken when a radiation incident occurs. This approach includes convening an immediate RSC meeting to discuss the event and decide on the appropriate actions required, and this was seen as an example of good practice.

Although the documentation would benefit from a review to ensure all details about the processes in place are included in the policy, inspectors were assured of the radiation safety of service users by the processes and procedures in place within this facility and the awareness of staff of these 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	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	Substantially 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	Compliant

Compliance Plan for UPMC Bon Secours OSV-0006849

Inspection ID: MON-0033181

Date of inspection: 23/08/2021

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:

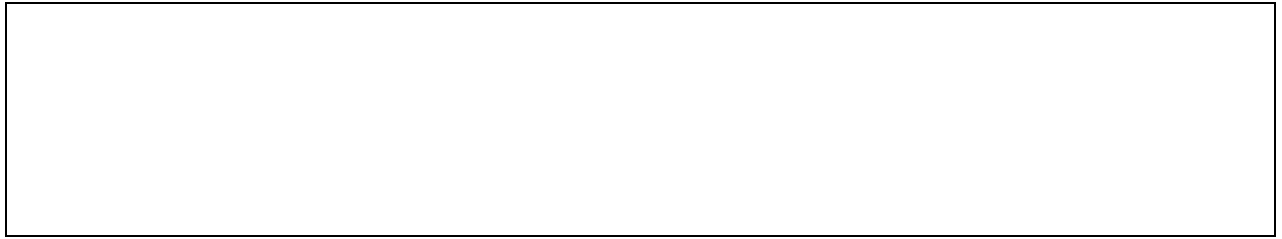
- **Substantially compliant** - A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.
- **Not compliant** - 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 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>As per Regulation 8, (5a) "documented justification for that individual by the practitioner, in consultation with the referrer" will be implemented as follows:</p> <p>Practitioners will be responsible for verifying the exposure and appropriate documentation. This will be incorporated into the CT planning scan stage and the treatment delivery for every patient.</p> <p>Documented and signed justification for medical exposures will be added to the departmental time out process. This will be recorded in the electronic medical record by two practitioners.</p> <p>For each CT planning scan, this will be added to the CT sim set up sheet to be verified by two practitioners. This will include justification of the referral.</p> <p>For daily treatment, the patient journal will be used to document time out and justification by two practitioners.</p> <p>Justification will also be checked at the pre-treatment radiation therapist chart check and weekly radiation therapist chart check. This will include verifying the correct site from radiology/pathology/histology/clinical notes and radiation dose prescription.</p> <p>This update will be completed by the 18th of October 2021. The policy and procedures will be updated to reflect these additions and staff education and training will also be completed by the 18th of October 2021.</p> <p>From 1st of November, departmental audits will include auditing compliance to documentation of justification. This addition will be communicated to the undertaking through the operational quality report in the quarterly joint venture board meetings.</p>	



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 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	18/10/2021