The Regulation and Quality Improvement Authority

Inspection Report

3 and 4 December 2025

Altnagelvin Hospital, North West Cancer Centre, Radiotherapy Department, Breast Radiotherapy Pathway

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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ and The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R

1.0 Service information

Organisation/Registered Provider: Western Health and Social Care Trust (WHSCT)	**Department Inspected:** **WHSCT North West Cancer Centre Radiotherapy Department** Breast Radiotherapy Service
Name of Employer: Dr Brendan Lavery, Medical Director WHSCT	**Radiotherapy Services Manager (RSM):** Mr Pat Shiels
Radiotherapy Clinical Lead: Dr Ahmed Bedair	**Head of Radiotherapy Physics Service(HRPS):** Ms Mary Costelloe

Brief description of how the service operates:

The radiotherapy service (RT service) provides radical external beam treatment for breast, prostate, urology, lung, upper and lower GI, head and neck disease, and a recently introduced superficial service. It provides palliative radiotherapy for all palliative cases. Brachytherapy and paediatric treatments are not provided in this department, where these are required a clinical referral is made to the Belfast Cancer Centre, radiotherapy department, for this service. The RT service operates 8.30am to 4.30pm Monday to Friday, with a standby service 4.30pm to 6.30pm. There is multidisciplinary team on call at weekends and bank holidays 9am to 5pm.

The service is provided to patients from a catchment area which includes WHSCT, the northern sector of the Northern Health and Social Care Trust (NHSCT) and County Donegal in the Republic of Ireland (ROI).

Before the inspection Ms Costelloe, HRPS, Mr Shiels, RSM, and key members of the radiotherapy team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed the following radiotherapy service has been provided between January 2024 and December 2024, 1267 computerised tomography (CT) planning scans and 267 magnetic resonance (MR) planning scans. There were 377 palliative courses and 718 radical courses of radiotherapy delivered. This was made up 1114 new courses with 12438 total fractions delivered. The superficial service provided four courses with 20 fractions in total. The inspection focused on the breast radiotherapy pathway. There were 369 new breast courses and 2744 treatment fractions; including 211 breast courses involving deep inspiration breath hold (DIBH).

The department has two pre-treatment CT scanners, one of which is for backup purposes only and is primarily utilised by the radiology diagnostic service. There is one MR scanner in the radiology diagnostics department which is available on a sessional basis for RT planning scans.

The service has Varian Eclipse licences for virtual simulation with four work locations and for treatment planning with eight work locations. It was confirmed that the software is deployed via Citrix and is accessible across the radiotherapy department (50 plus locations). There is a superficial kV unit in place which is now operational. Radiotherapy treatment is provided by three linear accelerators and one has iterative cone-beam computed tomography (iCBCT) in place. Varian respiratory gating for scanners (RGSC) is provided on all three linear accelerators and on the two CT scanners.

All accelerators are equipped with Image-guided radiation therapy (IGRT) technology. All equipment used for planning and treatment is networked to ARIA the Oncology Management System (OMS). A dedicated mould room is also provided.

The department is staffed by radiotherapy staff including 9.8 whole time equivalent (WTE) consultant clinical oncologists, two WTE clinical oncologist specialist registrars on a rotational basis and 32.87 WTE therapeutic radiographers. It was positive to note the appointment of a consultant therapeutic radiographer for urology, with another consultant therapeutic radiographer post presently being recruited for the breast service. The radiotherapy physics service is provided by six WTE Medical Physics Experts (MPEs), eight registered clinical scientists, one trainee clinical scientist, six dosimetrists and 3.5 radiotherapy engineers. The team is also supported by an MPE (diagnostics) contracted from Regional Medical Physics Service (RMPS) based in the Belfast Health and Social Care Trust (BHSCT). In addition a third party provider MPE service has been appointed to support a clinical trial project.

The radiotherapy department strives to be a paperless department and this is highly commendable.

It was good to note that the radiotherapy service quality management system (QMS) is certified by Caspe Healthcare Knowledge Systems (CHKS) as meeting the requirements of the standard BS EN ISO 9001:2015 and CHKS have also accredited the service as being compliant with its own Cancer Service standard in January 2024. The Physics Service has been accredited in March 2024 by UKAS to BS 70000:2017 as part of the Medical Physics and Clinical Engineering (MPACE) accreditation programme.

2.0 Inspection summary

On 3 and 4 December 2025, warranted IR(ME)R inspectors from the Regulation and Quality Improvement Authority (RQIA), with advice being provided by the United Kingdom Health Security Agency (UKHSA) staff carried out an IR(ME)R inspection of Altnagelvin North West Cancer Centre Radiotherapy department – Breast radiotherapy service, as part of RQIA's IR(ME)R inspection programme.

For the 2025/26 inspection year the inspections for radiotherapy services focused on the following key themes:

- Breast radiotherapy pathway to include the referral process, entitlement of duty holders, justification and authorisation process, optimisation and clinical evaluation
- IR(ME)R governance, including arrangements for compliance with IR(ME)R for the breast radiotherapy service
- Equipment quality assurance (QA) for breast radiotherapy
- The study of the risk of accidental or unintended exposures along the breast radiotherapy pathway
- Any other areas identified through the review of the submitted self-assessment form and supporting documentation

The purpose of our focus was to minimise risk to service users and staff, whilst being assured that ionising radiation services were being provided in keeping with Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.

Previous areas for improvement were also reviewed.

The service was notified of the inspection date and time; and requested to complete and submit a SAF and include supporting documentation to be reviewed in advance of the inspection. The site inspection process included:

- Discussion with management and staff
- Examination of relevant radiotherapy/breast radiotherapy documentation
- Review of the department and facilities
- Review of patient records to ensure compliance with IR(ME)R
- Discussion with patients/representatives (where appropriate)

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as follows:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- Carers and comforters

3.0 How we inspect

RQIA is responsible for monitoring, inspecting and enforcement of IR(ME)R. The inspection process includes the gathering and review of information we hold about the service, examination of a variety of relevant written procedures, protocols and records, and discussion with relevant staff. RQIA inspection reports reflect on how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

The information obtained is then considered before a decision is made on whether the service is operating in accordance with the relevant legislation and professional standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the relevant staff in charge and detailed in the Quality Improvement Plan (QIP).

As already stated, prior to the inspection, the service was requested to complete a SAF and provide RQIA with all relevant supporting information including written policies and procedures. This information was shared with UKHSA prior to the inspection and was used to direct discussions with key members of staff working within the breast radiotherapy service and provide guidance for the inspection process.

It is the responsibility of the Employer to ensure compliance with legislation, standards and best practice, and to address any deficits identified during our inspections.

4.0 What people told us about the service

As patients were awaiting or immediately recovering from radiotherapy treatment, it was deemed inappropriate to seek to speak to these patients on the days of the inspection.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

<table>
<tr><th colspan="3">Areas for improvement from the last inspection of the wider radiotherapy service on 29 and 30 November 2023</th></tr>
<tr><th colspan="2">Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018</th><th>Validation of compliance</th></tr>
<tr><td rowspan="2">Area for Improvement 1

Regulation: 6 Schedule 2.1(b)

Stated: First time</td><td>The Employer must ensure entitlement records for consultant clinical oncologists reflect all their duty holder roles including that of an operator and the electronic entitlement matrix is updated accordingly.</td><td rowspan="2">Met</td></tr>
<tr><td>Action taken as confirmed during the inspection:
It was confirmed that following the last inspection the Radiotherapy Clinical Lead updated entitlement records for clinical oncologists to reflect all their duty holder roles including that of an operator. The IR(ME)R Duty Holders Matrix MPT-RPR-001 was updated within Q-Pulse. This area for improvement has been addressed. Further detail on entitlement is outlined in section 5.2.1 of this report.</td></tr>
</table>

Area for Improvement 2 **Regulation:** 6(3) **Stated:** First time	The Employer must ensure training and competency underpin the entitlement process and is evidenced prior to the entitlement of staff.	**Met**
	Action taken as confirmed during the inspection: Management confirmed staff training and competency records fully underpin the entitlement process across all disciplines. New staff are not entitled until any required training is completed and competency achieved. This area for improvement has been addressed.	
Area for Improvement 3 **Regulation:** 6(2) **Stated:** First time	The Employer must carry out IR(ME)R refresher training for all radiotherapy staff with a focus on the duty holder roles and responsibilities within the radiotherapy patient pathway.	**Met**
	Action taken as confirmed during the inspection: Management and staff confirmed there is a rolling programme of IR(ME)R training for all staff which is monitored by management. Records of this training were reviewed. This area for improvement has been met.	
Area for improvement 4 **Regulation:** 12(9) **Stated:** First time	The Employer must establish an explicit clinical evaluation audit for all parts of the radiotherapy pathway.	**Partially Met**
	Action taken as confirmed during the inspection: Limited elements of clinical evaluation had been included in a number of audits. However, an explicit clinical evaluation audit for all parts of the radiotherapy pathway had not been conducted. This area of improvement has been partially met and is stated for a second time Further details are outlined in section 5.2.1 of this report.	

Area for improvement 5 **Regulation:** 6 Schedule 2.1(j) **Stated:** First time	The Employer must further develop Employers Procedure (EP) J and the imaging procedure to provide sound frameworks for the carrying out and recording of clinical evaluation for all types of exposures undertaken across the radiotherapy pathway.	**Met**
	Action taken as confirmed during the inspection: Employer's procedures were revised by Head of Radiotherapy Physics and Radiotherapy Services Manager. Imaging Quality Procedure was revised by Imaging Specialist Radiographer and Principle Clinical Scientist with input from Lead Treatment Radiographer and Treatment Radiographer. Aria encounters, checklists, and journal functionality to be reviewed to ensure efficient capturing of clinical evaluation for all exposures. This area for improvement has been met.	
Area for Improvement 6 **Regulation:** 6(2) **Stated:** First time	The Employer must establish a rolling programme of core IR(ME)R audits and consider the involvement of members of the multidisciplinary team (MDT) in carrying these out to raise awareness of IR(ME)R roles and responsibilities.	**Partially Met**
	Action taken as confirmed during the inspection: Management confirmed an inclusive review took place of the North West Cancer Centre (NWCC) Radiotherapy: • audit procedure • audit tracker • audit template The NWCC audit programme was developed containing a rolling programme of core IR(ME)R audits, with MDT involvement. However, IR(ME)R compliance audit was limited and is further discussed in section 5.2.1. This area for improvement has been partially met and is stated for a second time.	

Area for Improvement 7 **Regulation:** 7 **Stated:** First time	The Employer must further develop action plans to include how findings are to be shared, timeframe for re-audit and a clear final sign off. This should also be reflected in the audit tracker system.	**Met**
	Action taken as confirmed during the inspection: Audit action plans have been reviewed as part of a recent overhaul of audit processes for the Radiotherapy Service resulting in a more robust recording of audit action plans. This area for improvement has been met. Further details on clinical audit is outlined in section 5.2.1 of this report.	
Area for improvement 8 **Regulation:** 8(2) **Stated:** First time	The Employer must further develop the study of risk with a focus on accidental and unintended exposures outlining clear risks and mitigation measures.	**Met**
	Action taken as confirmed during the inspection: The study of risk has been devised on a specific area arising from an accidental and unintended exposure, it outlined clear risks and mitigation measures. This area of improvement has been met. Further detail on the study of risk is outlined in section 5.2.4.	
Area for Improvement 9 **Regulation:8** **Stated:** First time	The Employer must consider having one overarching incident/near miss management policy and procedure which fully reflects practice; and ensure the Trust Adverse Incident Policy includes reference to IR(ME)R and the radiotherapy department.	**Met**
	Action taken as confirmed during the inspection: The Trust Adverse Incident Policy includes reference to IR(ME)R and the radiotherapy department. A clear incident/near miss management policy and procedure is in place which fully reflects practice. This area for improvement has been met. Incident management is further discussed in section 5.2.4 of this report.	

Area for Improvement 10 **Regulation:** 8(3) **Stated:** First time	The Employer must further develop the trend analysis of incidents and near misses; and ensure trend analysis run consecutively.	**Met**
	Action taken as confirmed during the inspection: A detailed trend analysis of incidents and near misses that runs consecutively was in place. This area of improvement has been met. Further details are outlined in section 5.2.4 of this report.	
Area for improvement 11 **Regulation:** 6 Schedule 2.1 **Stated:** First time	The Employer must amend EP K, EP I and EP C as outlined in section 5.2.5 of this report	**Met**
	Action taken as confirmed during the inspection: Employer's procedures have been updated since the previous inspection. This area for improvement has been met. Further details are outlined in section 5.2.2 of this report.	

5.2 Inspection findings

5.2.1 Is the breast service pathway in accordance with the legislation, professional standards and guidance?

A referral is a request for an exposure or treatment to be performed, not a direction to undertake an exposure. A referral must be made by an appropriately entitled registered health care professional as defined by IR(ME)R. The referrer must supply sufficient medical data for the practitioner to enable justification. The referrer must also supply accurate up to date information to enable the operator to correctly identify the individual to be exposed.

The radiotherapy department operates an electronic IR(ME)R referral system built within the Encompass platform. The referral process was described in detail as follows; a clinical referral will be made to the service by either a discussion of the patient's case at the relevant multi-disciplinary team (MDT) meeting or (more commonly for palliative radiotherapy) a doctor to doctor discussion of an individual patient. Information in relation to the patent, including clinical notes, access to radiology and/or report and histology reports, are provided to the IR(ME)R referrer in order for them to accept the clinical referral.

The patient will have a new patient appointment with an oncologist who is suitably entitled to refer patients to treat that particular site with radiotherapy, where the decision to go ahead with radiotherapy treatment will be made between the doctor and the patient.

If the patient is to proceed with breast radiotherapy an electronic IR(ME)R referral must be completed by the entitled referrer. The management and staff clearly outlined arrangements for referrals in relation to prioritising, timing future examinations and the referral cancellation process. It was confirmed that all IR(ME)R referrers for breast radiotherapy are consultant clinical oncologists. However, with the introduction and further planned development of the consultant radiographer's role, it is anticpated that they may be entitled as referrers with a defined scope of practice. The entitled referrers are listed on the entitlement database matrix which is accessible to all staff.

Referral guidelines are included in anatomical site specific clinical protocols. A review of the breast clinical protocol found it to be overall comprehensive and robust. It is positive to note reference to international best practice (ESTRO Guidance). Management and staff clearly described arrangements for follow up of patients in relation to such matters as toxicity, however this detail was not outlined in the clinical protocol. An area of improvement has been made on this matter.

A review of patient records noted that the identification of the referrer and practitioner outlined on the radiotherapy referral form as follows:

'Referrer or Referrer and Practitioner:
Consultant:
Practitioner Second Sign if required:'

By requesting information in this way the individual duty holder who has acted as the referrer and practitioner may not be identifiable in certain situations. If an individual is only acting as the referrer, not the referrer and practitioner, it may not be identified, as both options may be indicated by a single signature. Additionally, upon review of patient referral records it was identified that there is not a mandatory question within the referral relating to pregnancy status. Therefore there is no evidence to demonstrate that the referrer provides the practitioner with information pertaining to pregnancy, prior to the justification of the planning CT exposure. Employer's Procedure C (enquiries of individuals to establish pregnancy and breastfeeding status), outlined clearly the role of the operator in relation to pregnancy enquires. However, the procedure did not outline the referrer's role on this matter in relation to providing sufficient medical data such as pregnancy status where relevant, within the referral form.

An area of improvement has been identified to:

- review and amend the format of the radiotherapy referral form to ensure that the referrer and practitioner are unambiguously identifiable
- ensure all relevant information (including pregnancy status where relevant) is provided to the practitioner prior to justification of the planning imaging exposure
- update Employer's Procedure C to reflect the process by which the referrer provides sufficient medical data, including the pregnancy status of the individual, where relevant.

Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within the organisation. They must have the knowledge and experience to authorise on behalf of the Employer, that the duty holder or a group of duty holders have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

The Employer has the responsibility to ensure that all practitioners and operators are adequately trained to perform the tasks defined within their scope of practice.

Evidence of training and competency must underpin the entitlement process and such records must be available for inspection.

An entitlement matrix providing a robust overview of each individual's IR(ME)R duty holder roles and corresponding scope of practice, summarised by task was in place. The matrix utilised a traffic light system to identify when review is due (amber) or exceeded (red). When inspectors spoke to staff on site, they demonstrated the use of the matrix to check and confirm entitlement and scope of practice. However, the matrix contained some ambiguous terminology, and specific tasks were not listed with the correct IR(ME)R duty holder roles. An area for improvement has been identified to ensure terminology utilised within the matrix should be reviewed to reduce ambiguity and remove unclear terminology.

Systems are in place to check the professional qualifications and appropriate registration of relevant employees.

Individuals are informed of their entitlement and corresponding scope of practice via individual entitlement records. Both the individual and the entitler sign this document to record entitlement has been granted and understood. Each individual entitlement record is held in Q Pulse and is reviewed annually, often at appraisal. It was noted that there is no direct system link between the overview matrix and individual records. It was advised to consider establishing a link for ease of access to the relevant training and entitlement records.

The format of individual entitlement records reviewed were ambiguous on occasions. Although standard titles were utilised, the detail recorded below each varied, and sometimes described tasks that were not related to the corresponding duty holder role. One heading "restrictions" had two differing interpretations outlined by management.

Discussion took place which identified ambiguity around the role of the practitioner and the task of plan approval. This is further discussed within the justification and authorisation section of this report.

A consultant radiographer's entitlement record was reviewed and it was identified their individual entitlement was recorded across multiple records, one of which was not easily accessible on the electronic system. As a result it was difficult to view the individual's entitlement and corresponding scope of practice in totality.

It is acknowledged there has been strenuous efforts made since the previous IR(ME)R inspection to implement a robust entitlement process across a complex service and much good work has been done particularly in devising and refining the overarching entitlement matrix.

However, as a result of the review of staff entitlement records and discussions with management and staff it has been established that there remains some further development to be carried out in relation to entitlement and an area for improvement has been identified as follows to assist:

- ensure that individual IR(ME)R entitlement records are reviewed and strengthened, utilising a standardised template, with clear, unambiguous terminology, and a format which supports future review and update.

Employer's Procedure B (identification of individuals entitled as duty holders), sets out the arrangements for entitlement and overall provides a sound framework for the entitlement process.

However it was advised to amend it in light of any changes to the entitlement process as a result of this inspection. Employer's Procedures are further discussed in section 5.2.2 of this report.

Justification and authorisation process

The duty holder roles of operator and practitioner was examined in relation to the justification and authorisation of exposures. Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place.

Justification and authorisation was discussed with staff, who demonstrated an understanding of the process and this was further evidenced in a randomly selected number of patient records.

Breast treatment plans at present are not authorised under guidelines and are always justified and authorised by an entitled practitioner, who is a specialised breast consultant clinical oncologist. Authorisation of the treatment exposures is demonstrated via the treatment prescription and plan approval. However, ambiguity was identified when discussing the approval of plans in the absence of the prescribing practitioner. The inspection team outlined that where a consultant clinical oncologist justifies an individual's treatment plan, and records authorisation via the plan, they are acting as a practitioner. Responsibility for the practitioner's task of justification cannot be delegated to an individual acting as an operator.

Through discussion it was identified that the department is moving towards "per protocol" sign off for simple breast radiotherapy plans. This process will involve appropriately entitled operators authorising treatment exposures via plan approval, in accordance with set criteria. Advice was provided that the department must clearly document the "per protocol" process and ensure all duty holders involved clearly understand their corresponding role and responsibility. In accordance with Regulation 11(5), the operator must authorise exposures in accordance with guidelines issued by a named practitioner.

An area of improvement has been identified as follows:

- review and strengthen Employer's Procedure B, to ensure the process of justification and authorisation is clearly outlined
- ensure appropriate authorisation guidelines, issued by a named practitioner, are in place where treatment exposures are authorised by entitled operators.

It was confirmed that the breast radiotherapy treatment service does not include carers and comforters exposures as their involvement would not be justified.

Optimisation

Optimisation is a key principle of the radiation protection framework within IR(ME)R and is required for all medical exposures. Optimisation requires a multidisciplinary approach. Effective communication between staff groups is essential including consultant oncologists, therapeutic radiographers, medical physicists and clinical technologists.

For therapeutic exposures the practitioner must ensure optimisation of both target volumes, outlines organs of interest and set dose targets and constraint.

Operators must select appropriate equipment and methods to ensure doses are kept as low as reasonably practicable (ALARP) and consistent with the therapeutic purpose.

Staff and management outlined a range of measures in place to ensure that medical exposures are optimised.

- Robust training programme
- Written clinical protocols
- QA programmes for written procedures, equipment and methods
- Employer's procedures
- Routine equipment maintenance
- Equipment quality assurance
- Incident management
- Management of near misses
- Clinical audit
- IR(ME)R safety audits
- Dose audit for radiotherapy planning CT Scans
- Local adoption of national dose reference levels (DoRLs) for radiotherapy planning CT Scans

The department had adopted national consent forms developed by the Royal College of Radiologists (RCR) which include site specific information on the benefit and risk of breast radiotherapy. Staff confirmed that patients received detailed patient information booklets, and breast patients are invited to attend a pre-education session where treatment process and side effects of treatment are discussed. On the first day of treatment operators reconfirm that the patient has received benefit and risk information and a discussion to ensure consent remains valid.

Clinical evaluation

The Employer must ensure that a clinical evaluation of the outcome of all exposures is recorded, including relevant factors associated with the exposure. In practice, clinical evaluation might include the recording and interpretation of therapeutic implications, interpretation of planning or verification images and toxicities in relation to therapeutic exposures. Clinical evaluation is an operator function. Individuals who carry out clinical evaluation should be adequately trained and entitled.

Breast radiotherapy pathway includes a range of medical exposures (planning, treatment and verification exposures) and the approach to clinical evaluation for each of these is different. The evaluation must be timely and accurate such that it informs patient's care.

The carrying out of the operator task of clinical evaluation was examined across the breast pathway. A range of entitled operators carry out this task, which is reflected in their individual scope of practice. It was confirmed clinical evaluation is recorded in ARIA during all stages of the treatment pathway.

Employer's Procedure J sets out the arrangements for clinical evaluation of all radiotherapy medical exposures, however, important information shared in the SAF and through discussion with staff was not included in the Employer's Procedure.

An area of improvement has been identified in relation to amending Employer's Procedure J to ensure further detail is captured for the clinical evaluation of each exposure including how it is carried out, where it is recorded and who is carrying out the task.

At the conclusion of treatment an 'end of treatment summary' is completed in line with relevant procedures and protocols. This summary includes details of the treatment site, dose and fractionation, start and finish dates and overall treatment duration. Any decisions to deviate from the intended treatment prescription and the reasons are documented.

As stated in section 5.1 of this report as a result of the previous IR(ME)R inspection an area of improvement was made to establish an explicit clinical evaluation audit for all parts of the radiotherapy pathway. On review it was noted that limited elements of clinical evaluation had been included in a number of audits. However, an explicit clinical evaluation audit for all parts of the radiotherapy pathway had not been conducted. This area of improvement has been assessed as partially met and is stated for a second time. Further advice was also provided on this matter.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the breast radiotherapy pathway largely complies with the legislation and the addressing of area of improvements outlined will assist in ensuring robust adherence to IR(ME)R. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Are there appropriate IR(ME)R governance arrangements in place to ensure compliance with the legislation?

Organisational Structures and Governance Committees

The overall responsibility for ensuring compliance with IR(ME)R lies with the Employer. The role of IR(ME)R Employer in the WHSCT is held by the Medical Director.

The WHSCT Radiation Safety Policy (RSP) sets out the organisational structures, lines of accountability and governance structures for ionising and non-ionising radiation services. The RSP reviewed was a draft copy dated May 2025 which had yet to be ratified and issued. The copy submitted contained numerous comments from a range of modality management. It was noted under section 4 'Responsiblities', it refers to delegating responsibility for IR(ME)R from the WHSCT Chief Executive to the WHSCT Medical Director. As stated the IR(ME)R Employer for WHSCT is the Medical Director. It was advised the above wording in relation to delegation of responsibilities is misleading and should be reviewed. An area of improvement has been made on this matter.

The Radiation Safety Committee is responsible for developing the RSP and reports activities through to the Clinical and Social Care Governance subcommittee and onward to the Trust Board as detailed in the organisational structure set out in the RSP. It was confirmed representatives from the radiotherapy service sit on the RSP committee. The governance framework includes a range of monthly meetings including Radiotherapy Operational Meetings, Radiotherapy Governance Meetings and Higher Management Team Meetings.

These report to Acute Governance meetings as required and to Clinical and Social Care Governance meetings where the Medical Director attends as the Employer.

Management outlined the monthly radiotherapy governance meeting with MDT attendance, including three section leads (radiotherapy, physics and medical), as well as three section managers. Others may also attend. All aspects of governance are discussed at this meeting. Actions are managed via an action log which is reviewed and discussed at each meeting.

The governance meeting feeds into the Hospital Management Team (HMT) for each directorate. This is a monthly meeting chaired by the acting Assistant Director for the directorate. The radiotherapy department provide a quarterly report to this meeting, which includes Key Performance Indicators (KPIs), incidents, risk assessments, staffing and workforce. It was confirmed pressures and issues are escalated to this forum.

A Radiation Protection Supervisor/modality report is submitted by radiotherapy to the Trust radiation protection working group (RPWG). It reports on IR(ME)R, including significant accidental unattended exposures (SAUE), audit and training. The RPWG is chaired by the Medical Director and convenes three times each year, and a radiotherapy report is submitted at each.

However, a review of a RPS/modality report for the last RPWG meeting (09/10/25) highlighted the report did not contain sections pertaining to IR(ME)R but rather focussed on IRR assurance. As a result, an area of improvement has been identified to ensure the radiotherapy RPS/modality report is reviewed and updated to reflect information on IR(ME)R assurance such as IR(ME)R audit, clinical audit, SAUE information, IR(ME)R training and entitlement, as well as updates on Employer's Procedures.

Staff described the meetings relating to the breast radiotherapy pathway which include weekly peer review meetings. These are multi-disciplinary and include representation from clinical oncologists, radiographers, MPE and planners. Patients who are being planned and treated are discussed. Peer review includes topics not limited to contouring, but also on treatment review and image guidance. Where issues occur there is daily access to specialist radiographers, clinical oncologists or MPE's. On the treatment units there are informal daily huddles each morning, where issues can be raised. It was confirmed that team update meetings (TUMS) occur once a month.

The physics team confirmed dosimetry weekly meetings and planning weekly meetings are held separately. The dosimetry meetings discuss any issues or information on Quality Assurance (QA) or planned maintenance. The physics team meet on the first Tuesday of each month.

In addition it was good to note the radiotherapy and physics managers meet with their counterparts in Belfast Trust regularly. It was confirmed that a remote monthly operational meeting with the Republic of Ireland (ROI) clinical representatives in relation to patients from the ROI undergoing radiotherapy treatment in WHSCT radiotherapy department is held.

Communication

Management and staff confirmed there was good communication within the breast service. There are a range of meetings held to promote robust communication and good governance within the physics team, consultant clinical oncologists and the therapeutic radiographers. Minutes are disseminated to staff, updates are shared via email and the opportunity to add items to the agenda are also put forward.

There is a central point in the staff area for access to procedures, clinical protocols, treatments for the week ahead and other relevant information. The team can also contact each other via email and through other electronic means.

It was good to note the breast radiotherapy team liaises closely with ward nursing staff, to ensure robust scheduling of treatment.

The management described clear communication escalation procedures. The RSM and HRPS can contact the director via telephone and will if required inform the Employer.
Updates to standard operating procedures or any new documents are disseminated amongst staff via Q pulse. All staff have access to Q pulse, which also hosts audit results, PowerPoint presentations and educational material.

Clinical Audit

IR(ME)R tells us that clinical audit means the systematic examination or review of medical radiological procedures which seek to improve the quality and outcome of patient care through a structured review, whereby medical radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated and the application of new standards if necessary.

It was evident the breast radiotherapy service has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement.

The department shared that the previous process for audit, relied on the quality manager to co-ordinate. This role was vacant for a prolonged period of time and it negatively impacted the audit programme. However, it was encouraging that a new quality manager had been appointed and that there was recognition that a new process for audit had to be implemented within the department. It was confirmed that the audit module within Q Pulse shall now be used to manage and co-ordinate audit, including the management of areas of non-compliance identified, and subsequent actions required. The process will become automated, with pre-programmed email alerts to staff utilised. This will enhance the resilience of the audit programme. The process has only recently been introduced. Audits are identified by the audit group, which includes the head of radiotherapy physics, radiotherapy service manager, and lead clinical oncologist. A summary of audits is shared with the governance meeting.

The breast clinical audits shared were discussed. A positive example of clinical audit was shared via the Partial Breast Irradiation (PBI) Audit which was structured with clear objectives and findings. However, it was identified not all the audits shared met the definition of a clinical audit. Advice was outlined in relation to points for clinical audit consideration including what feeds into the clinical audit schedule, the use of a structured template, identification of clear objectives or benchmarks, co-ordination and approval of clinical audit programme and ensuring learning identified is implemented and communicated.

It was noted that only a limited number of audits were completed for the breast service. Management outlined some contributing factors affecting capacity for clinical audit including staff shortages, the absence of an audit lead within the consultant clinical oncologist workforce and significant projects undertaken during 2025, such as the implementation of a new electronic referral system. It was positive to note that three consultant clinical oncologist posts will be shortly advertised, one of which will include clinical audit lead. As clinical audit is a legislative requirement and to ensure that the clinical audit process is reviewed and strengthened, an area of improvement has been identified on this matter.

Ambiguity was identified around difference and purpose of clinical and IR(ME)R audits. IR(ME)R audits are mechanism to ensure compliance with IR(ME)R and adherence to the Trusts Employer's Procedures, protocols etc. As outlined in section 5.1 a previous area for improvement was reviewed on the matter. It was noted that management had confirmed an inclusive review had taken place of the NWCC Radiotherapy audit procedure, audit tracker and audit template. Also that the audit programme was developed containing a rolling programme of core IR(ME)R audits, with MDT involvement.

However, the IR(ME)R compliance audits were found to be limited and did not fully reflect a robust approach to ensuring IR(ME)R compliance across all radiotherapy matters. Advice was provided in relation to establishing a robust IR(ME)R audit programme and seeking support from the WHSCT radiology diagnostics team who have a rolling programme of IR(ME)R audits in place.

Overall, although a number IR(ME)R audits were noted within the audit programme, it was assessed that the previous area for improvement had been partially met and is stated for a second time.

Employer's Procedures (EPs)

'WHSCT Employers procedures for External Beam Radiotherapy' Employer's Procedures were in place which had been noted as 'active' from 20 November 2025. Management confirmed that the Employer's Procedures are ratified at the governance meeting. Any changes to the document are fully tracked. The document must be approved by the Radiotherapy Services Manager, Head of Radiotherapy Physics and Radiotherapy Clinical Lead. This was demonstrated via Q Pulse. The inspection team noted the significant delay from first approval (Radiotherapy Clinical Lead on the 12/05/2025) to the next approval (Radiotherapy Services Manager on the 15/08/2025) to the last approval noted on the 19/11/2025 by the Head of Radiotherapy Physics. It was queried whether each individual had approved the most recent version of the document. It was also unclear whether the document was shared or ratified at the Trust RPWG which includes the Employer. An area of improvement has been identified to ensure the ratification process for the Employer's Procedures is reviewed and updated to include ratification at the Trust RPWG, and the updated process should be detailed within Employer's Procedure D (QA programme for written procedures, protocols and equipment).

Overall the Employer's Procedures were well written. However, a number have already been highlighted in this report that require improvement.

In addition an area of improvement has been identified to amend and update the Employer's Procedures (EP) as follows:

- EP K review and strengthen to reflect all processes currently in place to minimise the probability and magnitude of accidental or unintended exposures
- EP G research, review and ensure it's accurate, reflective of practice and outlines clear arrangements for research patient identification
- EP I benefits and risks, ensure it fully reflects all the measures taken to inform patients of the benefits and risks as outlined by management and staff during inspection
- EP E patient radiation dose, ensure how patient radiation dose is recorded for planning CT is included
- EP B entitlement , amend statement on page 8 'IR(ME)R entitlement as a practitioner may be granted instantly in the following' as this is not in keeping with IR(ME)R

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that there are good governance systems in place and it is envisaged that the areas of improvement identified will help strengthen and support these systems. Particularly in relation to clinical and IR(ME)R audit. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation with regard to equipment quality assurance (QA)?

An up to date radiotherapy equipment inventory which contained all of the information as specified within the legislation is held and maintained by the head of radiotherapy physics. This list of equipment is kept under constant review and updated when there is a change.

The Employer has overall responsibility for ensuring that a QA programme for equipment which meets the requirements of IR(ME)R is in place.

It was noted that robust processes are in place. A detailed QA schedule was in place and records were managed in an access database which was reviewed during inspection. The overall QA schedule was found to be up to date with no work outstanding.

The management of the QA schedule was described and discussion included the risk management of any tests that might need to be delayed for operational reasons. Work instructions were reviewed and described individual QA tests to be completed, the detail of the test was described, and action / tolerance levels, escalation points and responsibilities were included. However, this information and also information outlined in the SAF relating to equipment was not outlined in Employer's Procedure D, quality assurance including equipment. An area of improvement has been identified to further develop Employer's Procedure D in relation to equipment QA.

The nature of the tests to be completed were informed by the local MPE and underpinned by national guidance such as IPEM Report 81 Physics Aspects of Quality Control in Radiotherapy, European guidance, American Association for Physicists in Medicine (AAPM), International Atomic Energy Agency (IAEA) and manufacturer guidance as appropriate. Work instructions for individual QA tests were linked to training records to support entitlement to ensure appropriately trained entitled operators completed the tests.

It was noted that QA is completed by appropriately trained and entitled staff. Review of completed training and QA records confirmed this.

Local documentation for each test outlines who is responsible for completion of the test, confirmation of the test, and how concerns or actions are to be escalated. Results of tests are recorded in an access database which allows trend analysis and audit. It was positive to note on site that the dose associated with each CT planning scan is now recorded and stored within the patient's notes (ARIA journal note recording DLP and CTDi). However, Employer's Procedure E (assessment of patient radiation dose), did not reflect this process and an area of improvement has been identified to update Employer's Procedure E to ensure the method for recording patient radiation dose is detailed for planning CT exposures. Please refer to section 5.2.2 for further details.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that there are robust and thorough arrangements in place for breast radiotherapy service equipment QA. The management and staff for radiotherapy physics and breast services demonstrated a very good understanding of their roles and responsibilities in this regard.

The areas of improvement will ensure the Employer's Procedures associated with equipment QA fully reflect practice. The inspection team acknowledge the commitment of staff in this regard.

5.2.4 Does the breast radiotherapy service have a robust study of risk in place as required under Reg 8 (2)?

Incident Management

Management and clinical staff described the internal process for reporting accidental or unintended exposures and how notifiable incidents are reported to the appropriate enforcing authority.

Management and staff confirmed there is a good culture of incident reporting across notifiable, non-notifiable incidents and near misses. However, the HRPS confirmed as part of the preparation for the inspection it was noted that not all SAUE's which have been identified departmentally have been notified to RQIA in accordance with Regulation 8(4). The corresponding notification forms had been completed and attached to the corresponding patient record, but unfortunately, they had not been notified to RQIA. Two of the SAUE's shared as evidence for the inspection, had not been notified to RQIA. Local systems failed to ensure the events identified were appropriately notified to RQIA.

The importance of a robust incident management system was highlighted to the department, not only as a legislative requirement, but to ensure events are appropriately investigated and identified learning drives continual improvement.

Therefore, an action plan to address the matter was requested to be devised and submitted to RQIA by 19 December 2025. The action plan should review and strengthen the process for identifying, investigating, notifying and sharing learning from potential or actual accidental or unintended exposures.

The actions required include:

- The department must review all incidents reported locally to ensure any SAUE events have been appropriately notified to RQIA.
- The documented process for incident management must be reviewed and strengthened, including incident identification, investigation, RQIA notification where applicable and sharing learning from potential or actual accidental or unintended exposures.
- The Event Reporting Procedure should be reviewed and updated to reflect strengthened processes and to remove ambiguous terminology and information. The procedure must be issued and shared with all appropriate staff.
- Integration of the DATIX Handlers Group into the wider governance structure should be considered as part of the wider review of incident management. Terms of reference for the group should be clarified and formalised to include purpose and clear lines of responsibility.

A robust action plan was submitted to RQIA on 19 December 2025 and it was found to outline all the necessary action to strengthen incident management. An area of improvement has been identified to fully implement the incident management action plan submitted to RQIA to strengthen the process for identifying, investigating, notifying and sharing learning from potential or actual accidental or unintended exposures.

The clinical decision as to when an incident should be classified as clinically significant accidental and unintended exposures (CSAUE) was discussed.

The Clinical Lead must decide if the incident is considered clinically significant and if so, the individual exposed or representative should be informed of the incident by the Clinical Lead or the practitioner. Employer's Procedure L outlines clear roles and responsibilities in relation to management of a CSAUE.

The NWCC analysis of incidents and near misses report January to December 2024 was reviewed and it was found to be a detailed analysis of radiotherapy incidents providing data that was fully interpreted to identify clear root cause analysis that could drive improvement. It was advised where thematic trends or significant events have been identified, it may be beneficial to develop and record a corresponding action plan with the analysis to document agreed actions and monitor progress. An area for improvement has been identified on this matter.

Staff demonstrated a good understanding of the action to take in the event of an incident or near miss occurring and confirmed learning from incidents and near misses are shared. Radiotherapy incidents are reviewed as part of the radiotherapy governance structures previously described. However, it is hoped the action plan devised in relation to incident management will strengthen the oversight arrangements of incidents.

Regulation 8 (2) requires the Employer to implement a quality assurance programme of radiotherapeutic practices which includes a study of the risk of accidental or unintended exposures. The study of risk needs to be clearly stated as unintended or accidental exposures.

The department summarised the process for developing and reviewing studies of risk of accidental or unintended exposures. The department undertook a robust analysis of risk associated with actual or potential accidental or unintended exposures (AUE) involving verification imaging. An initial study was completed, which is reviewed every 6 months. To identify all areas of risk associated with actual or potential AUE involving verification imaging, a multidisciplinary working party was formed. Staff surveys were undertaken, and results were communicated internally via staff meetings. Actions have been taken to minimise disruptions within the treatment-controlled areas, including attaching signs to the treating operator seats, to minimise the risk of disruption. It was noted the assessment did not include the risk of equipment malfunction during imaging, which is a common contributing factor nationally. The department noted that this was a less frequent contributing factor locally. It is recommended the study of risk considers all potential risks which may attribute to accidental or unintended exposures, including equipment malfunctions. Local process for managing equipment malfunctions or defective equipment may be recorded as current mitigations, including escalation pathways. Learning from the study was shared with both radiography, physics and medical staff, via operational and governance meetings. The study has also been shared with HTM and the CCSG meeting.

The department noted that the process of development is a positive example of how the outcome of the study of risk has informed practice. To build on this good work, an area of improvement has been identified to extend the study of risk to include the entire radiotherapy pathway. Management were receptive to this advice.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that department require to strengthen arrangements with respect to the management of incidents and the areas for improvement outlined will assist on this matter.

The meaningful work carried out on the study of risk is acknowledged and the area of improvement outlined will further develop the study of risk. The inspection team acknowledge the commitment of staff in this regard.

6.0 Conclusion

There were 17 areas of improvement identified as a result of this inspection. These are fully outlined in the appended quality improvement plan (QIP).

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the NWCC radiotherapy department is operating within the legislative framework and maintaining safe standards of practice for patients.

The inspection team would like to extend their gratitude to the management team and staff for their contribution to the inspection process.

7.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R and other published recommendations which promote current best practice to improve the quality of service experienced by patients.

Total number of areas for improvement	17

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The Employer should confirm that these actions have been completed and return the completed QIP via BSU.Admin@rqia.org.uk for assessment by the inspector.

Quality Improvement Plan

Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Area for improvement 1 **Ref:** Regulation 6(4) **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure the clinical protocol for breast radiotherapy clearly describes arrangements for follow up of patients in relation to such matters as toxicity. Ref 5.2.1
	Response by Employer detailing the actions taken: The Breast Clinical Protocol has been amended to reflect that patients continuing on SACT will have their Radiotherapy follow-up care managed by the SACT team upon completion of their Radiotherapy and patients will be discharged to Self Directed Aftercare (SDA) at the appropriate time.Page 30 of Breast Clinical Protocol.
Area for improvement 2 **Ref:** Regulation 10(5) & Schedule 2.1(c) **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure the following : • review and amend the format of the radiotherapy referral form to ensure that the referrer and practitioner are unambiguously identifiable • ensure all relevant information (including pregnancy status where relevant) is provided to the practitioner prior to justification of the planning imaging exposure • update Employer's Procedure C to reflect the process by which the referrer provides sufficient medical data, including the pregnancy status of the individual, where relevant. Ref 5.2.1
	Response by Employer detailing the actions taken: - Radiotherapy referral form amendment has been submitted to ENCOMPASS team for change to be made electronically to have Referrer separate from Practitioner- see attachment with proposed change. -Referrers have to select if patient has child bearing capacity on the referral form. If "No" has been selected, the pregnancy status declaration disappears from the form, if "yes" is selected then it is visible. Pregnancy status is considered at referral but due to the time delay of possibly weeks before any planned exposure to radiation, this may change. The confirmation of pregnancy status is made at discussion of Risk Vs Benefits and recorded on the patient consent form. Pregnancy status is checked again by the operator prior to any exposure being delivered and recorded on the patient ID check form. We have requested a change to the referral form so that the pregnancy status answer remains visible upon completion, and does not disappear if "no" is selected.

	- Additional information has been added to Section C, Employer's Procedures to capture this.
Area for improvement 3 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure terminology utilised within the entitlement matrix is reviewed and upated to reduce ambiguity and remove unclear terminology. Ref 5.2.1
	Response by Employer detailing the actions taken: Please see attached draft Letter of Entitlement to individual Therapy Radiographers , which is proposed to be held in Q-Pulse People module. This will be reviewed and updated annually at Staff Appraisal. For new staff we are proposing staged entitlement as competencies are attained.
Area for improvement 4 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall review and strengthen IR(ME)R entitlement templates to ensure a standardised approach with clear, unambiguous terminology, and a format which supports future review and update. Ref 5.2.1
	Response by Employer detailing the actions taken: Work is ongoing on this improvement as we try to find the best way to capture all the required information and record it, in an easy to read format to allow staff to check and confirm any signatures are entitled for the roles they have undertaken. We have liaised with Diagnostic Radiography colleagues to review their matrix.
Area for improvement 5 **Ref:** Regulation 11 Schedule 2.1(b) **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure the following: • review and strengthen Employer's Procedure B, to ensure the process of justification and authorisation is clearly outlined • ensure appropriate authorisation guidelines, issued by a named practitioner, are in place where treatment exposures are authorised by entitled operators. Ref 5.2.1
	Response by Employer detailing the actions taken: - Employer's procedures have been reviewed and amended, to capture these points. See pages 7 & 8 in attached Employer's procedures. - The imaging protocol clearly defines what additional exposures are permitted to confirm correct patient preparation or set-up on treatment. Any additional imaging exposures beyond those permited are authorised by a MPE after assesment and discussion. At CT planning, any additional exposures or increased scan length will require Practitioner authorisation and justification before being done, and this will be noted in ARIA journal patient record.

Area for improvement 6 **Ref:** Regulation 12(9) Schedule 2.1(j) **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure Employer's Procedure J is amended to include further detail for the clinical evaluation of each exposure, including how it is carried out, where it is recorded and who is carrying out the task. Ref 5.2.1 **Response by Employer detailing the actions taken**: The Employer's Procedure has been amended to capture this, page 24.
Area for improvement 7 **Ref:** Regulation 12(9) Regulation 6(2) **Stated:** Second time **To be completed by:** 4 March 2026	The Employer must establish an explicit clinical evaluation audit for all parts of the radiotherapy pathway. Ref 5.2.1 **Response by Employer detailing the actions taken**: See attached proposed audit schedule, which contains a breakdown of the various patient pathway components and planned audits of these.
Area for improvement 8 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure that the draft Radiation Safety Policy is amended in relation to the responsibilities of the Employer. Ref 5.2.2 **Response by Employer detailing the actions taken**: The Draft has been amended - please see attached,. Following discussion at the last WHSCT Radiation Protection Working Group(RP WG), it has been agreed that the Employer Role will move from the Medical Director to the Chief Executive. This will be implemented when the draft Trust Radiation Safety Policy is ratified at the next WHSCT RP WG in May 2026. This change is reflected in this new draft.
Area for improvement 9 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure the 'Radiotherapy RPS/modality report' is reviewed and updated to include aspects of IR(ME)R assurance. Ref 5.2.2 **Response by Employer detailing the actions taken**: Please see attached

Area for improvement 10 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 4 March 2026	The Employer shall ensure that the clinical audit process is reviewed and strengthened. Ref 5.2.2
	Response by Employer detailing the actions taken: We have liaised with other Departments and will structure our audits under separate categories for IRR and IRMER and identify specific audits to meet each category within IRMER and the clinical evaluation of the Radiotherapy Pathway, see attached audit schedule for 2026-27.
Area for improvement 11 **Ref:** Regulation 6 (2) **Stated:** Second time **To be completed by:** 4 March 2026	The Employer must establish a rolling programme of core IR(ME)R audits and consider the involvement of members of the multidisciplinary team in carrying these out to raise awareness of IR(ME)R roles and responsibilities. Ref 5.2.2
	Response by Employer detailing the actions taken: See attached audit schedule, the Therapy Radiographers and Medical Physics teams have already identified new staff across all grades,to be part of the audit team undertaking regular audits. The Medical team have been asked to identify middle grade Dr's and allocate audits to them.
Area for improvement 12 **Ref:** Regulation 6 Schedule 2.1(d) **Stated:** First time **To be completed by:** 4 March 2026	The Employer must ensure the ratification process for the Employer's Procedures is reviewed and updated to include ratification at the Trust RPWG, and the updated process should be detailed within Employer's Procedure D (QA programme for written procedures, protocols and equipment). Ref 5.2.2
	Response by Employer detailing the actions taken: The ratification of the Employer's Procedure for External Beam Radiotherapy will be taken to the next meeting of the WHSCT RPWG for ratification, and this has been added to section D.

Area for improvement 13 **Ref:** Regulation 6 (1) Schedule 2.1 **Stated:** First time **To be completed by:** 4 March 2026	The Employer must amend and update the Employer's Procedures (EPs) as follows: • EP K review and strengthen to reflect all processes currently in place to minimise the probability and magnitude of accidental or unintended exposures • EP G research, review and ensure it's accurate, reflective of practice and outlines clear arrangements for research patient identification • EP I benefits and risks, ensure it fully reflects all the measures taken to inform patients of the benefits and risks as outlined by management and staff during inspection • EP E patient radiation dose, is reviewed and updated to reflect how the planning exposure patient dose is recorded in practice. • EP B entitlement, amend statement on page 8 'IR(ME)R entitlement as a practitioner may be granted instantly in the following' as this is not in keeping with IR(ME)R Ref 5.2.2
	Response by Employer detailing the actions taken: See draft Employer's procedures with additions to address above comments.
Area for improvement 14 **Ref:** Regulation 6.1 Schedule 2.1(d) **Stated:** First time **To be completed by:** 4 March 2026	The Employer must further develop Employer's Procedure D in relation to equipment QA. Ref 5.2.3
	Response by Employer detailing the actions taken: See draft revision in section D
Area for improvement 15 **Ref:** Regulation 8 **Stated:** First time **To be completed by:** 4 February 2026	The Employer must fully implement the incident management action plan submitted to RQIA to strengthen the process for identifying, investigating, notifying and sharing learning from potential or actual accidental or unintended exposures. Ref 5.2.4
	Response by Employer detailing the actions taken: The draft sent in December is now in current practice.

Area for improvement 16 **Ref:** Regulation 8 **Stated:** First time **To be completed by:** 4 March 2026	The Employer must ensure an action plan is developed and recorded with the analysis of incidents to document agreed actions and monitor progress where thematic trends or significant events have been identified. Ref 5.2.4
	Response by Employer detailing the actions taken: The study of risk is now embedded in annual audit programme but from monthly Datix Handler meetings we may identify a need to undertake a relevant Study of Risk if any themes or trends or major incident occurred.
Area for improvement 17 **Ref:** Regulation 8(2) **Stated:** First time **To be completed by:** 4 April 2026	The Employer must extend the study of risk to include the entire radiotherapy pathway. Ref 5.2.4
	Response by Employer detailing the actions taken: The previous two Study of Risk audits were focused on treatment delivery of radiotherapy. The next Study of Risk will be focused on Human Error as a factor at any stage of the treatment pathway. This covers the process from patient referral, planning, treatment delivery and review. We continue to explore The Study of Risk and network with other centres to improve our compliance. We have looked at the tri-annual report from UKHSA and their identified trends and themes and reviewed our reported coded incidents against these- to benchmark for similarities and outliers.

Please return all information to BSU.Admin@rqia.org.uk

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