Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Ionising Radiation (Medical Exposure) Regulations Inspection Report (Announced)

Radiotherapy Department, North Wales Cancer Treatment Centre, Glan Clwyd Hospital, Betsi Cadwaladr University Health Board

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Contents

1. What we did

Full details on how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Radiotherapy Department at North Wales Cancer Treatment Centre, Glan Clwyd Hospital, Betsi Cadwaladr University Health Board on 28 and 29 January 2025. During our inspection we looked at how the department complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and two Specialist Radiation Protection Scientists from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. The inspection was led by a HIW Senior Healthcare Inspector.

During the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. One questionnaire was completed by a patient, and 40 were completed by staff. Feedback and some of the staff comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

Note the inspection findings relate to the point in time that the inspection was undertaken.

2. Summary of inspection

Quality of Patient Experience

Overall summary:
Staff were courteous, ensuring patient privacy and dignity with waiting areas and individual changing rooms available. Patients praised the care, environment and treatment received. Staff involved patients in care decisions, explaining treatments thoroughly. Parking challenges were noted and the need for better accommodation for patients traveling long distances was highlighted.

Timely care was provided, with any delays effectively communicated to patients. Emergency radiotherapy was available during weekends and holidays. Bilingual signage and information were present, though appointment letters were only in English. Staff could access translation services if needed. The department ensured rights and equality, with good compliance in mandatory training and accessibility for all patients.

This is what we recommend the service can improve:

- Parking options and consideration of the needs of patients travelling longer distances for treatment
- Bilingual appointment letters for those that prefer Welsh language communication.

This is what the service did well:

- Kind, friendly and helpful staff
- Welcoming and spacious environment.

Delivery of Safe and Effective Care

Overall summary:

Overall, there was good compliance with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R). The employer had written procedures and protocols in place as required under IR(ME)R. Staff engaged in the inspection demonstrated a clear understanding of their roles and responsibilities under IR(ME)R. Suitable arrangements were in place to provide safe and effective care to patients.

This is what we recommend the service can improve:

- Continue to update documentation and procedures to comply with amendments to IR(ME)R
- Streamline document management systems and associated processes

- Audit and log incomplete referrals to ensure identification of themes and address required learning
- Strengthen training and assessment of competencies for medical and medical physics staff
- Review and update operator entitlement for medical and medical physics staff
- Strengthen audit processes for clinical and IR(ME)R audits
- Increase and improve the mechanisms in place to feedback incident trends to IR(ME)R employer.

This is what the service did well:

- Staff were positively engaged in the inspection process.
- The documents provided to HIW as part of the inspection showed a good understanding of the IR(ME)R requirements.
- Robust overview of radiographer training records and scope of practice evidenced.
- Positive examples of referrer and practitioner scope of practice evidenced.
- Wide range of clinical and IR(ME)R audits undertaken and used to inform service development, monitor IR(ME)R compliance and drive quality improvement.

Quality of Management and Leadership

Overall summary:
During the inspection, staff feedback was mixed. While over half recommended the organisation as a workplace, many felt the service was understaffed. Comments from staff highlighted issues with management recognition and support. Staff praised their immediate managers but felt senior management was not always aware of their challenges.

We noted there were some interim leadership roles and long term vacancies, which need to be permanently recruited to. The self-assessment form was comprehensive, and staff engaged fully with the inspection process.

The department promoted opportunities for patient feedback.

This is what we recommend the service can improve:

- The Health Board should review the interim leadership positions in the department and develop an effective plan to secure a stable and effective leadership team.

- Improve and increase communication mechanisms by which the IR(ME)R employer is made aware of incidents
- Strengthen local training in accordance with IR(ME)R Schedule 3
- The Health Board is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report.

This is what the service did well:

- Multidisciplinary working with other cancer centres.
- The management team demonstrated a commitment to learn from HIW's inspection findings and make improvements where needed.
- The staff team was committed to providing a good service and were patient focussed.

3. What we found

Quality of Patient Experience

Patient feedback

We spoke with patients that had attended the centre for treatment. Their feedback included terms like:

"Fantastic"
"Brilliant"
"Spot on"
"Caring"

Person-centred

Health promotion

We saw a variety of leaflets were displayed in the main waiting room for patients and their carers. These provided written information about the different types of cancer and cancer treatments. They also provided information on the support available.

Information for patients and their carers, included what to expect when they attended and also details of post-treatment care. Leaflets and posters as well as the health board website also included links to the websites and contact details of other organisations who produced their own information leaflets and who can provide help and support for persons affected by cancer.

Dignified and respectful care

During our inspection, we found staff were courteous to patients and they made efforts to protect patient privacy and dignity.

Sub waiting areas were located near the treatment rooms, which provided a greater level of privacy away from the main waiting room. Individual changing rooms were available, providing privacy when patients were required to change out of their clothes for their treatment. We also saw doors to rooms where treatment was performed were closed when being used.

We spoke with five patients during inspection and all were complimentary of the care, environment and treatment received.

All staff who answered the question in the HIW questionnaire told us patients' privacy and dignity were maintained in the department. The physical environment also helped promote patient privacy and dignity.

Individualised care
All staff who answered the question in the HIW questionnaire told us patients were involved in decisions about their care. The patients that we spoke with agreed.

Staff members confirmed that they explained what individual treatment entailed and shared specific examples of giving patients time to understand the processes involved.

Staff and some patients reported that challenges with parking meant that many patients amended their journey times to accommodate time finding a parking space.

We were told that many patients travel a distance to attend their radiotherapy appointments, staff confirmed that overnight accommodation for these patients was challenging. Transport was provided, however staff recognised that the repeated journey to and from the department may be a disincentive to attend for radiotherapy.

The employer should review and improve processes in place to ensure that the needs of patients travelling for regular radiotherapy appointments are met.

Timely

Timely care
Staff told us when unexpected delays were experienced these would be communicated to patients on the day of their appointments. We were told patients would be informed verbally by reception staff. We also saw a large sign in both waiting areas that was used to inform patients of any delays. Patients seen during the inspection were treated promptly.

Staff described suitable arrangements to provide emergency on-call radiotherapy treatments during weekends and public holidays.

Equitable

Communication and language
We saw bilingual signage, in both Welsh and English, displayed within the department. There were also symbols displayed to inform patients they may

converse with staff in Welsh. We saw some staff wearing lanyards to show patients they were Welsh speakers. We heard Welsh being spoken to patients throughout our inspection.

Written patient information leaflets available in the department were available bilingually. Patient appointment letters were only available in English.

The Health Board is required to provide HIW with details of the action taken to ensure that patients can receive letters in the preferred language they wish to use to communicate.

Posters were displayed advising patients who were or might be pregnant to inform staff prior to them receiving their treatment.

Staff we spoke to told us they could access a translation service, if required, to assist communication with patients whose first language was not English.

Rights and equality

We found patient rights were protected and promoted in the department. We were told equality, diversity and inclusion training formed part of the Health Board mandatory staff training programme. Data provided to HIW showed good staff compliance with such training.

Staff explained the arrangements in place to make the service accessible to all, such as wheelchair access. The department was accessible with wide doors, clear corridors and spacious treatment rooms.

Delivery of Safe and Effective Care

Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017 (as amended)[1]

Employer's Duties: establishment of general procedures, protocols and quality assurance programmes

Procedures and protocols
The employer had established written procedures and protocols as required under IR(ME)R 2017.

We reviewed all IR(ME)R 2017 documentation submitted in advance of the inspection and spoke to duty holders and senior management to confirm understanding of processes and practice. The documents provided showed a good understanding of IR(ME)R 2017. However, the employer must further refine these documents based on the specific feedback given during inspection and in line with amendments to IR(ME)R 2017.

Documentation, including Employer's Procedures and other IR(ME)R related documentation was managed departmentally via a shared drive, with manual processes in place for the review, update and communication of updated documentation. Some staff members told us that they had experienced challenges in accessing this drive. We noted an example of challenges related to this when we reviewed radiographer training records. Cone Beam CT imaging competencies had been made available to staff without due process, and were available without appropriate document control.

Overall, we found that the policies and procedures were in place, however they:

- Relied on manual processes for the review, update and communication of updated documentation
- Lacked a formal document control solution to manage documentation and streamline processes
- Had not all been updated to comply with amendments to IR(ME)R
- Contained duplicate information with inconsistent detail on occasion.

The employer should ensure the current document management system is reviewed and strengthened. The opportunity should be taken to enhance

[1] As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 and the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024

accessibility, reduce duplication of information across documents, eliminate manual maintenance and monitoring processes which are reliant on key staff members. Consideration should be given to resourcing and supporting a suitable electronic document management system (DMS).

The employer must streamline the current document management system and associated operational processes to strengthen document management.

The self-assessment, staff feedback and on-site inspection demonstrated the department was very paper heavy, with the completion of many tasks along the patient pathway recorded both on paper and electronically. This created duplication of effort and ambiguity surrounding primary source data as part of the patient record. Some patient records that we reviewed included amendments and additions that were not always signed and dated.

The employer must review and update processes and ensure that patient records and care pathway information and amendments are signed, dated and clear.

Discussions during the inspection highlighted opportunities to streamline patient records through optimisation of recent software updates to the oncology management system, treatment planning system and software imaging solution. This would need to be scoped and planned with staged definitive timeframes and appropriate supporting infrastructure (e.g. additional monitors, or licences, staff time). This would strengthen processes and ensure better use of locally available systems.

Referral guidelines

The employer had established referral guidelines and suitable arrangements were described for making these available to individuals entitled as referrers.

Arrangements were in place for brachytherapy services to be provided by another employer (Employer B). The other employer has entitled a NWCTC referrer, who submits a referral for brachytherapy treatment, and all other IR(ME)R tasks are provided by Employer B. We reviewed documentation that confirmed this arrangement was managed under a contract between the two healthcare providers. The contract documentation reviewed expired in 2020 and requires an update. The employer must also ensure that corresponding brachytherapy for gynaecological cancer departmental documentation is reviewed and updated to reflect the requirement to share and make available appropriate radiotherapy and brachytherapy dose information to both the NWCTC and Employer B. Clinical protocols should also be shared between sites to ensure both services are compatible and reflective of each other.

The employer must review and update the contract and corresponding treatment documentation to reflect the requirement to share and make available appropriate radiotherapy and brachytherapy dose information between employers. Clinical protocols should also be shared between sites to ensure that both services are compatible and reflective of each other.

The review of patient records during inspection, recent IR(ME)R audit of referral processes (2023) and discussion with staff identified the following risks:

- Inconsistent provision of patient identifiers
- Incomplete referrals with mandatory information such as pregnancy status missing
- Use of multiple hospital numbers (reflecting 3 referring hospital site systems)
- Delay in referral due to the manual process of delivering paper referral from outlying clinics.

The employer should consider the adoption of an electronic referral system with inclusion of mandatory fields and user specific logins should be considered to mitigate risks identified.

In the interim period it is recommended that incomplete referrals are included in the local incident learning system, to monitor trends and support the identification of actions for improvement.

Dose reference levels for typical localisation or verification exposures
It is positive to note that local dose reference levels (DoRL) have been developed for standard Computed Tomography (CT) planning scans, and are available to operators via local procedures. Local DoRL for radiotherapy planning CT scans are within National DoRL. Evidence of regular CT DLP audits was evidenced on site. Typical verification imaging doses were available in documents shared. Evidence of local dose audits for verification exposures was not seen.

It is positive to note the development of a Dose Reference Level Procedure in accordance with the requirements of the IR(ME)R Amendment Regulations 2024.

Medical research
We were told the department participated in research involving medical exposures. The arrangements for this were set out in an overarching document. The completed self-assessment form described suitable governance arrangements for research trials, the process for managing research exposures and the measures in place to ensure adherence to dose constraints.

Entitlement
There was a suitable employer's written procedure to identify individuals entitled to act as referrer, practitioner, or operator within a specified scope of practice. This clearly described the task of entitlement was delegated from the Chief Executive to the Executive Director of Allied Health Professions and Health Science (EDAHPHS) for the co-ordination of radiation-related Health Board activities.

The EDAHPHS has overall responsibility for deciding who could act as IR(ME)R duty holders. The Health Board's Ionising Radiation Policy (RP01) described how the task is delegated down to services.

The Clinical Director and Heads of Service entitle staff members as duty holders in accordance with local procedures. Entitlement documentation, including corresponding scopes of practice, were reviewed for each duty holder role on site. Positive examples of referrer and practitioner scope of practice were evidenced outlining 'level' of entitlement and tumour site linked to individual entitlement with dates and sign-off included. Robust overview of radiographer operator scope of practice was also evidenced. Entitlement records for the operator duty holder role for medical staff and medical physics staff require strengthening.
We reviewed the assessment of training and competencies for duty holders during the inspection. We noted that the documentation evidencing training and competency for medical staff and medical physics staff also required strengthening.

The employer must

- **Strengthen the training and assessment of competencies for medical staff and medical physics staff**

- **Strengthen recording of continuing education and training after qualification**

- **Review and update operator entitlement for medical staff and all staff groups within medical physics.**

Patient identification
The employer had an up to date written procedure in place for staff to follow to correctly identify patients prior to their exposure. This aimed to ensure that the correct patient had the correct exposure. The procedure set out that staff were

required to ask the patient for their name, date of birth and address to confirm their identity and that these should be verified against primary source data.

Detail included within the procedure also outlined the required steps to identify different types of patients including individuals who may lack capacity, individuals with sensory impairments and individuals who speak an alternative language. Staff we spoke with were able to clearly describe the steps they routinely took in order to correctly identify patients prior to examinations within the department.

Written procedure and staff conversations confirmed that there was always a minimum of two operators involved in the exposure, and both must hear the active response from the patient, have sight of the primary source data to confirm identification and sign the treatment card to indicate joint responsibility for patient identification.

Further clarification by managers confirmed that the two operators involved in the exposure duplicated the task of patient identification. This process was introduced following a radiation incident involving the incorrect identification of patient several years ago.

Following discussions around efficiencies and the effectiveness of the second check, the department agreed to review the patient identification process.

Individuals of childbearing potential (pregnancy enquiries)
There was an employer's written procedure in place for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding.

The self-assessment form confirmed that with all radiotherapy planning exposures and first treatment exposure, individuals of child-bearing capability aged 12-55yrs (inclusive) are asked if there is any chance they could be pregnant. They were also asked to sign a declaration stating they understand they should not become pregnant during their course of treatment. The sample of referral and treatment documentation we reviewed evidenced operators had made enquiries regarding the pregnancy status of individuals in accordance with the employer's written procedure.

Staff we spoke to were able to describe the action they would take to make pregnancy enquires of individuals. This was consistent with the employer's written procedure.

The employer should review and update the pregnancy enquiry procedure to include actions where a pregnancy has been confirmed and the exposure is subsequently justified.

Benefits and risks
Suitable arrangements were described for providing patients with adequate information on the benefits of having the exposure and the risks associated with the radiation dose. We were told this information was provided to patients during discussions as part of the consent to treatment process.

Written information leaflets were also provided to patients to help support these discussions and a copy of the written consent form was also available for patients. Written information leaflets were available in waiting rooms during the inspection.

Clinical evaluation
There was an employer's procedure in place which set out the arrangements regarding clinical evaluation of medical exposures undertaken within the department, including planning, verification and treatment exposures. The procedure detailed that exposures completed at each stage of the patient pathway must be evaluated by trained duty holders and described how this was evidenced.

Clinical evaluation procedure reviewed included some ambiguous terminology such as "images that are surplus to requirement." During the inspection staff agreed to refine this language.

The employer should review and update departmental documentation pertaining to clinical evaluation to remove ambiguous terminology.

Non-medical imaging exposures
The employer's IR(ME)R documentation clearly stated non-medical imaging exposures are not carried out in the radiotherapy department.

Employer's duties: clinical audit
We were provided with a range of examples of clinical and IR(ME)R audits that had been carried out within the department. These included an IR(ME)R audit related to pregnancy enquiries, referral and entitlement process audits. It was positive to note the development of a Clinical Audit Procedure in accordance with the requirements of the IR(ME)R Amendment Regulations 2024. Discussion with staff on site demonstrated that audit outcomes are utilised locally to inform and evaluate service development, monitor IR(ME)R compliance and drive quality improvement. Consideration should be given to strengthening audit processes by standardising audit documentation across disciplines, including evidence of appropriate actions taken in response to audit findings, such as action plans.

The employer should consider strengthening the process of clinical and IR(ME)R audit by addressing the following areas for improvement:

- **Implementation of an annual multidisciplinary clinical audit programme**
- **Consistent use of standardised audit documentation**
- **Clear identification of areas for improvement**
- **Development of corresponding action plan where required**
- **Communication of results and re-audit when necessary**
- **Review and update the clinical audit procedure to reflect changes in process.**

Employer's duties: accidental or unintended exposures

There was an employer's written procedure in place for the reporting, recording, investigating and the analysis of significant accidental or unintended exposures involving radiation. This clearly described individuals' roles and responsibilities and the thresholds for when such incidents were required to be reported. The arrangements for informing the referrer, practitioner and the patient were also well described in the written procedure.

We reviewed recent accidental or unintended exposures and it was positive to see the multidisciplinary collaborative approach to review and subsequent learning actions taken as a result.

It was positive to note the implementation of peer review across multiple treatment sites (for example neurology, head and neck and colorectal), with further roll out planned. It is also positive to note collaboration across sites to facilitate the peer review process. Following discussion of a recent SAUE reported to HIW, it was concluded the roll out of peer review across all sites would contribute to the mitigation of risk of future delineation errors.

Upon review of documentation related to accidental or unintended exposures, two areas for improvement were identified. The employer must update actions with a plan to ensure :

- **The implementation of peer review across all sites**
- **The extension of referral criteria within clinical protocols to include essential investigations e.g. histology report, physical examination and diagnostic imaging (images and reports).**

On review of information in the Self-Assessment Form (SAF) and corresponding supporting evidence, it was unclear who informs the patient or their representative when a clinically significant accidental or unintended exposure occurs. Subsequent discussion with staff confirmed the responsible oncologist

carries out this task. **This detail should be added to the corresponding procedure.**

Duties of practitioner, operator and referrer
Staff we spoke with demonstrated a good understanding of their duty holder roles and responsibilities under IR(ME)R 2017.

Justification of individual exposures
Arrangements were described for the justification and authorisation of each exposure performed at the radiotherapy planning and re-planning, verification, and treatment stages of the patient's care pathway. Although there are local written procedures and protocols in place describing justification and authorisation of each exposure, some ambiguity and inconsistencies were identified within supporting documentation.

Documentation detailing the justification and authorisation of concomitant verification imaging exposures should be reviewed to ensure this process is clearly and consistently described.

Optimisation
The employer had arrangements in place for the optimisation of exposures including planning, verification and treatment exposures. These arrangements aimed to ensure that radiation doses delivered to patients, as a result of exposures, were kept as low as reasonably practicable.

Computed tomography (CT) planning protocols were optimised, audited and local dose reference levels applied in accordance with national guidance. Verification imaging was site specific and described in clinical protocols. Senior managers confirmed that treatments were individually planned and verified to ensure that the optimal treatment technique, machine and beam arrangement was chosen, to minimise the exposure doses while maintaining target coverage.

As part of the treatment planning process for radiotherapy, any of the relevant patients' organs at risk for the exposure must be defined. During discussions with staff, it was clearly understood that this was an operator task, with planning staff and clinical oncology staff trained to undertake this function. These structures were reviewed at time of plan approval with the clinical oncology staff taking on responsibility for this task.

Formalisation and progression of CBCT dose optimisation was discussed with MPEs during inspection. We were told of collaboration between NWCTC and Employer B for Cone Beam Computed Tomography CBCT)verification imaging dose

optimisation. This work was ongoing and would replace the default settings currently used in the clinical department.

The employer is required to provide HIW with details of the action taken to progress optimisation of CBCT verification imaging dose.

Paediatrics
Documentation reviewed and conversations with senior managers confirmed that NWCTC did not treat children.

Carers or comforters
The SAF confirmed that carers and comforters are not allowed to remain with patients during any medical exposure. Local IR(ME)R documentation, "Guidance for the exposure of carers and comforters" was seen and confirmed this.

Expert advice
There were three Medical Physics Experts (MPEs) appointed to provide expert advice and support to the department, a fourth individual had submitted a portfolio to the MPE certification body and was awaiting the outcome. We were informed that MPE support, advice and oversight was provided in a number of areas within the department. Areas of support included providing training to staff, equipment testing and QA, exposure dose evaluation, undertaking audits and investigation of accidental or unintended exposures. Staff we spoke to confirmed that they were able to contact an MPE for advice and support where necessary, on an ad hoc basis.

Equipment: general duties of the employer
We reviewed the IR(ME)R equipment log and noted that there is aging equipment within the department. This included two 14 year old Trilogy Linear Accelerators, one of which is removed from clinical use, whilst the other continues to be used clinically. The risks associated with the aging equipment within the department needs to be reviewed and used to inform the current risk register record. It would be positive to have clear time frames for replacement.

The employer should conduct an assessment of risk for the Linear Accelerator (installed 2010), and use this to inform the current risk register record. Acceptable performance criteria and definitive timelines for continued clinical use must be agreed and recorded.

During the review of the SAF we were informed that an in-house spreadsheet was used for manual calculations for virtual simulation planned treatments. The confirmation of the monitor units involved a repeat of the same calculation in place of a fully independent methodology. Risks associated with an in-house

spreadsheet were discussed and staff suggested adoption of a locally available dose check calculation software.

The employer should ensure current processes for planning simple or palliative treatments and 'extended FSD's' are reviewed and strengthened.

Safe

Risk management

Senior managers we spoke with described the risk management arrangements and assessments in place within the department. We were also informed that all relevant documents were available to staff.

All but two staff who answered the HIW staff questionnaire said their organisation encourages them to report errors, near misses or incidents and most felt staff who are involved in an error are treated fairly. Most who answered said they would feel secure raising concerns about unsafe clinical practice but less than half are confident their concerns would be addressed (18/40). Evidence reviewed during the inspection indicated that staff members were not routinely involved in incident investigation and feedback on why something may be externally notifiable or subsequent action taken was not always given.

The employer should reflect and act on comments received around reporting errors, near misses and incidents and the subsequent actions needed.

Processes should be reviewed and strengthened to ensure staff members are involved in the investigation, and receive appropriate feedback in regard to why something has been externally notified as well as subsequent action taken.

The departmental study of risk was found to be succinct, user friendly and informed by incident analysis as well as baseline assessments. This could be improved by including an action plan to monitor actions and record progression.

The employer should include an action plan within the departmental study of risk to monitor and record the progression of actions associated with the study.

During the inspection it was noted that the twice yearly multi-disciplinary incident analysis meetings had stopped.

The employer should reinstate regular multi-disciplinary, incident analysis meetings. This should be supported by an incident analysis report, and

subsequent action plan to record and monitor actions identified to address areas for improvement.

Infection prevention and control (IPC) and decontamination

All areas of the department we saw were visibly clean and tidy and the equipment we saw was also clean.

The majority of staff who completed the questions in the HIW questionnaire told us their organisation implements and effective infection control policy and confirmed there is an effective cleaning schedule in place. We were told infection prevention and control training formed part of mandatory staff training. Data provided to HIW showed very good staff compliance with this training.

Safeguarding of children and safeguarding adults

Staff we spoke to were aware of the Health Board safeguarding policies and procedures and where to access these. Staff were also able to describe the actions they would take should they have a safeguarding concern.

We were told safeguarding training formed part of the mandatory staff training programme. Data provided to HIW showed good staff compliance with this training.

Effective

Patient records

We reviewed four referral and treatment records. All referral documentation is currently paper based. The records mostly showed evidence of the employer's written procedures being followed by staff, however one record:

- Did not include three unique patient identifiers on the referral form
- Recorded diagnosis only and indications were not recorded
- Previous history information had been annotated on the paper referral without details of who recorded the note or when (name or date).

The employer must perform a records audit with subsequent actions to ensure that referral and treatment records are complete.

Efficient

Efficient

Senior staff described patient care pathways were kept under continuous review as part of the service improvement and efficiency process.

It was positive to note that radiotherapy access to MRI and PET CT has been considered in future plans within radiology, this should ensure efficient and timely access to appropriate imaging for patients.

Quality of Management and Leadership

Staff feedback

As part of our inspection, discussions were held with senior managers for the service, as well as a selection of staff working within the department. Additionally, a staff survey was made available to provide all staff working within the department with the opportunity to provide their views. Responses received through HIW questionnaires were mixed. While over half the staff would recommend their organisation as a place to work, few staff felt there were sufficient staff for them to do their job properly.

The Health Board is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report.

Staff comments included:

We received several comments on the service, some are shown below:

> *"My immediate manager is available and helpful for my day to day work related issues. My head of department does not recognise or even acknowledge our difficulties in my work area."*

> *"Numerous risk assessments have been completed over the years about the challenges we face. We feel like they are ignored and swept under a massive rug! When we try to implement changes there is little support from my manger, rather he try's to implement change in an area where he know nothing about! We have tried several approaches to resolve our many issues - going to very senior manager, HR, Occy Health and even our unions over the years. We feel disrespected, undervalued and our motivation for work is low."*

> *"Radiotherapy planning is run by 2 separate work groups and there is a large disparity in the management of the different groups which causes a lot of bad feeling and conflict within the group. Inappropriate staffing levels and skill mix mean hitting the workload targets is very difficult which can impact the quality of care the patients receive. Concerns have been raised by the staff numerous times over the years, but no changes have been made. Clearer management and communication could help to improve the problems currently being faced."*

> *"The staff always try to give 100% to patients in their care. Staff will give time and support to patients. Staff provide a supportive environment to colleagues."*

Leadership

Governance and leadership

The Chief Executive of the Health Board is the designated employer under IR(ME)R. They have overall responsibility for ensuring the regulations were complied with. Where appropriate the employer had delegated tasks to other professionals working in the Health Board to implement IR(ME)R.

Senior staff submitted details of the organisational structure. Clear lines of reporting and responsibilities under IR(ME)R were described and demonstrated. However, we found interim arrangements were in place for some leadership roles and work should be progressed to recruit individuals to these roles permanently.

The Health Board should review the interim leadership positions in the department and develop an effective plan to secure a stable and effective leadership team.

The self-assessment form completed by the department ahead of the inspection was submitted within the agreed timescale and was comprehensive. All staff engaged fully with the inspection process and managers demonstrated a commitment to acting on HIW's inspection findings, making improvements where needed.

The inspection team reviewed mechanisms and methods in place to ensure that effective communication to the IR(ME)R employer were in place. In order to further strengthen these methods, **the radiotherapy department should consider submitting a radiotherapy incident analysis report to the Radiation Protection Committee to present and share learning, as well as provide a method of communication to the employer.**

Senior staff described the arrangements in place to monitor the quality and safety of services provided in the department and to provide assurance to the Health Board as part of the governance and monitoring arrangements. Half the staff who answered the question in the HIW questionnaire (20/40) told us they would recommend their organisation as a good place to work. The remainder of staff told us they would not. Most staff who answered the question (30/40) told us their organisation was supportive, with the remainder disagreeing with this.

Workforce

Skilled and enabled workforce
Multiple disciplines work within the department including Clinical Oncologists, Clinical Oncology Registrars, Consultant/Advanced Practice Radiographers, Radiographers, MPEs, Clinical Scientists, Dosimetrists and Clinical Technical Officers. The department also provided clinical placements for Radiotherapy and Radiotherapy Physics students. It was evident the staff team was committed to providing a good service and were patient focussed.

Senior staff reported there were some long term vacancies at the time of the inspection in relation to Radiotherapy staff, which would need to be recruited to meet recommendations made by relevant professional bodies. Senior leaders shared their plans with the inspection team.

We reviewed the training records in relation to IR(ME)R for four staff. We noted that a record of annual reading was currently limited to Local Rules and suggested that the departmental IR(ME)R documentation was included in the annual reading.

Training records related to Radiographer IR(ME)R training were seen and were comprehensive. We also reviewed data showing staff compliance with the Health Board mandatory training programme. Staff were expected to complete training on a range of topics relevant to their role. The data showed a good level of staff compliance with mandatory training.

Most respondents who answered felt they had appropriate training to undertake their role.

There were some areas where training compliance was not as well evidenced. Departmental radiation protection training, for example following the recent IR(ME)R amendment, was not evidenced during the review of Clinical Oncologist and Medical Physics training records.
The employer should strengthen local radiation protection training in accordance with IR(ME)R Schedule 3.

Staff members that we spoke with during the inspection expressed satisfaction with their roles and the support they received from their teams.
The responses indicated a strong sense of collaboration and dedication among the staff.
The data provided to us also showed the majority of staff had received an appraisal of their work within the last 12 months.

Culture

People engagement, feedback and learning

We saw posters prominently displayed in the department detailing how patients can feed back. These allowed patients to provide feedback or make a complaint. We also saw an electronic tablet was available in the main waiting area for patients to use to provide feedback. There was information displayed on other organisations patients can contact for help and advice on making a complaint.

4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A – Summary of concerns resolved during the inspection

The table below summarises the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection			

Appendix B – Immediate improvement plan

Service: Radiotherapy Department, North Wales Cancer Treatment Centre

Date of inspection: 28 and 29 January 2025

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	No immediate assurance or non-compliance issues were identified					
2.						

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative:

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Radiotherapy Department, North Wales Cancer Treatment Centre

Date of inspection: 28 and 29 January 2025

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

	Risk/finding/issue	Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	Many patients travel a distance to attend their radiotherapy appointments, overnight accommodation for these patients was challenging. Staff recognised that the repeated journey to and from the department may be a disincentive to attend for radiotherapy.	The employer should review and improve processes in place to ensure that the needs of patients travelling for regular radiotherapy appointments are met.	Standard – person Centred	Recommendation that patients meeting a specified criteria could be eligible for up to 25 nights local accommodation to be funded through charities. Agreed in principal, Procedure to be circulated to senior leadership team in April 2025 and cascaded to cancer centre staff.	Cancer Services General Manager	May 2025

2.	Patient appointment letters were available in English only.	The Health Board is required to provide HIW with details of the action taken to ensure that patients can receive letters in the preferred language they wish to use to communicate.	Standard - Equitable	Translate all current Radiotherapy appointment letters to Welsh and send both Welsh and English versions.	Radiotherapy Services Manager	September 2025, but will be dependent on translation services
3.	Documentation within the department • Relied on manual processes for the review, update and communication of updated documentation • Lacked a formal document control solution to manage documentation and streamline processes	The employer must streamline the current document management system and associated operational processes to strengthen document management.	IR(ME)R - Regulation 6(4)(b) and Schedule 2(k)	Discuss with South Wales colleagues. Obtain quotes for electronic document management system e.g. iPASSPORT. Once costings known enquire about charity funding. In the interim, a spreadsheet is currently used to track review dates for clinical protocols.	Radiotherapy Services Manager	May 2025 December 2025 April 2026

	• Had not all been updated to comply with amendments to IR(ME)R • Contained duplicate information with inconsistent detail on occasion.			This will be adopted for the whole quality management system Review documents and update to comply with IR(ME)R amendments where necessary. This will be done prior to the external quality management system audit due in Oct 2025.		June 2025 Sept 2025
4.	Many tasks along the patient pathway were recorded both on paper and electronically. This created duplication of effort and ambiguity surrounding primary source data as part of the patient record. Some patient records that we reviewed included amendments and additions that were not always signed and dated.	The employer must review and update processes and ensure that patient records and care pathway information and amendments are signed, dated and clear.	IR(ME)R - Regulation 6(4)(b) and Schedule 2(k)	Staff reminded to sign and date any documentation at monthly staff meeting and via email. A patient pathway audit is scheduled for June 2025, and this issue will be included within this audit. Use of an electronic carepath is being	Radiotherapy Services Manager Radiotherapy Services	Completed 13/03/25 June 2025 April 2026

				implemented within the department, although there is some paper duplication while we transition.	Manager and Head of Radiotherapy Physics	
5.	Contract documentation reviewed expired in 2020 and requires an update	The employer must review and update the contract and corresponding treatment documentation to reflect the requirement to share and make available appropriate radiotherapy and brachytherapy dose information between employers. Clinical protocols should also be shared between sites to ensure that both services are compatible and reflective of each other.	IR(ME)R - Regulation 6A(2)	Signed contract (April 24-25) between BCUHB and other employer is available. Clinical protocol has been shared via email with other employer. The existing brachytherapy procedure will be strengthened to include IR(ME)R amendments. Once completed, this can be approved by both parties.	Cancer Services General Manager Radiotherapy Services Manager	Completed 24/3/25 Completed 24/3/25 July 2025 September 2025

6.	The review of patient records during inspection, recent IR(ME)R audit of referral processes (2023) and discussion with staff identified the following risks: • Inconsistent provision of patient identifiers • Incomplete referrals with mandatory information such as pregnancy status missing • Use of multiple hospital numbers (reflecting 3 referring hospital site systems)	The employer should consider the adoption of an electronic referral system with inclusion of mandatory fields and user specific logins should be considered to mitigate risks identified. In the interim period it is recommended that incomplete referrals are included in the local incident learning system, to monitor trends and support the identification of actions for improvement.	IR(ME)R - Schedule 2(k) Regulation 8(3)(a) and (b)	Remind referrers via email to fully complete the requests. Incomplete referrals to be highlighted to the referrer and a spreadsheet generated to track themes. All referrers to Radiotherapy have been reminded to use NHS number as unique identifier (via email)	Radiotherapy Services Manager Radiotherapy Services Manager	April 2025 Completed 23/3/25

	• Delay in referral due to the manual process of delivering paper referral from outlying clinics.			Also included within annual Entitlement to Refer for Radiotherapy letter. An electronic referral solution is being investigated. South Wales centres have already begun this process in the manner we would likely adopt. Advice will be sought following their experience.	Radiotherapy Clinical Lead Consultant Radiotherapy Services Manager	April 2025 April 2026
7.	Entitlement records for the operator duty holder role for medical staff and medical physics staff require strengthening. We noted that the documentation evidencing training and competency for medical	The employer must • Strengthen the training and assessment of competencies for medical staff and medical physics staff • Strengthen recording of continuing	IR(ME)R - Regulation 6(3)(a)(b) Schedule 2(b)	Medical staff and radiotherapy physics staff will adopt the recommendations of the RCR /IPEM Radiotherapy Board guidance for compiling training records.	Radiotherapy Clinical Lead Consultant Head of Radiotherapy Physics	April 2026 to allow completion of all annual reviews

	staff and medical physics staff also required strengthening	education and training after qualification • Review and update operator entitlement for medical staff and all staff groups within medical physics.				
8.	The procedure reviewed did not include actions when a pregnancy was confirmed and exposure justified	The employer should review and update the pregnancy enquiry procedure to include actions where a pregnancy has been confirmed and the exposure is subsequently justified.	IR(ME)R - Regulation 11(3)(d)(i)	Documentation around confirmed pregnancy has been reviewed and strengthened. A section regarding unintentional exposure of a pregnant patient has been included.	Radiotherapy Services Manager	Completed 20/3/25
9.	The clinical evaluation procedure reviewed included some ambiguous terminology	The employer should review and update departmental documentation pertaining to clinical evaluation to	IR(ME)R - Regulation 12(9) and Schedule 2 (j)	Documentation reviewed and ambiguous terminology removed.	Radiotherapy Services Manager	Completed 20/3/25

		remove ambiguous terminology.				
10.	We reviewed clinical and IR(ME)R audits and concluded that they could be strengthened	The employer should consider strengthening the process of clinical and IR(ME)R audit by addressing the following areas for improvement: • Implementation of an annual multidisciplinary clinical audit programme • Consistent use of standardised audit documentation • Clear identification of areas for improvement • Development of corresponding action plan where required • Communication of results and re-audit when necessary	IR(ME)R - Regulation 7	Standardised documentation is already in place for Quality Management system audits. This should also be utilised for clinical and IR(ME)R audits. Staff have been advised of this via email. An additional section has been added to the existing form to include communication of results and action plan development. Timetable to be drawn up at the next radiotherapy oversight meeting.	Radiotherapy Services Manager Radiotherapy Services Manager,	Completed 24/3/25 May 2025

		• Review and update the clinical audit procedure to reflect changes in process.		A quarterly audit meeting will then be scheduled to share and debate audits. Update of clinical audit procedure to include IR(ME)R schedule 2 (o) requirements.	Head of Radiotherapy Physics, Radiotherapy Clinical Lead Consultant, Department RCR Clinical Audit Lead	Commencing September 2025 April 2025
11.	Following discussion of a recent SAUE reported to HIW, it was concluded the roll out of peer review across all sites would contribute to the mitigation of risk of future delineation errors	The employer must update actions with a plan to ensure: • The implementation of peer review across all sites • The extension of referral criteria within clinical protocols to include essential investigations e.g. histology report, physical examination and diagnostic	IR(ME)R - Regulation 12(2) and Schedule 2(k)	Service will implement current RCR guidance: Radiotherapy target volume definition and peer review, second edition 2022 and review all job plans. Update referral criteria at protocol review date. Cross reference recorded dates for protocol review and address any overdue	Radiotherapy Clinical Lead Consultant Radiotherapy Clinical Lead Consultant	April 2026 to allow completion of all job plan reviews. May 2025

		imaging (images and reports).		and agree realistic completion plan so updates are through all disease sites.		
12.	Local written procedures and protocols in place describing justification and authorisation of each exposure were reviewed. Some ambiguity and inconsistencies were identified within supporting documentation.	Documentation detailing the justification and authorisation of concomitant verification imaging exposures should be reviewed to ensure this process is clearly and consistently described.	IR(ME)R - Regulation 11(1)(b-c) & 11(2)	Documentation reviewed and ambiguous terminology removed.	Radiotherapy Services Manager	Completed 20/3/25
13.	Ongoing collaboration was in place for CBCT image dose optimisation	The employer is required to provide HIW with details of the action taken to progress optimisation of CBCT verification imaging dose.	IR(ME)R - Regulation 12(3)	CBCT settings have been obtained from other employers and the selected settings will now be reviewed and implemented.	Head of Radiotherapy Physics	July 2025
14.	There were two 14 years old LINACs, one is still in clinical use.	The employer should conduct an assessment of risk for the Linear Accelerator (installed	IR(ME)R - Regulation 15(6)(a, (b) and (c)	Risk assessment is in place on the risk register. All linacs are subject to a QC	Head of Radiotherapy Physics	June 2026

		2010), and use this to inform the current risk register record. Acceptable performance criteria and definitive timelines for continued clinical use must be agreed and recorded.		schedule to demonstrate they continue to meet specifications from installation to last use. A business case is in development to replace the machine mentioned, and it is expected that the replacement machine will be in clinical use first quarter of '26-27 financial year.		
15.	An inhouse spreadsheet was used for manual calculations for virtual simulation planned treatments. There were risks associated with an in-house spreadsheet for this purpose.	The employer should ensure current processes for planning simple or palliative treatments and 'extended FSD's' are reviewed and strengthened	IR(ME)R - Regulation 12(3)	Work is underway to move away from manual calculations for planning virtual simulation treatments and use the treatment planning system and secondary dose calculation used for "planned" treatments.	Head of Radiotherapy Physics	Jan 2026

				This work includes review of the current extended FSD treatments.		
16.	Staff feedback confirmed that those staff involved in investigations are not routinely informed of actions.	Processes should be reviewed and strengthened to ensure staff members are involved in the investigation, and receive appropriate feedback in regard to why something has been externally notified as well as subsequent action taken.	IR(ME)R - Regulation 8(2)	Monthly quality assurance memo includes details of all incidents and is emailed to all staff. Any externally reportable incidents will also be discussed in the monthly staff meetings.	Radiotherapy Services Manager, Head of Radiotherapy Physics, Radiotherapy Clinical Lead Consultant	Completed. Quality assurance memos sent monthly. Staff meetings held monthly
17.	The departmental study of risk did not include an action plan to monitor actions or record progression.	The employer should include an action plan within the departmental study of risk to monitor and record the progression of actions associated with the study.	IR(ME)R - Regulation 8(2)	Action plan to be incorporated into the departmental study of risk.	Radiotherapy Services Manager	May 2025

18.	The twice yearly multi-disciplinary incident meetings had stopped.	The employer should reinstate regular multi-disciplinary, incident analysis meetings. This should be supported by an incident analysis report, and subsequent action plan to record and monitor actions identified to address areas for improvement.	IR(ME)R - Regulation 8(3) (a) and (b)	Twice yearly incident meeting to be reinstated. 6-month and annual incident analysis reports have already been produced. First meeting is scheduled for 2/4/2025, following which an action plan will be drawn up to record and monitor any improvements identified. Incident trends are also reviewed twice-yearly at Local and overarching Radiation Protection Committee meeting	Radiotherapy Services Manager	April 2025
19.	Not all records reviewed were complete.	The employer must perform a records audit with subsequent actions to ensure that referral and	IR(ME)R - Regulation 7	A records audit has been incorporated into the timetable of audits for the quality management system.	Radiotherapy Services Manager	August 2025

		treatment records are complete.		It is scheduled for July 2025, following which any areas for improvement will be identified and acted upon.		
20.	Some staff comments were shared with department leaders	The Health Board is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report.	Standard - Workforce	Staff engagement is monitored through analysis of the annual NHS staff survey. For cancer services, while showing an overall improvement from 2023 to 2024 the staff engagement index is a little above that of the average NHS Wales staff. An action plan to improve further is in development and will be in place by Apr 2025.	Cancer Services General Manager	Action Plan Apr 2025 followed by implementation
21.	Some key positions in the department were interim.	The Health Board should review the interim leadership positions in the department and develop an	Standard - Leadership	Radiotherapy Services Manager post will be re-advertised in April/May 2025.	Cancer Services General Manager	May 2025

		effective plan to secure a stable and effective leadership team.				
22.	It was not always clear how the employer became aware of incident analysis and themes.	The radiotherapy department should consider submitting a radiotherapy incident analysis report to the Radiation Protection Committee to present and share learning, as well as provide a method of communication to the employer.	IR(ME)R - Regulation 8(3)(a) and (b)	The local Radiation Protection Committee meeting is held twice-yearly and information about radiotherapy incidents is currently shared at these meetings. Information can then be escalated to the overarching Radiation Protection Committee if necessary. A monthly datix incident report is produced by Once for Wales risk management team. This is a standing item on the monthly	Radiotherapy Services Manager	Next meeting is June 2025

				radiotherapy oversight meeting agenda under quality.		
23.	There were some areas where training compliance was not well evidenced.	The employer should strengthen local radiation protection training.	IR(ME)R Schedule 3.	The record of annual reading is expanded to all relevant staff and in addition to Local Rules will include departmental IR(ME)R documentation. IR(ME)R staff updates are carried out approx. every 3 years.	Radiotherapy Services Manager Radiotherapy Clinical Lead Consultant Head of Radiotherapy Physics	July 2025

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Vicki Wilson

Job role: Interim Radiotherapy Services Manager

Date: 24/3/2025