Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Radiotherapy Department – North Wales Cancer Treatment Centre / 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 people in Wales receive good quality healthcare

Our values

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

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

Our priorities

Through our work we aim to:

Provide assurance:	**Provide an independent view on the quality of care**
Promote improvement:	**Encourage improvement through reporting and sharing of good practice**
Influence policy and standards:	**Use what we find to influence policy, standards and practice**

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced remote Ionising Radiation (Medical Exposure) Regulations inspection of the Radiotherapy Department at the North Wales Cancer Treatment Centre (NWCTC) within Betsi Cadwaladr University Health Board on 16 and 17 March 2021.

Our team, for the inspection comprised of two HIW Inspectors and a Senior Clinical Officer from the Medical Exposures Group of Public Health England, who acted in an advisory capacity.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017
- Met the Health and Care Standards (2015).

Further details about how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found in Section 5 and on our website.

2. Summary of our inspection

Following review of the information provided and discussions with staff, evidence was available to demonstrate exposures to ionising radiation were being undertaken safely within the department in compliance with IR(ME)R 2017.

All of the employer's procedures and protocols reviewed were very well detailed and demonstrated compliance with IR(ME)R 2017. Additionally, staff demonstrated a good awareness of the procedures in place, as well as a clear understanding of their duty holder roles and responsibilities.

There was evidence of an experienced and committed workforce, with a good team working ethos. Overall, staff were happy with the level of support provided to them.

There was very positive feedback provided by patients around their experiences attending the department. All of the patients who completed a questionnaire agreed that they had been treated with dignity and respect by the staff within the department.

This is what we found the service did well:

- Evidence provided indicated that adequate arrangements had been implemented by the service to allow for effective infection prevention and decontamination within the service. Arrangements had been strengthened as a result of COVID-19
- Information provided indicated that there were adequate arrangements in place to meet the communication needs of patients attending the department

- Arrangements were in place to allow patients to submit feedback on their experiences of using the department, and clear processes were described in relation to dealing with and responding to informal and formal concerns received by the service

- Good evidence was provided to demonstrate how the service was recording, analysing, risk assessing and introducing mitigations for near misses and incidents within the department.

This is what we recommend the service could improve:

- Ensure relevant documentation is updated to clearly set out the staff responsible for defining organs at risk as part of the planning process prior to treatment

- Ensure routine supervision and appraisals are being carried out, to allow for training and development needs to be identified and monitored

- Ensure all staff have completed the relevant mandatory training as part of their roles.

3. What we found

Background of the service

Betsi Cadwaladr University Health Board was established on 1 October 2009 and provides primary, community, mental health and acute hospital services for a population of around 690,000 people, across the six counties of North Wales (Anglesey, Gwynedd, Conwy, Denbighshire, Flintshire, and Wrexham).

The health board has three main hospitals (Ysbyty Gwynedd in Bangor, Ysbyty Glan Clwyd in Bodelwyddan and Wrexham Maelor Hospital), along with a network of community hospitals, health centres, clinics and mental health units.

The North Wales Cancer Treatment Centre, based at Ysbyty Glan Clwyd, opened in June 2000 and is the sole provider of radiotherapy treatment for the population of North Wales. The Radiotherapy Department consists of both planning and treatment departments, as well as a mould room where special beam shaping devices are made for individual patients who need further customisation of their treatment. Treatment is provided using a range of equipment including linear accelerators[1] and orthovoltage units[2].

The department employs a number of staff including consultant oncologists, radiographers and clinical scientists. The department also has advice and support provided by four Medical Physics Experts (MPE)[3], who are employed by the health board.

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[1] A linear accelerator is a machine used to deliver external beam radiation treatments to cancer patients.

[2] An orthovoltage unit is a machine used to deliver treatment either on or close to the skin surface e.g skin cancer.

[3] An MPE is a person having knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure in diagnostic radiology, nuclear medicine

and radiotherapy, whose competence in this respect is recognised by a competent authority. All employers who carry out medical exposures are required in IR(ME)R to appoint a suitable medical physics expert.

Quality of patient experience

As part of our remote inspection, we reviewed some of the arrangements in place to communicate with and obtain feedback from patients regarding the services provide.

Overall, there was very positive feedback provided by patients about their experiences when attending the department.

Information provided indicated that there were adequate arrangements in place to meet the communication needs of patients attending the department.

Arrangements were in place to allow patients to submit feedback on their experiences of using the department, and clear processes were described in relation to dealing with and responding to informal and formal concerns received by the service.

As part of our remote IR(ME)R inspection methodology, we developed an online patient survey, to allow patients to provide their views and experiences on the services provided within the department. This survey was publicised via a poster displayed within the department in the lead up to our inspection, as well as on the HIW social media pages. A total of 22 questionnaires were completed.

Patients were asked in the questionnaire to rate their overall experience provided by the service. Responses received were positive with nearly all patients rating the service as either ‘excellent’ or ‘very good’. Patient comments included:

> *“The staff in radiotherapy are the absolute best in the whole Cancer Treatment Centre and I've tried all the departments.”*

> *“Great radiographers very accommodating dignified and respectful”*

“Everyone that I have met from my first day of attending have been so nice and helpful”

“The service was very good and excellent caring staff helped me through the experience.”

Dignified care

All of the patients who completed a questionnaire agreed that they had been treated with dignity and respect by the staff within the department. The majority of patients also felt that they were able to maintain their own privacy, dignity and modesty during their appointments.

Nearly all patients who completed a questionnaire felt that they were listened to by staff during their appointment and all patients confirmed that they were asked to confirm their personal details before starting their procedure or treatment. Also, the majority of patients felt that they were able to speak to staff about their procedure or treatment without being overheard by other people.

Patient information

There was an employer’s written procedure in place in relation to the provision of information about treatment and patient consent to radiotherapy treatment. This procedure detailed that verbal discussions between staff and patients must be undertaken prior to any exposures, to cover issues including the benefits and risks of the exposure. Discussions extend to alternative treatments, including no treatment. Staff confirmed that these discussions regularly take place within the department and that evidence of the discussions was being recorded on the appropriate consent form, which patients were able to have a copy of. It was positive to note the department had adopted a site-specific consent form for breast and prostate treatments to ensure consistency of information shared with these patient groups.

The majority of patients who completed a questionnaire told us that they had been provided with enough information to help them understand the benefits and

risks of their treatment options. Additionally, the majority of patients confirmed that they were as involved as they wanted to be in relation to decisions about their treatment.

Staff confirmed that information leaflets were made available to patients and the majority of patients who completed our questionnaire confirmed that they had been provided with information on how to care for themselves during and following treatment, as well as details on who to contact for advice should they experience any after effects from any exposures received.

Communicating effectively

We were informed that there was a hearing loop system available in a clinic room adjacent to the department's main reception area, to assist patients wearing hearing aids to communicate with staff. Staff also confirmed that, where required, information is written down for patients with any hearing impairments to enable adequate communication. We were informed that the provision of any other communication aids, such as the large print or Braille, would be sourced on request.

Staff informed us that the preferred language of patients was recorded on the booking form and arrangements could be made for translators to attend the department for the patient's appointment or translation support can be provided over the phone.

Additionally, we were informed that there were Welsh speaking staff working within the department. Staff also confirmed that there were notices displayed within the department advertising the provision of Welsh speaking staff to patients.

Timely Care

Staff we spoke with confirmed that there were boards displayed within each of the department's waiting areas that provided information on any anticipated delays to patient appointments. We were informed that reception staff were also kept up to date of any delays, to allow them to inform patients on their arrival. Any patients already in the waiting room when an issue occurs, which will impact

the appointment times, would be informed by a member of staff. However, half of the patients who completed our questionnaire stated that they were not informed on arrival of how long they would likely have to wait before having their procedure or treatment.

Improvement needed

The health board should review the arrangements in place to ensure that patients are routinely being informed of expected waiting times within the department.

Individual Care

Listening and learning from feedback

Senior managers confirmed that arrangements were in place to allow patients to provide feedback on their experiences using the department. We were informed that the health board Patient and Liaison Service[4] (PALS) was available to listen and respond to any comments, queries or concerns from patients. We were also informed that monthly reports were provided to the department detailing any feedback received from patients and that summaries of feedback received was displayed within the department.

Responses received via our staff survey highlighted that not all staff were aware of the arrangements in place to collate patient feedback. Additionally, 20 percent of staff who responded indicated that they did not receive regular updates on patient experience feedback received by the department.

Staff explained that on the occasions verbal concerns were received by patients, attempts were initially made, where possible, to try to resolve the issues immediately. However, if the patient still wanted to raise a formal complaint, they

[4] https://bcuhb.nhs.wales/health-services/health-services1/patient-and-carer-experience-team/patient-safety-and-experience/contact-the-patient-advice-and-liaison-service-pals/

would be signposted to the Putting Things Right[5] (PTR) NHS Wales complaints procedure. Senior managers confirmed that information was displayed within the department relating to the PTR procedure, as well as the Community Health Council[6] (CHC).

Improvement needed

The health board must ensure that arrangements are in place to provide staff with regular updates on the patient experience feedback received by the service.

[5] 'Putting Things Right' (PTR), is the integrated process for the raising, investigation of and learning from concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a Responsible body in Wales.

[6] https://bcuhb.nhs.wales/community-health-council/

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

Overall staff we spoke with had a clear understanding of their duty holder roles and responsibilities in line with IR(ME)R 2017.

Information provided indicated that adequate arrangements had been implemented to allow for effective infection prevention and decontamination within the department.

Following review of the information provided and discussions with staff, evidence was available to demonstrate exposures were being undertaken safely within the department in compliance with IR(ME)R 2017.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had a comprehensive and 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 in accordance with the requirements of IR(ME)R 2017. 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. This approach is in line with current UK guidance[7].

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.

Individuals of childbearing potential (pregnancy enquiries)

The employer had a written procedure in place in relation to the process for establishing the pregnancy status of individuals of childbearing age, prior to any exposures, as part of their planning or treatment exposures. This procedure aimed to ensure that such enquires were being made in a standard and consistent manner by staff.

Details within the procedure included the age range of the patients who should be asked about pregnancy, which was between 12 and 55 years. However, senior staff confirmed that the service did not treat patients under 16 years old, which was reflected in documentation reviewed.

The procedure set out the process staff should follow depending on the individual's response and outlined the staff responsible for the relevant tasks. Additionally, guidance was included for staff in relation to undertaking pregnancy enquires for different types of patients they may encounter, this included patients with specific communication needs and transgender or non-binary patients.

Staff we spoke with were able describe their responsibilities in regards to undertaking pregnancy enquiries, which were in line with the employer's procedure. We were also informed that posters were displayed throughout the

[7] Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017

department advising individuals to inform staff if they either are or think that they may be pregnant.

Following review of the relevant section within the employer's Ionising Radiation Protection Policy, we highlighted that there was some references to terminology from IR(ME)R 2000 i.e. women of childbearing age. The employer should ensure that this section within the policy is reviewed and updated to refer to the terminology from IR(ME)R 2017 i.e. individuals of childbearing potential.

Improvement needed

The employer must ensure that the pregnancy enquiry section (8.3) within the Ionising Radiation Protection Policy is updated to reflect terminology from IR(ME)R 2017.

Non-medical imaging exposures

There were no non-medical exposures[8] performed within the department. This was clearly stated within the employer's Medical Exposures Manual for Radiotherapy.

Referral guidelines

There were established referral guidelines in place and adequate arrangements were described for making these available to individuals entitled to refer patients to the department. We were informed that the referral guidelines and clinical protocols were available on the health board intranet and that all entitled referrers were also made aware of the guidelines and process for referring as part of their induction.

[8] Non-medical imaging exposures include those for health assessment for employment purposes, immigration purposes and insurance purposes. These may also be performed to identify concealed objects within the body

Additionally, the employer had a written procedure in place setting out the referral process for individuals to follow. The procedure set out the information that must be provided by the referrer to ensure that the referral would be valid. This information included the relevant personal details, clinical history, type of treatment required, treatment site and the signature of the individual making the referral. The procedure detailed that should there be insufficient referral information submitted, the referrer should be asked to provide it as soon as possible to prevent any delays.

Senior managers confirmed that referrals to the department were made via a paper referral form. Once received, the form is registered by administrative staff and then reviewed for completeness by pre-treatment radiographers, before an appointment is booked. We were informed that as a result of COVID-19, an online referrals mailbox was set up to allow for referrals to also be submitted to the department electronically. Senior managers told us that the standard referral system was still paper, however there were plans to develop and implement the electronic referral system fully in the future.

Arrangements were in place for brachytherapy services to be provided at Clatterbridge Cancer Centre (CCC) in Liverpool, by a NWCTC consultant. The relevant consultant holds an honorary contract with CCC and is entitled to act as a referrer, practitioner and operator for gynaecology brachytherapy there. The consultant also holds an ARSAC licence at CCC for gynaecology brachytherapy. This ensures continuity of care for patients who will often undergo external beam treatment at NWCTC and brachytherapy at CCC. This arrangement is managed under an annual contract between the two healthcare providers.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different IR(ME)R roles of the professionals involved in referring, justifying and providing the radiotherapy exposures to patients. The Ionising Radiation Protection Policy detailed the

specific duty roles and responsibilities in line with IR(ME)R, which are referrer[9], practitioner[10] and operator[11] (known as duty holders).

The policy included details around the requirements that must be met before an individual can be formally entitled to become a duty holder. Further information around these requirements for duty holders was also detailed within the Medical Exposures Manual for Radiotherapy. Staff we spoke with demonstrated a good awareness and understanding of duty holder requirements.

Senior managers described the arrangements for notifying staff of any changes to the policies and procedures in place within the department. We were informed that changes were discussed verbally with staff during team meetings and monthly staff memos were circulated via email with a read receipt, which detail any changes that staff need to be aware of.

Justification of Individual Medical Exposures

There were employer's procedures in place which set out the arrangements for the justification and authorisation[12] of exposures at the planning, verification, treatment and re-planning phases of the patient pathway. Information provided and discussions with staff in relation to the arrangements in place demonstrated compliance with IR(ME)R 2017.

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[9] Under IR(ME)R a referrer is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures

[10] Under IR(ME)R a practitioner is registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.

[11] Under IR(ME)R an operator is any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure..

[12] Justification is the process of weighing up the expected benefits of an exposure against the possible detriment for that individual from the exposure. Authorisation is the evidence that justification has taken place

Optimisation

The employer had arrangements in place for the optimisation[13] 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 responsibility, with planning staff and clinical oncology staff trained to undertake this function. However, following review of the evidence provided and discussions with staff, it was highlighted that there was a lack of clarification within the relevant documentation in regards to the staff responsible for defining organs at risk.

[13] Optimisation refers to the process by which individual doses are kept as low as reasonably practicable.

Due to the high doses of radiation delivered during radiotherapy, it was stated carers and comforters[14] are not permitted to be present during treatments for their safety. This was evidenced in the Medical Exposures Manual for Radiotherapy.

Improvement needed

The employer must ensure that the relevant documentation is updated to clearly set out the staff responsible for defining organs at risk as part of the planning process prior to treatment.

Diagnostic reference levels

IR(ME)R 2017 requires that diagnostic reference levels are established for radio-diagnostic examinations. This requirement does not apply to radiotherapy exposures.

However, it was noted local dose reference levels had been applied to CT planning protocols in accordance with national guidance[15]. The employer's CT planning scan procedure did include details of the expected dose exposure for each treatment site. We were informed that this information was displayed within the CT control area, available electronically and was subject to audit. This exemplified the department's commitment to optimisation of exposures and adoption of best practice.

Paediatrics

[14] Under IR(ME)R 2017, carers and comforters are individuals who are knowingly and willingly exposed to ionising radiation through support and comfort of those undergoing exposure.

[15] National Diagnostic Reference Levels (NDRLs) from 19 August 2019 - GOV.UK (www.gov.uk)

Senior managers confirmed that the service does not provide treatment to paediatric patients (individuals under 16 years of age). This was detailed within the Medical Exposures Manual for Radiotherapy.

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. Senior managers confirmed that all exposures were being evaluated with the resulting findings recorded within the patients' notes.

Equipment: general duties of the employer

The employer had an inventory (list) of the equipment used within the department. Following review of this document it was noted that IR(ME)R 2000 was referenced, instead of IR(ME)R 2017. Additionally, we highlighted that the inventory could be extended further in accordance with national guidance[16], to include equipment that can influence the dose delivered, such as the respiratory gating system, oncology management system (Aria) and the in-house calculator for manual calculations.

Senior managers confirmed that there was a quality assurance (QA) programme in place for all equipment within the department. We were informed that the QA programme was implemented following MPE advice and sign off. Senior managers confirmed that the ongoing equipment QA programme does have routine MPE involvement and as part of our inspection we were shown evidence of the electronic schedule used to monitor and record equipment QA.

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[16] IR(ME)R: Implications for Clinical Practice in Radiotherapy
https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf

Improvement needed

The employer must ensure that the equipment inventory is updated to refer to IR(ME)R 2017.

The employer should consider expanding the equipment listed on the department inventory to include equipment that can influence the dose delivered in line with national guidance.

Safe care

Managing risk and promoting health and safety

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.

Nearly all staff members who completed our survey said that they would know how to report concerns around unsafe clinical practice and would feel secure to do so. However, three members of staff responded to state that they would not know how to report concerns relating to unsafe clinical practice.

Improvement needed

The health board must ensure all staff are provided with information outlining the required steps to report any concerns in relation to unsafe clinical practice within the department.

Infection prevention and control

Information provided by staff we spoke with indicated that adequate arrangements were in place for effective infection prevention and decontamination within the department. We were informed that these arrangements had been strengthened as a result of COVID-19.

Senior managers confirmed that support and advice was provided on a daily basis from the outset of the pandemic and arrangements were in place to monitor compliance.

We were informed that adaptations had been made to the department to comply with the relevant guidance, for example the waiting rooms were reorganised to allow for social distancing, additional hand sanitiser stations have been installed, a restriction on maximum number of people permitted in each room was introduced and the frequency of cleaning within the unit was increased, to allow for additional decontamination of relevant department areas.

Staff confirmed that prior to any appointments arrangements were in place to check whether patients had any relevant symptoms. Additionally, on arrival, patients' temperatures are taken and further questions are asked again in regards to symptoms. We were informed that procedures were in place to allow staff to undertake exposures of symptomatic patients if required.

Every patient who responded to our survey indicated that they felt that the department was clean. Additionally, patients who had visited the department within the last year, following the outbreak of the COVID-19 pandemic, confirmed that Covid compliant procedures were 'very evident'.

Responses received via our staff survey indicated that almost every member of staff felt that the department had implemented the necessary environmental and practical changes in regards to COVID-19 compliance.

Senior managers confirmed that the department had a routine delivery of PPE and that there is a central hub they could contact should there be any issues. Staff we spoke with confirmed that they had sufficient access to PPE and that adequate training and guidance on its use had been made available to them. Additionally, nearly every member of staff who completed our survey, confirmed that there has been sufficient access to PPE.

Staff we spoke with confirmed that they had received infection prevention and control training, which was reflected in the staff responses to our survey, with nearly all staff confirming that they have received training. However, one member

of staff responded to say that they had not had any training relating to infection prevention and control. This issue is covered further in the 'Workforce' section.

Safeguarding children and adults at risk

Staff we spoke with demonstrated an awareness of the required action should they have any safeguarding concerns. Senior managers confirmed that there was a flow chart available outlining the necessary steps to take in relation to escalating any concerns, which included the relevant contact numbers. We were also informed that advice and support was available through a social worker, who worked with the department.

Staff we spoke with confirmed that they had undertaken the safeguarding training. Additionally, almost all staff who responded to our survey also confirmed that they had completed the training. However, one member of staff indicated that they had not undertaken safeguarding training. Again, this issue is covered further in the 'Workforce' section.

Effective care

Quality improvement, research and innovation

Clinical audit

Evidence was provided of the IR(ME)R audit schedule in place for the department. This document listed the audits scheduled to be completed and when, as well as the staff member responsible for completing the audit. Information detailed on the document also included the findings from completed audits, as well as the relevant following up action, staff members responsible and timescales.

As part of the evidence submitted, we saw several positive examples of the clinical and IR(ME)R audits which had been completed. Senior managers confirmed that findings from completed audits were routinely shared with department staff via the monthly memos circulated.

Expert advice

As previously mentioned, there were four MPEs appointed to provide expert advice and support to the department. All four of the MPEs were listed on the approved list for RPA 2000, the certified body for MPEs.

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.

Medical research

Senior managers confirmed that the radiotherapy department participates in research involving medical exposures. We were informed that the service only participates in clinical trials approved by the Health Research Authority and the health board Research and Development Internal Review Panel.

There was an employer's procedure and policy in place that set out the arrangements for undertaking research procedures involving medical exposures within the service and included details around the method and staff responsibilities.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Health and Care Standards

There was an organisational management structure in place which set out clear lines of reporting and accountability.

All of the employer's procedures and protocols reviewed were very well detailed and demonstrated compliance with IR(ME)R 2017. Additionally, staff demonstrated a good awareness of the procedures in place.

There was evidence of an experienced and committed workforce, with a good team working ethos. Overall, staff were happy with the level of support provided to them.

Governance, leadership and accountability

There was a radiotherapy management structure in place, which set out the clear lines of reporting for the service. There was also governance organigram which set out the governance arrangements in place for sharing relevant information from the department staff up to the health board's executive board.

Senior managers confirmed that whilst it had been challenging to undertake face to face team meetings following the COVID-19 outbreak, due to restrictions on individuals allowed in rooms within the department , efforts have been made to utilise Microsoft Teams to carry out team meetings with department staff. As previously, detailed, we were informed that monthly memos were circulated to staff to ensure they were provided with regular updates.

Prior to our inspection, HIW require senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW with detailed information about the department and the employer's key policies and procedures in place, in respect of IR(ME)R 2017. This document was used to inform the inspection approach.

The self-assessment form was completed to a high standard, demonstrating an understanding of the regulations and their implementation into clinical practice. It was returned to HIW within the agreed timescales and was comprehensive. When additional clarity was required regarding some of the responses provided, senior staff provided the additional information promptly.

On the days of our inspection, senior management staff made themselves available and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the issues highlighted.

Representatives from all of the other Welsh radiotherapy departments were also invited by the service to join relevant parts of the inspection. This demonstrates an openness and willingness to share learning by NWCTC.

Duties of the employer

Entitlement

As previously detailed, the employer had procedures in place for the identification and entitlement of referrers, operators and practitioners, as required under IR(ME)R 2017. Evidence provided demonstrated that there was an adequate system in place for entitling staff to become duty holders. Information reviewed set out the process in place and also outlined the relevant requirements before individuals could become an entitled referrer, operator or practitioner.

We were informed that all entitled staff employed by the health board, received a letter outlining their entitlement and scope of practice. Documents were also available listing the staff members entitled for each of the duty holder roles. These documents also included the scope of practice for each individual.

Overall, department staff we spoke with had a good understanding of their duty holder role and their scope of entitlement under IR(ME)R.

Procedures and protocols

Senior managers confirmed that the health board Chief Executive was designated as the employer under IR(ME)R. However, we were informed that whilst the CEO retains the overall responsibility associated with being the employer, the CEO had delegated the associated responsibilities for the coordination of the radiation related health board activities to the Executive Director of Therapies and Health Science. This arrangement was clearly detailed in the documentation reviewed.

There were employer's procedures in place in relation to the quality assurance arrangements for the employer's written procedures and protocols. Information included the frequency of procedure reviews and also the document owners, who were responsible for ensuring that reviews took place when they were required. Additionally, it was detailed that any updates must be authorised by the Radiotherapy Services Manager or the lead MPE, and following any updates, arrangements must be made to communicate the relevant changes to staff.

As previously detailed, staff we spoke with confirmed that they were able to access relevant policies and procedures when required. Additionally, senior managers confirmed that arrangements were in place to notify relevant staff on the occasions where updates were made to written procedures or protocols.

Overall, all of the employer's procedures and protocols provided as evidence were very well detailed and demonstrated compliance with IR(ME)R 2017. Also, information detailed within the procedures reviewed reflected the responses provided by staff we spoke with throughout our inspection.

Significant accidental or unintended exposures

There was an employer's procedure in place setting out the required actions should an incident occur or is suspected to have occurred, which may have caused an accidental or unintended exposure to patients. The procedure detailed the process to be followed by relevant staff to ensure that the suspected incident

is appropriately investigated, documented, and if required, reported to HIW in a timely manner.

Staff we spoke with demonstrated an awareness of the key steps required following the occurrence of an incident within the department. Staff also confirmed that feedback from incidents was provided to the department via monthly memos.

There was good evidence provided to demonstrate how the service was recording and analysing errors, near misses and incidents. A summary analysis document was provided which clearly set out the relevant information, which included a breakdown of overall figures for 2020, the key issues highlighted and the action identified to mitigate similar issues occurring. In addition, a study of risk which focused on accidental and unintended exposures was shared as part of the self-assessment form. This focused on key areas identified in the annual analysis with mitigations identified and implemented. Senior managers confirmed that there were plans to undertake the analysis and study of risk exercise on an annual basis, which we would fully encourage.

Staff and resources

Workforce

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.

Overall, staff indicated that they were happy with the level of support and engagement from their immediate line manager. It was clear from our discussions with senior managers and feedback received from department staff that the service consists of experienced and committed workforce, with a good team working ethos.

Feedback received from staff indicated that the majority felt that there were sufficient staffing levels within the department to allow them to perform their roles. Additionally, all staff confirmed that they were satisfied with the quality of care

that they were able to provide to patients. However, there were some concerns raised in relation to the challenges faced by the service due to the staffing numbers, which we were informed had impacted on the ability for staff to undertake some of their non-clinical responsibilities. Senior managers confirmed that whilst they felt the staffing levels were safe, there were plans to undertake a review to identify the improvements required to ensure that there were sufficient staffing levels in all areas of the department consistently, to allow staff to complete all of the requirements of their roles.

Senior managers informed us that there was a process in place to ensure that all staff received annual personal appraisal development reviews (PADRs) and have completed their mandatory training. We were told that fortnightly manager meetings took place to review issues including PADR and training compliance. Nearly all staff who responded to our survey confirmed that they had received their annual PADR. However, three members of staff indicated that they had not had a PADR discussion within the last 12 months. Also, as previously detailed responses received through our survey indicated that not all staff had undertaken the required mandatory training.

Senior managers confirmed that arrangements were in place to allow staff to access additional wellbeing support if required. However, feedback received indicated that not all staff working within the department were aware of the additional support available to them.

Improvement needed

The health board must ensure that all staff receive routine PADRs, to allow for training learning and development needs to be identified and monitored.

The health board must ensure that all staff have undertaken the required mandatory training as part of their roles.

The health board must ensure that all staff are provided with information on the additional wellbeing support available to them.

4. What next?

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.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a non-compliance notice. The issuing of a non compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- 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.

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.

5. How we inspect services that use ionising radiation

HIW are responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations 2017 and its subsequent amendment (2018).

The regulations are designed to ensure that:

- Patients are protected from unintended, excessive or incorrect exposure to medical radiation and that, in each case, the risk from exposure is assessed against the clinical benefit
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology
- Volunteers in medical research programmes are protected

We look at how services:

- Comply with the Ionising Radiation (Medical Exposure) Regulations
- Meet the Health and Care Standards 2015
- Meet any other relevant professional standards and guidance where applicable

Our inspections of healthcare services using ionising radiation are usually announced. Services receive up to seven weeks' notice of an inspection.

The inspections are conducted by at least one HIW inspector and are supported by a Senior Clinical Officer from Public Health England (PHE), acting in an advisory capacity.

Prior to the inspection, the service is required to complete a self-assessment form and provide supporting documentation as evidence. The two day remote inspection consists of discussions with senior managers and operational staff

working within the department, in relation to the policies and procedures in place.

To allow us to collate additional views, relevant patient and staff surveys are conducted in the weeks leading up to our inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

These inspections capture a snapshot of the standards of care relating to ionising radiation.

Further detail about how HIW inspects the NHS can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries 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

Hospital: North Wales Cancer Treatment Centre, Ysbyty Glan Clwyd

Ward/department: Radiotherapy Department

Date of inspection: 16 and 17 March 2021

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.

Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues were identified on this inspection.				

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):

Appendix C – Improvement plan

Hospital: North Wales Cancer Treatment Centre, Ysbyty Glan Clwyd

Ward/department: Radiotherapy Department

Date of inspection: 16 and 17 March 2021

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.

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Quality of the patient experience				
The health board should review the arrangements in place to ensure that patients are routinely being informed of expected waiting times within the department.	5.1 Timely access	When a patient first attends for treatment, they will be advised that appointments will be expected to run to time. However if there are any delays, this will be communicated via a	Patricia Evans Radiotherapy Services manager	Patients to be informed regarding daily waiting times with

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		noticeboard displayed in all patient waiting areas. If there is to be a significant delay or machine breakdown, patients will be informed by radiographers on an individual basis. A survey of patient views on daily waiting times, and how they would like to be informed of delays will be undertaken.		immediate effect and ongoing. Survey to be completed by September 2021.
The health board must ensure that arrangements are in place to provide staff with regular updates on the patient experience feedback received by the service.	6.3 Listening and Learning from feedback	Patient feedback received electronically will be continued to be emailed to all departmental staff by the radiotherapy services manager when received. Written feedback received directly from patients and via the Patient and Carer Advice Team (P.A.L.S.) will be	Patricia Evans Radiotherapy Services manager	Immediate effect and ongoing.

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		displayed on the staff notice board for all staff to read.		
Delivery of safe and effective care				
The employer must ensure that the pregnancy enquiry section (8.3) within the Ionising Radiation Protection Policy is updated to reflect terminology from IR(ME)R 2017.	Regulation 6 Schedule 1 (c)	The Trust Ionising Radiation Protection Policy RP01 is due for review in Sept 2021. The draft revision has already been updated to reflect the IR(ME)R 2017 terminology. The policy is awaiting approval by the overarching Radiation Protection Committee (RPC) meeting, and will then	Peter Hiles, Julian MacDonald: Radiation Protection Advisors	Draft revision completed 06.05.2021. RPC approval 18.06.2021 Board ratification by

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		be fully ratified prior to the end of Sept 2021		end of Sept 2021
The employer must ensure that the relevant documentation is updated to clearly set out the staff responsible for defining organs at risk as part of the planning process prior to treatment.	Regulation 12(2)	The organs at risk outlining task can be delegated to suitably competent operators. The clinician has overall responsibility. Relevant documentation will be reviewed and updated alongside the introduction of automated outlining, within the coming 3 months. In the meantime, all involved in organ at risk outlining and review, will be reminded of their responsibilities in this process.	Jaap Vaarkamp Head of Radiotherapy Physics	By September 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that the equipment inventory is updated to refer to IR(ME)R 2017.	Regulation 15(2)	Equipment inventory has now been updated to refer to IRMER 2017	Jaap Vaarkamp Head of Radiotherapy Physics	Completed 27.04.2021
The employer should consider expanding the equipment listed on the department inventory to include equipment that can influence the dose delivered in line with national guidance.	Regulation 15(2)	Equipment inventory has been expanded in line with national guidance	Jaap Vaarkamp Head of Radiotherapy Physics	Completed 27.04.2021
The health board must ensure all staff are provided with information outlining the required steps to report any concerns in relation to unsafe clinical practice within the department.	6.3 Listening and Learning from Feedback 7.1 Workforce	Staff will be reminded of the process of how to report a concern regarding unsafe clinical practice within the department. Staff will be signposted to the WP4a Trust Policy: *Procedure for Staff to Raise Concerns* . Staff can also	Patricia Evans Radiotherapy Services manager Jaap Vaarkamp	Via the next departmental staff meeting on 12.05.2021 and to be

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		speak to a member of the departmental management team, their union representative, professional body and can also contact the Human Resources department for advice. Staff can also access the Safe Haven Reporting system via the Trust Intranet page which is due to launch the *Speak Out Safely* approach which is to support staff to raise concerns in BCUHB.	Head of Radiotherapy Physics	emailed to all staff via staff meeting minutes. New staff will be informed as part of their induction training.
Quality of management and leadership				
The health board must ensure that all staff receive routine PADRs, to allow for training	7.1 Workforce	PADR compliance will be monitored every 2 weeks via the report to the	Patricia Evans	To be addressed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
learning and development needs to be identified and monitored.		regular fortnightly management meetings. This is an ongoing process and those staff who are overdue a PADR will be prioritised	Radiotherapy Services manager Jaap Vaarkamp Head of Radiotherapy Physics	with immediate effect
The health board must ensure that all staff have undertaken the required mandatory training as part of their roles.	7.1 Workforce	Mandatory training compliance will be continually monitored but departmental managers and staff who are overdue will be scheduled time away from clinical duties to complete their training. Cover will then be provided to achieve this.	Patricia Evans Radiotherapy Services manager Jaap Vaarkamp Head of Radiotherapy Physics	All staff to be up to date with mandatory training by September 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The health board must ensure that all staff are provided with information on the additional wellbeing support available to them.	1.1 Health Promotion, Protection and Improvement 7.1 Workforce	Staff will be signposted to the Trust procedure WP33, Staff Mental Health, Wellbeing and Stress Management. They will also be reminded to read the information on display in the staff room, and be advised to ensure they read the Trust all users emails regarding Health and Wellbeing support	Patricia Evans Radiotherapy Services manager Jaap Vaarkamp Head of Radiotherapy Physics	Next staff meeting on 12th May 2021 and electronically via minutes following the meeting

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): Patricia Evans

Job role: Radiotherapy Services Manager

Date: 30/04/2021