Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Radiotherapy Department, South West Wales Cancer Centre, Singleton Hospital - Swansea Bay University Health Board

Inspection date: 28 and 29 September 2021

Publication date: 30 December 2021

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

Communications Manager

Healthcare Inspectorate Wales
Welsh Government

Rhydycar Business Park

Merthyr Tydfil

CF48 1UZ

Or via

Phone: **0300 062 8163**

Email: **hiw@gov.wales**

Website: **www.hiw.org.uk**

Digital ISBN 978-1-80391-538-8

Contents

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 Ionising Radiation (Medical Exposure) Regulations inspection of the Radiotherapy Department at the South West Wales Cancer Centre, based at Singleton Hospital in Swansea, part of Swansea Bay University Health Board on 28 and 29 September 2021.

Our team for the inspection comprised of two HIW inspectors and a Senior Clinical Officer from the Medical Exposures Group (MEG) of Public Health England (PHE), who acted in an advisory capacity. As part of this inspection, an additional Senior Clinical Officer was also present to observe, as part of the peer review programme within MEG.

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 were being undertaken safely within the department in compliance with IR(ME)R 2017. Overall, staff we spoke with had a clear understanding of their duty holder roles and responsibilities in line with IR(ME)R 2017.

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 from patients about their experiences when attending the department. We saw that arrangements were in place to promote the privacy and dignity of patients and found that staff treated patients in a kind, respectful and professional manner.

Issues were highlighted by staff around available capacity and space within the department to enable them to carry out the relevant tasks required as part of their roles.

This is what we found the service did well:

- Good working relationships between Medical Physics Experts and staff working within the department.
- Information provided indicated that adequate arrangements had been implemented to allow for effective infection prevention and decontamination within the department.
- Well-developed duty holder training and competency records available
- Evidence of good entitlement and scope of practice documentation with further plans to develop the process

This is what we recommend the service could improve:

- Employer’s written procedures and associated documents, highlighted in this report, should be reviewed and updated to ensure that they accurately detail and reflect the agreed practice
- Arrangements should be implemented to ensure that patient experience feedback, as well as any subsequent actions is routinely made available to staff and patients
- Ensure robust plans are in place to confirm that there are adequate staffing levels to allow staff to carry out their relevant roles.

3. What we found

Background of the service

Swansea Bay University Health Board was established on 1 April 2019, after responsibility for providing healthcare service within the Bridgend County Borough Council area passed to the newly formed Cwm Taf Morgannwg University Health Board.

Swansea Bay UHB provides primary, community, hospital and mental health services to the people Swansea and Neath Port Talbot. The health board provides services to a population of around 390,000 people.

The Radiotherapy Department at the South West Wales Cancer Centre, based at Singleton Hospital Swansea, has patients referred for radiotherapy treatment from hospitals across the South West Wales Cancer Network, which include; Neath Port Talbot, Singleton, Morriston, Prince Phillip, Glangwilli, Withybush and Bronglais hospitals.

The Radiotherapy Department consists of both planning and treatment areas. The planning area includes a CT scanner and a mould room where beam shaping and immobilisation devices are made for individual patients who need further customisation of their treatment. The treatment area includes a fleet of linear accelerators[1] used to verify and deliver external beam radiotherapy and clinic rooms for patient review.

The radiotherapy department employs a number of staff including Clinical Oncologists, Therapeutic Radiographers and Assistant Practitioners. The department has advice and services provided by staff who are employed by the Swansea Bay University Health Board, but are placed in a different Directorate within the Singleton Hospital to the Radiotherapy Department. These staff include Clinical Scientists, Dosimetrists, Medical Technical Officers and Medical Physics Experts (MPEs)[2].

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

[2] 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

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

There was very positive feedback provided by patients about their experiences when attending the department.

Overall, we saw that arrangements were in place to promote privacy and dignity of patients and found that staff treated patients in a kind, respectful and professional manner.

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

Patient feedback mechanisms were in place. However, the service needs to ensure that findings and subsequent actions taken as a result of feedback received are routinely shared with patients and staff.

As part of the inspection process HIW issued both online and paper surveys to obtain patient views on the service provided within the department. In total, there were 52 patient responses received.

Patients were asked in the survey to rate their overall experience provided by the service. With the exception of one response, all patients that responded rated the service as 'very good' or good. Patients told us:

> *"Excellent from my scanning appointment to my treatment"*
>
> *"It was first class treatment. The staff were all extremely professional and understanding to all my needs"*
>
> *"The service I am receiving is compassionate and professional."*
>
> *"A highly professional service provided by all staff who were very friendly and answered all questions."*

"Staff very friendly and inform you of all treatment. They are also very respectful."

"The level of service provided was excellent all staff attentive and very pleasant and, most importantly, had plenty of time to listen and advise"

Staying healthy

There was substantial amount of information available within the department's main reception and waiting areas in relation to radiotherapy treatment and the cancer support available to patients and their families. However, we identified there was limited information available for patients in regards to general health care advice and support. The health board should consider providing further information on topics such as healthy lifestyles and smoking cessation.

Posters were displayed within the department advising patients to inform staff if they have any existing medical conditions. Additionally, there were posters displayed throughout the department advising patients of the importance of letting staff know if there was a likelihood they may be pregnant. This is important to prevent potential harm to unborn babies from the high energy rays (ionising radiation) used during radiotherapy and is required under IR(ME)R.

Improvement needed

The health board should consider providing additional general health care advice and support information within the department.

Dignified care

During our time in the department we observed staff speaking to patients in a polite, sensitive and professional manner.

We did not overhear any sensitive conversations taking place within the department during our visit. We were informed that patients are taken to a vacant room or office to have private conversations, when required. Out of the 50 patients who responded to the relevant question on our survey, 47 confirmed that they were able to speak to staff about their procedure or treatment without being overheard by other people, and three said they were not.

Within the department's main treatment waiting area, there were two changing cubicles available for patients. These cubicles were fitted with curtains for

privacy, to allow the patient to change into appropriate clothing for treatment if required. However, the patient would then need to walk across the main waiting room area to the treatment room. This issue was highlighted in the previous HIW IR(ME)R report following an inspection completed on 14 and 15 November 2017. Within the previous report, it was recommended that the health board relocate the changing cubicles away from the main waiting area.

Senior managers informed us that discussions and plans for relocating the changing facilities had been ongoing, however, these plans have been affected due to staffing changes, COVID-19 and also other development work being carried out within the department. Senior managers also informed us that the infrastructure and space available within the department is a challenge.

Whilst we understand the challenges faced by the physical constraints, we are still of the view that this arrangement could compromise patient dignity and should be reviewed again.

During our time on the department we did not see any patients using these cubicles. Additionally, with the exception of one, all patients who completed our survey said that they had been treated with dignity and respect and all patients confirmed that they were able to maintain their own privacy, dignity and modesty during their appointments.

The department waiting area had been reorganised to allow for social distancing between patients. The amount of chairs had been reduced, but the number of seats available appeared appropriate for the number of patients attending during our time within the department.

Patient information

As previously detailed, information was displayed and available for patients to take throughout the department in relation to various cancers, as well as the associated treatment and support available to patients.

Staff we spoke to confirmed that patients were provided with information relating to the options for treatment, including no treatment, prior to any planning or treatment exposures. We were informed that all patients were made aware of the benefits and risks of planning, treatment and verification exposures via discussions with staff at the time of consent in accordance with IR(ME)R. Consent was undertaken in line with the health board procedure and using national consent forms where available. This is documented on the relevant consent form and a copy made available to the patient.

Written information provided to the patient as part of the consent process also refers to the benefit and risk of radiation associated with their radiotherapy treatment. Completed copies of consent forms and examples of written information were seen during inspection.

With the exception of one, all patients who responded to our survey stated that they felt that they were involved as much as they wanted to be in decisions about their treatment. Additionally, the vast majority of patients confirmed that they felt that they had been given clear information to understand the benefits and risks of their treatment options.

Communicating effectively

All patients who responded to our survey said they felt that they were listened to by staff during their appointment.

We were informed that a hearing loop was available within the department that could be set up for us to assist people attending wearing hearing aids to communicate with staff. Senior managers confirmed that the department is normally notified in advance if there is a patient scheduled to attend the department with any sensory impairments. Therefore, arrangements can be made to access interpreters where required.

The majority of information displayed within the department was available in English and Welsh. We were informed that there were some Welsh speaking staff working within the department. However, it was not immediately obvious within the public areas of the department that patients could speak in Welsh if they wished to do so. The availability of Welsh speakers working within the department or via communication support could be better promoted to help deliver the 'Active Offer'[3].

Three patients who responded to our survey stated that their preferred language was Welsh and all patients who responded stated that they had been able to communicate to staff in their preferred language, as well as access healthcare information in their preferred language.

[3] An 'Active Offer' means providing a service in Welsh without someone having to ask for it. The Welsh language should be as visible as the English

Improvement needed

The health board is required to ensure that action is taken to promote the availability of Welsh speaking staff / support within the department to help deliver the 'Active Offer'.

Individual Care

Timely care

Of the 51 patients who responded to the relevant question on our survey, 50 confirmed that it was "very easy" or "fairly easy" to get an appointment for their procedure.

Within the department waiting areas there were large electronic screens that displayed information in relation to any expected delays for each of the machines in use. We were also informed that radiographers routinely inform patients on arrival if they know that there is likely to be a significant delay to their procedure or treatment.

Listening and learning from feedback

Senior staff we spoke with described the arrangements in place to respond to any verbal concerns raised by patients. We were informed that attempts were made, where possible, to try to resolve the issues with the patient quickly and efficiently. Where this is not possible, the patients are signposted to the health board concerns process. Staff confirmed that all complaints received, including verbal, are reported via Datix (electronic incident reporting system). Information was available within the department waiting areas in relation to the all Wales NHS complaints procedure, known as Putting Things Right (PTR)[4].

We were informed that arrangements were in place to allow patients to provide feedback on their experiences within the department. For example patient

[4] '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.

surveys have previously been undertaken and we were informed that there were plans to undertake further surveys in the future.

Responses received via our staff survey highlighted that the vast majority who responded to the relevant question were aware of the patient feedback mechanisms in place, however, around 20 percent of staff stated that they either “did not” or “did not know” whether regular updates were provided to them in regards to patient feedback received by the service. Additionally, there were no methods in place to share the results or actions taken as a result of previous surveys with patients.

Improvement needed

The health board should ensure that arrangements are in place to provide staff and patients with regular updates on the patient experience feedback received by the service, as well as any subsequent actions taken**.**

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 and in compliance with IR(ME)R 2017. However, we identified a few areas where procedures and associated documentation needed to be updated to reflect the agreed clinical practice.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had an up to date written procedure for staff to follow to correctly identify patients prior to their exposure. This is aimed to ensure that the correct patient has the correct exposure, in accordance with the requirements of IR(ME)R 2017. The procedure set out that staff were expected to confirm the patient's full name, date of birth and home address. This approach is in keeping with current professional guidance[5] . Photographic identification was used as an additional identifier prior to treatment.

[5] https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf

The procedure also detailed the steps staff should take if they encounter different types of patients including individuals who may lack capacity, individuals with a hearing impairment and individuals unable to communicate in English.

Staff we spoke with were able to describe the correct procedure to identify patients prior to any exposures within the department. Additionally, all patients who responded to the question on our survey said that they were asked to confirm their personal details before starting their procedure or treatment. As part of our inspection we reviewed a sample of patient records, all records reviewed evidenced that patient identification checks had been carried out by staff, in accordance with the written procedure.

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.

The procedure set out the process staff should follow depending on the individual's responses. Senior managers confirmed that individuals aged between the age of 12 and 55 must be asked if there is any chance that they could be pregnant. However, it was highlighted that the employer's procedure we reviewed did not include the lower age limit. This detail should be included within the procedure and any associated documents for staff to follow.

As part of the pregnancy enquiry process, we were informed that the patient also has to sign an electronic pregnancy declaration, as part of the consent process, to confirm that the check has been undertaken, that the risks have been explained to them and that they have confirmed that they are not pregnant. This information is then stored on the patient's record. It was positive to note that on the occasions that the patients are unsure whether they're pregnant, arrangements are made for blood tests to be undertaken prior to any exposure.

Following review of the employer's procedure and discussions with senior staff, it was highlighted that there needed to be an explicit statement, within the procedure, to ensure staff are aware that on the occasions exposures are to proceed with a known pregnancy, the patient would need to provide their consent again. This issue is detailed further within the 'Justification of Individual Medical Exposures' section.

Staff we spoke with, as part of our inspection were able to describe their responsibilities in regards to the enquiries required, which were in line with the

employer's procedure. Patient records reviewed provided evidence that pregnancy status checks had been carried out and recorded by staff for relevant patients.

As previously detailed, we saw evidence of posters displayed within the department advising patients to speak with staff if they either are or think they may be pregnant. Consideration of pregnancy was reported to be included in written information given to patients at time of consent.

Improvement needed

The employer should ensure that the written procedure in relation to pregnancy enquires is updated to detail the specific age range of patients that should be asked.

The employer should ensure that the written procedure in relation to pregnancy enquires is updated to detail the required action on occasions where an exposure is to proceed with a known pregnancy.

Non-medical imaging exposures

There were no non-medical exposures[6] performed within the department.

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. Site specfic referral guidelines were seen to be included in relevant clinical protocols reviewed as part of the inspection process. Additionally, we were informed that referral awarenss training is provided to relevant staff.

There was an employer's written procedure in place setting out the referral process for individuals to follow. In addition, the service had commissioned its oncology managment system (OMS) to include electronic site specific referral forms. This allowed patient referrals to be completed electronically on site or at

[6] 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

outlying clinics. Paper referrals had been removed. Referrals were routinely completed at time of patient consent.

Access to the electronic referral form was via individual passwords and restricted to those individudals entitled as referrers. The referral forms were site specific and were linked to the relevant clinical protocol. Access to specific referral forms was restricted to those referrers entitled for that site.

The relevant fields within the referral form were mandatory. This meant it was not possible to submit an incomplete referral. Each referral form included three patient unique identifiers and a pregnancy declaration where relevant. The referrer was clearly identifiable on the referral form.

Completed referrals were automatically available within the OMS to booking staff. Bookings were made in another part of the OMS by trained operators in accordance with local procedures and clinical protocols. The service should be commended for the development of this referral system.

We were informed that patients requiring brachytherapy treatment were referred to Velindre Cancer Centre in Cardiff. The robust arrangements for this practice were described by senior managers, however, consideration should be given to formally documenting this agreement with Velindre University NHS Trust.

As part of our inspection we reviewed a random sample of current patient referral documentation received by the department. Overall, the referral forms were completed to a high standard with all of the required information readily available within the referrals reviewed.

Improvement needed

The employer should consider formally documenting the arrangement in place with Velindre University NHS Trust for the treatment of brachytherapy patients.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different IR(ME)R roles of professionals involved in referring, justifying and providing radiotherapy exposures to patients. The health board policy on the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2017 detailed the specific

roles and responsibilities in line with IR(ME)R, which are which are referrer[7], practitioner[8] and operator[9] (known as duty holders).

The policy included guidance around the requirements that must be met before an individual can be formally entitled to become a duty holder. Staff we spoke with as part of our inspection demonstrated a good awareness and understanding of their duty holder roles under IR(ME)R.

Information provided indicated that the health board Medical Exposure Group, chaired by the health board Executive Director of Therapies and Health Science, has been established to oversee compliance with the policy and to consider patient safety matters arising from medical exposures throughout the health board.

The policy was supported by two underpinning procedures; Radiotherapy: IR(ME)R in Oncology and IR(ME)R in Radiotherapy Physics, which detailed the roles of the different duty holders in relation to radiotherapy exposures. These were consistent with practice described at time of inspection and were reflected in records reviewed.

As part of our inspection, we reviewed a sample of duty holder training, competency and entitlement records. Overall, the records reviewed were good and demonstrated compliance. Additionally, the systems in place to monitor compliance were well developed and robust. At the time of our inspection the service was in the process of transferring over from paper records to a fully electronic system and good plans for this transition were evident.

The arrangements for notifying staff of any changes to policies and procedures within the department were described to us. All staff have access to the electronic document management system in place, which flags up when updated documents need to be reviewed. Additionally, we were informed that key changes were discussed with staff in team and manager meetings, and also

---

[7] 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

[8] 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.

[9] 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

emails are circulated as and when required to provide relevant information to staff.

Justification of Individual Medical Exposures

There were employer's written procedures in place which set out the arrangements for the justification and authorisation[10] 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.

Senior managers described the process for the justification of patient exposures where pregnancy cannot be excluded. This included the practitioner explaining the benefits and risks of delaying the procedure and discussing all options available. However, it was highlighted that the practice described by staff was not reflected in the employer's procedure.

Improvement needed

The employer must ensure that the written procedures in relation to justification and authorisation are updated to reflect agreed practice in relation to exposures undertaken when pregnancy cannot be excluded.

Optimisation

The employer had arrangements in place for the optimisation[11] of planning, verification and treatment exposures. These arrangements aimed to ensure that radiation doses delivered to patients, as a result of planning and verification exposures, were kept as low as reasonably practicable (ALARP). All treatment exposures were individually planned and verified as part of the optimisation process.

Evidence was available, within the clinical protocols reviewed, detailing how exposures were individually planned and verified ensuring doses to non-target areas were ALARP.

---

[10] 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

[11] 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, carers and comforters[12] were not permitted to be present during treatments for their safety.

Diagnostic reference levels

IR(ME)R 2017 requires that diagnostic reference levels[13] are established for radio-diagnostic examinations. This requirement does not apply to radiotherapy exposures. However, it was noted that local estimated doses of standard CT protocols had been established for CT planning protocols in accordance with national guidance[14]. At the time of our inspection, we were informed that the estimate doses had been revised and were awaiting ratification for the newly commissioned CT scanner. In addition, dose estimates had been established for the imaging devices used for verification. This approach to establishing estimated doses exemplified the department's commitment to optimisation of exposures and adoption of best practice.

Paediatrics

Senior managers confirmed that the department does not provide radiotherapy treatment to children. However, it was highlighted that this was not documented in any of the department documentation reviewed. The employer should consider including a statement within the relevant documents detailing that the department does not provide paediatric treatment.

Clinical evaluation

Senior managers described the arrangements in place for the clinical evaluation of exposures[15] undertaken at the planning, verification and treatment stages. Following review of the references to clinical evaluation within the employer's procedures it was highlighted that the responsibilities for the clinical evaluation of each type of medical exposure should be better reflected within the associated documentation. Detail should be included to better reflect how planning,

---

[12] 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.

[13] The objective of diagnostic reference levels is to help avoid excessive radiation doses to patients. DRLs are used as a guide to help promote improvements in radiation protection practice.

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

[15] Clinical evaluation is important to help inform the next stage of a patient's care and treatment.

verification and treatment exposures are clinically evaluated and where this is evidenced within the patient record.

Additionally, it was also highlighted that the relevant training, competency and entitlement framework requirements for clinicians working in the department, needs to be updated to reflect the agreed practice, to allow them to carry out the operator functions for clinical evaluation.

Improvement needed

The employer should ensure that relevant employer's procedures are updated to reflect the agreed arrangements for clinical evaluation of all medical exposures undertaken within the department.

The employer should ensure that the training, competency and entitlement framework for clinicians is updated to clearly record the operator task of clinical evaluation.

Equipment: general duties of the employer

The employer had an inventory (list) of the equipment used within the department. The inventory contained the information required under IR(ME)R 2017.

There was a quality assurance (QA) framework in place for all equipment within the department. This was outlined in local procedures reviewed as part of the inspection process. Evidence was provided of the process and charts available for the department staff to follow, as well as the rota in place, which set out the QA requirements, tolerance levels, due date and responsible individuals. Senior managers confirmed that arrangements were in place to routinely monitor compliance with the required equipment QA.

Safe care

Managing risk and promoting health and safety

The department was signposted within the main hospital and there was level access throughout. This allowed patients with mobility difficulties to enter and leave the department safely.

Arrangements were in place to promote the safety of staff, patients and visitors. For example appropriate signage and restricted access mechanisms were in

place to deter and prevent unauthorised persons entering areas where radiotherapy equipment was being used.

Overall, the department appeared clean, well maintained and in a good state of repair. However, at the time of our inspection, there was some development work being carried out within the department for the installation of a new treatment machine. The area of the department where the work was being carried out was clearly signposted and there were mitigations in place to prevent unauthorised access to the area. There were no issues reported to us or observed to suggest the development work was affecting patient care and/or experience.

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 described the arrangements in place, including ensuring that relevant areas are routinely cleaned after every patient and the additional decontamination required on occasions where patients who have tested positive for COVID-19, attend the department for treatment. All staff who responded to our survey confirmed that decontamination arrangements were in place for relevant equipment and areas. Additionally, all staff felt that the necessary environmental and practice changes had been implemented within the department.

At the main entrance to the department, an IPC station had been set up which was manned by a healthcare support worker. All patients and visitors attending the department were asked whether they had any COVID-19 symptoms or had come into contact with anyone with COVID-19 recently. Hand sanitiser was then provided to the individual before they entered the main reception area.

Clear plastic screens had been installed on the main reception desk to protect staff and patients. A self check-in service was available on the reception desk, to allow patients to confirm arrival by scanning a QR code from their appointment letter. A one way system has been implemented within the main waiting areas; signs were displayed throughout to remind individuals of the two metre distance and hand sanitiser gel was available throughout the department.

As previously detailed, the chairs within the department waiting areas had been reduced and reorganised to allow for social distancing between waiting patients. Senior managers confirmed new wipeable chairs had been installed at the outset of the pandemic to allow for adequate cleaning.

Senior managers described the arrangements in place to ensure that patients were routinely screened for COVID-19. Prior to their appointment, patients are contacted via telephone to check whether they have any symptoms. This discussion also allows for the patient to be provided with information on the arrangements that will be in place when they arrive at the department. We were also informed that prior to the commencement of any treatment, the patient is required to have a COVID-19 test.

All patients who responded to our survey said that they felt that the department was clean and, with the exception of one, all patients confirmed that they felt that COVID-compliant procedures were very evident during their time in the department.

All staff are required to complete mandatory infection prevention and control eLearning training. Evidence provided as part of our inspection indicated that all staff were up to date with this training.

Senior managers confirmed that arrangements were in place to ensure that there was a sufficient supply of personal protective equipment (PPE) available within the department. All staff who responded to our survey confirmed that they have sufficient access to PPE. Additionally, we were informed that all staff have been fit tested and received training in regards to donning and doffing[16].

Safeguarding children and adults at risk

Senior managers confirmed that there was a safeguarding policy in place, which outlined the required action should staff have any concerns. We were also informed that there is a safeguarding lead for the hospital that is available for advice and support where required.

All staff who responded to the relevant question on our survey confirmed that they had completed safeguarding training. Additionally, the training records reviewed indicated that 96 percent of department staff were up to date with the required training. We were informed that the remaining staff were waiting for update training to be made available.

[16] Donning – putting on personal protective equipment (PPE); Doffing – taking off personal protective equipment (PPE)

Effective care

Quality improvement, research and innovation

Clinical audit

Evidence was provided of the clinical audit schedules in place within the department. This information set out the specific audits required in regards to different areas of the service. These included audits relating to patient referral, treatment and follow up. We were provided with evidence of good clinical audits completed by the service, which set out the findings and subsequent required actions. Additionally, it was noted that a re-audit system was in place to ensure that changes implemented as part of the audit response were routinely being monitored.

Senior managers confirmed that results from audits are shared with the multi-disciplinary team (MDT) and department staff to ensure staff are fully aware of findings and any subsequent changes to procedures. Additionally, we were informed that the service participates in national audit programmes to share findings and results with peers.

Expert advice

As previously mentioned, MPEs employed by the health board provide routine oversight and direct input, as well as ad-hoc advice and support to the department. We were informed MPEs were involved in practical aspects of the service including treatment planning, equipment QA, exposure dose evaluation, optimisation and analysis of any accidental or unintended exposures. We were also informed that there was MPE involvement in all relevant meetings relating to radiation exposures.

The role and responsibilities of the MPE were detailed in local procedures reviewed as part of the inspection process.

Staff we spoke with confirmed that they were able to contact an MPE for advice and support as and when required. There was clearly a positive relationship between medical physics and the radiotherapy staff within the department, which has enabled the service to develop.

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 that

participation in any clinical trial requires local approval by the health board Research and Development Internal Review Panel.

There was an employer's procedure in place that set out the arrangements for research studies involved ionising radiation exposures within the department, which 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

An organisational structure was in place for the overall radiotherapy department, with clear lines of reporting.

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.

Issues were highlighted by staff around available capacity and space within the department to carry out the relevant tasks required as part of their roles.

Governance, leadership and accountability

There was a radiotherapy structure chart in place, which set out the clear lines of reporting for the roles within the department. Additionally, a corporate organisational structure was in place which set out the arrangements for sharing information from the department up to the health board's executive board.

Senior managers confirmed that regular virtual meetings take place to ensure that staff are kept up to date with any issues or changes affecting the service. We were informed that the meetings are minuted to allow for any staff not in attendance to review the issues discussed. Additionally, we were informed that email updates are routinely sent to department staff relating to any guidance or procedural changes they need to be aware of.

As previously detailed, information provided evidenced that the service has undergone significant development since our previous inspection, which has been aided by the positive relationship between medical physics and the radiotherapy staff. To allow for the ongoing development, the service would benefit from establishing agreed multidisciplinary five and 10 year plans.

Prior to our inspection, HIW required 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 virtually. This demonstrates an openness and willingness to share learning by SWWCTC.

Duties of the employer

Entitlement

As previously detailed, the employer had procedures in place for the identification and entitlement of referrers, operators and practitioner, as required under IR(ME)R 2017. Evidence provided demonstrated that there was a well-developed process in place for entitling duty holders. Additionally, systems were in place to provide competence and induction training, as well as to check professional qualifications and registrations of all employees to underpin the entitlement arrangements in place.

Referrer awareness was included as part of the training provided to duty holders. The employer should consider adding a method to demonstrate that all individuals have read and understood the relevant employer's procedures detailed on the induction list.

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

Improvement needed

The employer should ensure that a method is in place to demonstrate that all individuals have read and understood relevant written procedures as part of the referrer awareness induction training.

Procedures and protocols

Senior managers confirmed that the health board Chief Executive (CEO) 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 compliance of radiation related activities within the health board to the Executive Director of Therapies and Health Science. This arrangement was clearly detailed in the documentation reviewed.

Overall, the employer's procedures and protocols provided as evidence were very well detailed and demonstrated compliance with IR(ME)R 2017. However, it was highlighted that two sets of employer's procedures were available for the service; one for radiotherapy and another for medical physics radiotherapy. The employer should amalgamate the employer's procedures to allow for there to be one set of procedures to cover the whole of the radiotherapy department. This will eliminate the risk of there being any discrepancies between the different sets of procedures in place.

Additionally, the service was operating using dual quality management systems (QMS); again one for radiotherapy and the other for medical physics radiotherapy. We were informed that both systems were centrally available to all duty holders and weekly meetings between QMS managers were in place to ensure consistency in approaches. It was reported that the systems were covered by a joint operational unit and it was positive to note that the first pathway audit had been completed for breast treatment. This audit covered the entire pathway with information collated from both QMS systems. We were informed that there were plans for similar audits of other clinical pathway. This should provide further assurances that potential gaps and overlap between the two QMS can be highlighted and addressed. Additionally, senior managers confirmed that there were future plans to streamline to one QMS system. This will offer further assurance of any combined risks from having two systems in place.

Information provided detailed that all procedures must be reviewed every two years as a minimum. All documents reviewed as part of our inspection were in date. There were systems in place to ensure that staff had access to relevant documentation and also to ensure they were routinely notified following any changes to written procedures or protocols in place within the department.

Improvement needed

The employer should ensure that there is a single set of employer's procedures in place which cover the whole of the radiotherapy department.

Significant accidental or unintended exposures

There were two employer's procedures in place setting out the required actions for reporting and investigating potential and actual accidental or unintended exposures. The procedures reviewed 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. However, it was highlighted that the HIW email address detailed within the procedure reviewed needs to be updated[17].

Senior managers described the arrangements in place in regards to accidental and unintended exposures, which reflected the documentation reviewed. We were also informed that all incidents must be reported via the incident reporting system (Datix) for analysis. Monthly spreadsheets were circulated to service managers, which contain details regarding any themes or trends highlighted.

In addition, a radiation summary of incidents and near misses, comparison of local and national trend analysis and a worked study of risk focused on accidental and unintended exposures were seen. We were informed that incident analysis was a standard agenda item on department management meetings and also this information was routinely shared and, where required, discussed with relevant staff working within the department.

Improvement needed

The employer should ensure that the written procedures in place in relation to significant accidental or unintended exposures is updated to detail up to date HIW contact details.

[17] Notifying IR(ME)R Incidents | Healthcare Inspectorate Wales (hiw.org.uk)

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, feedback received from staff indicated that they were happy with the level of support and engagement provided to them. Following feedback received, it was clear that there is a good team working ethos within the department, which has clearly enabled the progress evidenced following the previous HIW inspection.

Feedback received from staff indicated that around 54 percent who responded to the relevant question on our survey felt there were ‘always’ or ‘usually’ enough staff working within the department, to allow them to perform their roles. Discussions with department managers also highlighted that additional staff were required, especially with the pending introduction of the new treatment machine. Staff we spoke with felt that health board senior managers were aware of the staffing requirements and were working towards establishing the required staffing infrastructure within the department. The health board should ensure that the available infrastructure aligns with the future service development plans.

As previously outlined, concerns were highlighted by department managers around the limited space available to the radiotherapy service. We were informed that this issue has been exacerbated due to the installation of new equipment and the recent expansion of the adjacent nuclear medicine department. Whilst we appreciate the environmental limitations, given the concerns highlighted, a review of should be undertaken to ensure that the space available within the department is being fully utilised to enable staff to carry out their relevant roles.

We were informed that there was a system in place to ensure that all staff received their annual personal appraisal development reviews (PADRs). With the exception of two members of staff, all other staff, who responded to the question on our survey, confirmed that they had received their PADR within the last 12 months.

Evidence provided by the service indicated that the compliance rate for PADRs was 91 percent. However, the health board must ensure the remaining staff receive their appraisals as soon as possible. Also, five members of staff who responded to our survey stated that they did not feel that their training and development needs were discussed as part of their appraisal.

There were systems in place to monitor compliance with mandatory training. Evidence of training compliance was provided which demonstrated that compliance levels were very good, with an overall compliance percentage of 97 percent for department staff. Additionally, further information was provided detailing the reasons for the gaps in some staff members training compliance.

We were informed that arrangements were in place to allow staff to access additional wellbeing support if required. All staff who responded to the question on our survey confirmed that they were aware of the occupational health support available to them.

Improvement needed

The health board should provide HIW with an update on the ongoing plans to ensure that there is sufficient capacity within the department to allow staff to carry out their relevant roles.

The health board should undertake a review to ensure that the space available within the radiotherapy department is being fully utilised to assist staff in carrying out their relevant roles and to ensure that patient privacy and dignity is maintained.

The health board must ensure that all staff working within the department receive regular appraisal discussions with their line manager, which cover their training and development requirements.

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 twelve 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.

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: South West Wales Cancer Treatment Centre, Singleton Hospital

Ward/department: Radiotherapy Department

Date of inspection: 28 and 29 September 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):

Job role:

Date:

Appendix C – Improvement plan

Hospital: South West Wales Cancer Treatment Centre, Singleton Hospital

Ward/department: Radiotherapy Department

Date of inspection: 28 and 29 September 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 consider providing additional general health care advice and support information within the department.	1.1 Health promotion, protection and improvement	We will provide a range of general health information via notice boards, booklets and audio-visual media	Maureen Noonan (Radiotherapy Service Manager)	03.06.2022
The health board is required to ensure that action is taken to promote the availability of Welsh speaking staff / support within the department to help deliver the 'Active Offer'.	3.2 Communicating effectively	Posters have been sourced from the Welsh Language Assistant in the health board which includes the active offer to speak welsh. Information regarding welsh language courses for staff has also been circulated. This will be added to the audit schedule.	Nicki Davies (Radiotherapy Quality, Risk & Governance Lead)	03.01.2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The health board should ensure that arrangements are in place to provide staff and patients with regular updates on the patient experience feedback received by the service, as well as any subsequent actions taken.	6.3 Listening and Learning from feedback	The department has had limited feedback due to Covid, we have undertaken our own patient feedback which has been shared with staff. The electronic information board in the department will be used to feedback to patients. Feedback to all staff groups will be introduced through senior leadership management processes to the relevant staff group. Patient experience feedback will be a standing item on the agenda of the Radiotherapy Management meeting.	Maureen Noonan (Radiotherapy Services Manager)	Jan 2022
Delivery of safe and effective care				
The employer should ensure that the written procedure in relation to pregnancy enquires is updated to detail the specific age range of patients that should be asked.	Regulation 6 Sch.2 1(c)	All documentation has been updated to reflect this improvement. Can be provided on request	Nicki Davies (Radiotherapy Quality, Risk & Governance Lead)	Completed 07.10.2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer should ensure that the written procedure in relation to pregnancy enquires is updated to detail the required action on occasions where an exposure is to proceed with a known pregnancy.	Regulation 6 Sch.2 1(c)	All documentation has been updated to reflect this improvement. Can be provided on request	Nicki Davies (Radiotherapy Quality, Risk & Governance Lead)	Completed 07.10.2021
The employer should consider formally documenting the arrangement in place with Velindre University NHS Trust for the treatment of brachytherapy patients.	Regulation 6(4)	Documentation will be reviewed and updated. An end of treatment summary will be provided from Velindre and form part of the full patient record at the South West Wales Cancer Centre.	Mau-Don Phan (IR(ME)R Lead Clinical Oncologist)	01.02.2022
The employer must ensure that the written procedures in relation to justification and authorisation are updated to reflect agreed practice in relation to exposures undertaken when pregnancy cannot be excluded.	Regulation 6 (1)b	All documentation has been updated to reflect this improvement. Can be provided on request.	Nicki Davies (Radiotherapy Quality, Risk & Governance Lead)	Completed 07.10.2021
The employer should ensure that relevant employer's procedures are updated to reflect the agreed arrangements for clinical evaluation of all	Regulation 6 Sch.2	Documentation to be updated to reflect this improvement.	Nicki Davies (Radiotherapy Quality, Risk &	01.04.2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
medical exposures undertaken within the department.	1(j)	Training and Entitlement will be reviewed for Radiotherapy & Radiotherapy Physics staff groups.	Governance Lead) Ryan Lewis (Head of Radiotherapy Physics Services) Mau-Don Phan (IR(ME)R Lead Clinical Oncologist)	
The employer should ensure that the training, competency and entitlement framework for clinicians is updated to clearly record the operator task of clinical evaluation	Regulation 6 17(4)	Documentation will be updated to reflect this improvement. CT staff can request further scans as operators, a flow chart has been created to ensure consistency and compliance. Can be provided on request	Nicki Davies (Radiotherapy Quality, Risk & Governance Lead)	01.02.2022
Quality of management and leadership				
The employer should ensure that a method is in place to demonstrate that all individuals have	Regulation 6	A skilled list is being created in iPassport to ensure a digital record of the relevant	Mau-Don Phan (IR(ME)R Lead	01.02.2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
read and understood relevant written procedures as part of the referrer awareness induction training.	17(4)	written procedures have been read as part of the relevant referrer awareness training. This will be reviewed annually as a routine part of PADR/Appraisal	Clinical Oncologist) Maureen Noonan (Radiotherapy Services Manager) Ryan Lewis (Head of Radiotherapy Physics Services)	
The employer should ensure that there is a single set of employer's procedures in place which cover the whole of the radiotherapy department.	Regulation 6 (1)a	The team is committed to reviewing any document that comes up for review immediately and where possible merging with other similar documents from the relevant service (Radiotherapy, or Radiotherapy Physics) to a single employer procedure. All documents will be reviewed within 2yr review period	Maureen Noonan (Radiotherapy Services Manager) Ryan Lewis (Head of Radiotherapy Physics Services)	31.09.2023
The employer should ensure that the written procedures in place in relation to significant	Regulation 6 (1)b	Documents to be updated to ensure correct email for HIW. Change requests submitted in iPassport	Nicki Davies (Radiotherapy Quality, Risk &	31.05.2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
accidental or unintended exposures is updated to detail up to date HIW contact details.			Governance Lead) James Williams (Consultant Clinical Scientist)	
The health board should provide HIW with an update on the ongoing plans to ensure that there is sufficient capacity within the department to allow staff to carry out their relevant roles.	7.1 Workforce	Plans are in place as part of our Programme Business Case to assure HIW that all future replacement equipment and services have a robust workforce element within	Maureen Noonan (Radiotherapy Services Manager) Russell Banner (Lead Consultant Clinical Oncologist) Ryan Lewis (Head of Radiotherapy Physics Services)	31.06.2022
The health board should undertake a review to ensure that the space available within the radiotherapy department is being fully utilised to assist staff in carrying out their relevant roles and	7.1 Workforce	A SWWCC infrastructure board has now been established to look at overall space with appropriate representation. The requirement to ensure that the space	Ceri Gimblett (Associate Service Group	First scoping meeting of board

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
to ensure that patient privacy and dignity is maintained.		available within the radiotherapy department is being fully utilised to assist staff in carrying out their relevant roles and to ensure that patient privacy and dignity is maintained will be included as part of this new board	Director – Cancer Services)	planned for 02.12.2021
The health board must ensure that all staff working within the department receive regular appraisal discussions with their line manager, which cover their training and development requirements.	7.1 Workforce	We commit to annual appraisal / PADRs being completed every 12 months with all staff. Training and Development needs will be recorded and signed by reviewer and reviewee. Outstanding appraisals / PADRs will be completed by the end of the year.	Maureen Noonan (Radiotherapy Services Manager) Ryan Lewis (Head of Radiotherapy Physics Services) Mau-Don Phan (IR(ME)R Lead Clinical Oncologist)	31.12.2021

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): **Ceri Gimblett**

Job role: **Associate Service Group Director – Cancer Services**

Date: **16/11/2021**