

# **Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)**

Radiotherapy Department /  
Velindre Cancer Centre/ Velindre  
University NHS Trust

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## Contents

1.	What we did .....	6
2.	Summary of our inspection.....	7
3.	What we found .....	9
	Quality of patient experience .....	10
	Delivery of safe and effective care .....	16
	Quality of management and leadership .....	25
4.	What next? .....	30
5.	How we inspect services that use ionising radiation .....	31
	Appendix A – Summary of concerns resolved during the inspection .....	32
	Appendix B – Immediate improvement plan .....	33
	Appendix C – Improvement plan .....	34

**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 Velindre Cancer Centre within Velindre University NHS Trust on the 26 and 27 November 2019.

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

We found that arrangements were in place to promote the safety and wellbeing of patients when they visited the radiotherapy department for treatment.

Written policies and procedures had been developed to support staff to comply with the requirements of The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2017 as they apply to radiotherapy.

We identified that further efforts could be made to fully meet some of the Health and Care Standards (2015) in respect of promoting the availability of Welsh speaking staff, advising patients of delays and better informing patients of the Trust's complaint procedure.

We also identified that improvements could be made in relation to the governance of licences required under IR(ME)R 2017 and the detail recorded in training records for clinical oncologists.

This is what we found the service did well:

- Patients indicated they were very satisfied with the service they had received and praised the approach by staff
- Comprehensive written policies and procedures had been developed to support the department's compliance with The Ionising Radiation (Medical Exposure) Regulations 2017
- Senior staff were very receptive to our inspection and demonstrated a willingness to make improvements as a result
- Clear lines of management reporting and accountability within the department were described and demonstrated.

This is what we recommend the service could improve:

- Promote the availability of Welsh speaking staff working within the department to help deliver an 'Active Offer'.
- Better inform patients visiting the department of current waiting times and the Trust's complaints procedure

- The governance arrangements with regards to licences required under The Ionising Radiation (Medical Exposure) Regulations 2017
- The detail recorded within the training records of clinical oncologists so that they clearly demonstrated individuals' scope of practice.

### 3. What we found

#### **Background of the service**

Velindre Cancer Centre provides non-surgical oncology and palliative care to the population of south-east Wales and highly specialist cancer services for patients from other regions of Wales.

It is one of the largest cancer centres in the UK and is part of the Velindre University NHS Trust.

The radiotherapy department consists of both planning and treatment departments. A mould room is also located within the department where special devices are made for individual patients who need to be immobilised during treatment e.g. patients receiving radiotherapy treatment to their head or neck.

Treatment is provided using a range of equipment, including:

- linear accelerators - used to give treatment from outside the body by directing radiation beams at cancer to destroy it
- superficial and orthovoltage unit - used to give treatment either on or close to the skin surface e.g. skin cancer
- brachytherapy machine - used to give treatment from inside the body e.g. for prostate cancer

The service employs a number of staff including consultant oncologists, therapeutic radiographers, medical physics experts and clinical scientists.

For ease of reading the Velindre University NHS Trust will be referred to as the 'Trust' throughout the remainder of this report.



## 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.*

Comments from patients indicated they were highly satisfied with the level of service provided by staff in the department.

Patients told us that they had been given enough information about their treatment and had been involved in decisions about their care.

We saw that arrangements were in place to promote the privacy and dignity of patients and found that staff treated patients with respect.

Whilst the communication needs of patients were being met, we identified that improvements could be made to promote the availability of Welsh speaking staff. We also found that further efforts could be made to better inform patients of waiting times and the complaints procedure.

Before our inspection we invited the radiotherapy department to hand out HIW questionnaires to patients. This was to obtain their views on the service provided at the department. Questionnaires were also given to patients visiting the department during our inspection. In total, we received 26 completed questionnaires.

Patients were asked in the questionnaire to rate their overall experience provided by the service. Responses were very positive; the majority of patients rated the service as either 'excellent' or 'very good'. Patients told us:

*"Very efficient and compassionate service. Well organised and run"*

*"Service is excellent, but shows signs of strain and needs more investment, machines and staff"*

*"The service that I received was very nice and made me feel comfortable"*

Comments from one patient were particularly complimentary regarding the support and compassion shown by a member of staff towards the patient's relative.

Patients were asked in the questionnaires how the setting could improve the service it provides; suggested improvements included:

*“Could be warmer in the treatment area”*

*“New facilities when the new Velindre opens!”*

*“With regard to Q2, it would be nice to be able to speak in Welsh about the more personal/self-care elements of treatment. English would be my preferred language for more medical/technical aspects, not least because of the specialist language and lack of Welsh speaking professionals”*

## **Staying healthy**

Information for patients on how they could look after and care for their own health was displayed within the department. This included leaflets on how people could be helped to stop smoking as well as other leaflets particularly relevant to patients having radiotherapy treatment.

We saw posters prominently displayed advising patients of the importance of letting department 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.

Similarly, we also saw posters advising patients to let staff know if they had a cardiac pacemaker<sup>1</sup>. This is important since ionising radiation can cause damage to pacemakers resulting in them not working properly.

## **Dignified care**

All but one of the patients who completed a questionnaire agreed that they had been treated with dignity and respect by the staff at the hospital and every patient

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<sup>1</sup> A pacemaker sends electrical pulses to the heart to keep it beating regularly and not too slowly.

felt that they were always able to maintain their own privacy, dignity and modesty during their appointments.

All patients that completed a questionnaire felt that they were listened to by staff during their appointment. All but one of the patients also told us that they were able to speak to staff about their procedure or treatment without being overheard by other people.

Reception staff confirmed that a private room was available should a patient request to speak to staff privately, rather than at the reception desk.

Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly manner and asking about their welfare.

We saw that dignity gowns were provided for patients when they were required to remove their clothes during their procedure. This helped promote their dignity when waiting for and during their treatment.

Individual changing cubicles for patients were available near to the treatment rooms. These provided privacy when patients needed change out of their clothes into dignity gowns before and after their treatment.

The majority of comments from patients were very positive. However, the Trust may wish to explore whether improvement is needed given the small number of comments we received regarding patient dignity and respect and being able to speak to staff privately.

### **Patient information**

Every patient who completed a questionnaire told us that they had been given information on how to care for themselves following their treatment. All but one of the patients said that they had been given written information on who to contact for advice about any after effects from any treatments they had received.

The majority of patients that completed a questionnaire told us that they felt involved as much as they wanted to be in any decisions made about their treatment. All of the patients said that they had received clear information to understand the risks and benefits of their treatment options.

While the majority of comments from patients were very positive, the Trust may wish to consider whether improvement is needed in respect of providing patients with written contact details and involving them in decisions about their treatment.

We saw that a range of patient information leaflets were displayed in the main waiting area. These covered a variety of topics relevant to patients having radiotherapy treatments and were readily available for patients to take away with

them. This meant that patients had access to relevant information that they could refer to when at home.

The department also held radiotherapy 'open' evenings. These provided opportunities for patients and their relatives to visit the department, meet some of the staff and ask questions before starting treatment.

### Communicating effectively

Reception staff confirmed that a hearing loop was installed and working to assist people wearing hearing aids when communicating with staff. Senior staff also confirmed that written information could be printed in large print to help those with sight problems.

Senior staff described electronic tablets that were being used to help translate information for patients whose first language was not English. This aimed to improve communication between staff and patients. Senior staff confirmed that this initiative was in the pilot stage and that feedback so far had been very positive.

We saw that many patient information leaflets were available in Welsh. However, it was not immediately obvious within public areas of the department that patients could speak to staff in Welsh if they wished to do so. Comments made within one of the questionnaires supported our observations.

Senior staff confirmed that a number of staff, including therapy radiographers and consultants, could speak Welsh. We were told that usually patients wishing to converse in Welsh would notify staff when making appointments. However, senior staff were receptive to our comments and agreed that the availability of Welsh speakers working within the department could be better promoted and so help deliver an 'Active Offer'<sup>2</sup>.

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<sup>2</sup> 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.

It is a key principle of 'More than just words', the Welsh Government initiative for strengthening Welsh language provision in health and social services. <https://gov.wales/welsh-language-healthcare-more-just-words-action-plan-2019-2020>

### Improvement needed

The Trust is required to provide HIW with details of the action taken to promote the availability of Welsh speaking staff working in the department to help deliver the 'Active Offer'.

## Timely care

The majority of patients who completed a questionnaire told us that it was “very easy” to get an appointment at a time that suited them.

Around half of the patients who completed a questionnaire told us they had waited more than 15 minutes to have their procedure or treatment. Just over half of patients that completed a questionnaire said that they were not told on arrival how long they would likely have to wait before having their procedure or treatment.

A large screen was located in the main waiting area which informed patients of delays. However, given the comments we received staff should consider further ways to communicate delays to patients.

When delays did occur, senior staff explained that this was usually due to equipment breakdowns.

### Improvement needed

The Trust is required to provide HIW with details of the action taken to better inform patients visiting the department of current waiting times.

## Individual Care

### Listening and learning from feedback

The Trust had a procedure for responding to complaints. Arrangements were also in place for patients to provide feedback about their experiences of using the radiotherapy department.

The majority of patients who completed a questionnaire said they knew how to raise a concern or complaint about the services they had received. However, just over a third said they did not.

Given the comments we received, efforts should be made to better inform patients' of the Trust's complaints procedure.

Senior staff confirmed that wherever possible, complaints would be dealt with immediately (i.e. 'on the spot') to help resolve any issues as quickly and efficiently.

#### Improvement needed

The Trust is required to provide HIW with details of the action taken to better inform those patients using the department of the Trust's complaints procedure.

## Delivery of safe and effective care

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

We found that the radiotherapy department provided safe and effective care to patients.

Policies and written procedures required under The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 were available and up to date. These helped the department to comply with the requirements of the regulations as they apply to radiotherapy.

The department was clean and arrangements were in place to promote the safety of patients, staff and visitors to the department.

## Compliance with Ionising Radiation (Medical Exposure) Regulations

### Duties of employer

#### *Patient identification*

The employer had an up to date written procedure to correctly identify patients prior to them having their exposure. This covered planning and treatment exposures and other related procedures. This aimed to ensure that the correct patient had the correct exposure and is one of the written procedures required under IR(ME)R 2017.

The procedure clearly identified those staff responsible for correctly identifying patients. Staff were expected to ask patients to confirm their name, date of birth and address. This approach is in keeping with current UK guidance<sup>3</sup>.

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<sup>3</sup> Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017 <https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance>

The procedure also described alternative approaches that staff must use should patients be unable to verbally confirm their identity themselves, further promoting patient safety.

All patients that completed a questionnaire felt that they were listened to by staff during their appointment and were asked to confirm their personal details before starting their procedure or treatment.

Staff we spoke to were able to describe the correct procedure to identify patients.

#### *Individuals of childbearing potential (pregnancy enquiries)*

The employer had an up to date written procedure for making enquires with regard to an individual's pregnancy status, at the time of consent for radiotherapy, before planning exposures and before the first treatment exposure. Individuals are also requested as part of consent to inform staff immediately if they suspect their pregnancy status changes.

This aimed to ensure that such enquires were made in a standard and consistent manner. The procedure clearly identified those staff responsible for making relevant enquires and set out the actions they must follow depending on the individual's responses.

The written procedure included the age range of patients who should be asked about pregnancy in accordance with UK guidance<sup>4</sup>.

Staff we spoke to were able to describe their responsibilities with regards to the above procedure.

#### *Non-medical imaging exposures*

Non-medical exposures<sup>5</sup> were not performed at the radiotherapy department.

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<sup>4</sup> Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017. <https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance>

<sup>5</sup> 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.



This was clearly stated in the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department.

### *Referral guidelines*

The employer had established referral guidelines in place. Suitable arrangements were described for making these available to those entitled to act as referrers under IR(ME)R 2017.

The arrangements for making referrals were described within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department.

Comprehensive clinical protocols were available to support the requirement under IR(ME)R 2017 for written protocols to be in place for every type of standard radiotherapy practice. These were presented as (anatomical) site specific protocols and included details of the referral guidelines for radiotherapy planning and treatment.

Senior staff were receptive to our comments to include reference to the clinical protocols within the 'Referral' section of employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department.

### **Duties of practitioner, operator and referrer**

The employer had a suitable system in place to identify the different roles of the professionals involved in requesting and providing radiotherapy treatment to patients. The employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department identified, by staff group, who were entitled to be practitioners<sup>6</sup>, operators<sup>7</sup> and referrers<sup>8</sup> (known as duty holders).

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<sup>6</sup> 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.

<sup>7</sup> 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.

<sup>8</sup> 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

In radiotherapy the referrer and practitioner may be the same person e.g. a clinical oncologist<sup>9</sup>. An example of an operator working within a radiotherapy department is a therapeutic radiographer<sup>10</sup>, clinical scientist or clinical oncologist.

Staff working within the radiotherapy department were expected to comply with the employer's procedures. This was clearly stated within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department. Staff could access the procedures electronically via the department's computer system. We were told that all staff had computer access. Staff were discouraged from printing out the employer's procedures and to only access them via computer. This helped reduce the likelihood of staff accessing 'out of date' procedures. Staff we spoke to confirmed they could access the procedures.

Senior staff described a system for notifying staff of any changes to the employer's procedures. This was also set out within a written policy. This involved individual staff being emailed with details of any reviewed and updated procedures. Staff we spoke to confirmed they were aware of the system in place.

### **Justification of Individual Medical Exposures**

The employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department set out the arrangements for the justification and authorisation<sup>11</sup> of exposures.

This stated that only entitled practitioners were permitted to justify exposures and they were responsible for endorsing all relevant forms to evidence that justification had taken place. However, the employer's procedures should also describe clearly how authorisation is demonstrated for each type of exposure undertaken:

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<sup>9</sup> Clinical oncologists are doctors who use radiotherapy and chemotherapy to treat and manage patients with cancer. They also use a range of other treatments to treat cancers, without using surgery.

<sup>10</sup> Therapeutic radiographers use doses of x-rays and other ionising radiation to treat medical conditions - mainly cancer and tumours.

<sup>11</sup> 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

- Planning exposures
- Verification exposures
- Treatment exposures
- Re-planning exposures

We saw examples of patients' records that demonstrated authorisation (i.e. evidence of justification) of exposures.

#### Improvement needed

The employer is required to provide HIW with details of the action taken to include within the employer's procedures details of how authorisation is demonstrated for each type of exposure undertaken.

#### Optimisation

The employer had arrangements in place for the optimisation<sup>12</sup> of exposures.

These were set out within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department. In addition this was supported by written procedures that covered optimisation at various points in the patient's care pathway.

These arrangements aimed to ensure that radiation doses delivered to patients as a result of exposures are kept as low as reasonably practicable (also referred to as ALARP).

Due to the high doses of radiation delivered during radiotherapy carers and comforters<sup>13</sup> were not permitted to be present during treatments for their safety.

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<sup>12</sup> Optimisation refers to the process by which individual doses are kept as low as reasonably practicable.

<sup>13</sup> 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.

### *Diagnostic reference levels*

IR(ME)R 2017 requires diagnostic reference levels<sup>14</sup> are established for radio-diagnostic examinations. This does not apply to radiotherapy planning and treatment exposures.

Therefore the employer is not required to have a procedure in this regard for the radiotherapy service.

This was clearly stated within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department.

### *Paediatrics*

The employer had a policy in respect of paediatric (child) radiotherapy treatment as required under IR(ME)R 2017.

This aimed to prepare children for their radiotherapy treatment taking into account their specific care needs. It was clear from the policy that the department placed an emphasis on providing support and information about treatment to children and their families.

Children were treated and imaged according to specific paediatric protocols. Treatment plans for children were optimised at the planning stage so that the radiation doses involved were kept to a minimum.

The department had a designated children's waiting area. This was adjacent to the main waiting area and had a selection of age appropriate toys that children could play with, whilst waiting for their treatment.

### *Clinical evaluation*

Arrangements were in place for the clinical evaluation<sup>15</sup> of exposures.

These were set out within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department. This was supported by written

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<sup>14</sup> 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.

<sup>15</sup> Clinical evaluation is important to help inform the next stage of a patient's care and treatment.

procedures for each part of the patient care pathway including the planning, verification and treatment sessions.

Arrangements were described and demonstrated for recording findings within the patients' records.

### **Equipment: general duties of the employer**

The employer had an up-to-date inventory (list) of the equipment used within the radiotherapy department.

The inventory contained that information required under IR(ME)R 2017.

Multiple examples were seen on site of local written procedures, work instructions, Quality Assurance (QA) programme, equipment logs and meeting minutes to evidence compliance with IR(ME)R 2017 requirements. An approach to equipment QA which included tolerance and action levels informed by professional, national, international and manufacturer guidelines was described.

## **Safe care**

### **Managing risk and promoting health and safety**

The environment was well maintained and arrangements were in place to promote the safety of staff, patients and visitors to the department.

There was level access to the main entrance of the centre and the radiotherapy department was located on the ground floor. This allowed patients with mobility difficulties to enter and leave the department safely.

The department was clean and generally free from clutter and obvious trip hazards. Appropriate signage and restricted access arrangements were in place to deter and prevent unauthorised persons entering areas where radiotherapy equipment was being used. This helped promote the safety of patients and visitors to the department.

### **Infection prevention and control**

Arrangements were in place for effective infection prevention and control and decontamination.

There were no concerns given by patients over the cleanliness of the department; all of the patients who completed a questionnaire felt that, in their opinion, the department was 'very clean' or 'fairly clean'.

At the time of our inspection, all areas of the department were visibly clean and generally tidy. Senior staff explained that the compliance with hand hygiene

procedures was regularly audited by 'hand hygiene champions' and action taken as appropriate. Effective handwashing is important to reduce the spread of infection.

We saw that personal protective equipment (PPE) was readily available. Staff we spoke to confirmed that they always had access to PPE such as disposable gloves. The use of PPE together with effective handwashing is important to reduce the spread of infection.

Senior staff confirmed that cleaning staff are very thorough and prompt when asked to deal with any cleaning issues which may occur e.g. spillages.

### **Safeguarding children and adults at risk**

Arrangements were in place to promote and protect the welfare and safety of children and adults at risk.

Senior staff confirmed that a safeguarding lead person was available to offer help and advice around safeguarding matters. They also confirmed that safeguarding training formed part of the department's mandatory training programme.

Department staff we spoke to were able to describe their responsibilities and the action they would take should they have concerns about a patient's welfare.

## **Effective care**

### **Quality improvement, research and innovation**

#### *Clinical audit*

Senior staff provided details of a number of external clinical audits that had been conducted within the previous two years. An internal audit of the department's compliance with IR(ME)R 2017 had also been undertaken.

This supports the requirement for clinical audit under IR(ME)R 2017. Where areas for attention had been identified, we were told that action had either been taken or was being taken in this regard.

The employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department set out the arrangements for clinical audit.

### *Expert advice*

Medical Physics Experts<sup>16</sup> were appointed to work across the Trust as required under IR(ME)R 2017.

The employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department set out the role of the MPEs.

We were told that they were involved in every radiotherapeutic practice, provided advice on, and contributed to, such matters as required under IR(ME)R 2017. We also saw written evidence demonstrating an MPE's involvement within the radiotherapy service in this regard.

Staff who we spoke to also told us that they were able to contact an MPE for advice when necessary.

### *Medical research*

Senior staff confirmed that the radiotherapy department does participate in research involving medical exposures. This was through clinical trials and in accordance with multi-disciplinary approved trial protocols.

The arrangements for research trials were described in the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department. This demonstrated that such trials were appropriately overseen by and involved relevant department staff.

### **Record keeping**

We reviewed a sample of patient care records. We saw that these had been completed with appropriate details by those staff involved in the exposure.

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<sup>16</sup> A medical physics expert is a person who holds a science degree or its equivalent and who is experienced in the application of physics to diagnostic and therapeutic uses of ionising radiation.

## 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*

A management structure with clear lines of reporting and accountability was described and demonstrated.

Written procedures and management arrangements were in place to support the radiotherapy department's compliance with IR(ME)R 2017. However, whilst licences required under IR(ME)R 2017 were available, we identified that governance arrangements could be improved in this regard.

Comments from staff indicated that they felt supported by senior staff within the department.

Senior staff confirmed that there were a number of long term vacancies within the department and that current staffing levels were below professional recommendations. This was being actively managed by the Trust to minimise the impact on the delivery of services.

Training records demonstrated that staff had received training and had been assessed to ensure they were competent to perform their roles safely. However, we identified that further detail could be recorded in the training records for clinical oncologists.

Completion of other mandatory training was regularly monitored by senior staff, who were taking action to improve compliance with the Trust's own standards in this regard.

## Governance, leadership and accountability

A management structure with clear lines of reporting was described and demonstrated. We found that governance arrangements were in place to support the effective operation of the radiotherapy department.



Staff we spoke to confirmed that they felt supported by their line manager.

Senior management staff made themselves available on the days of the inspection and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the inspection.

Ahead of the 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 respect of IR(ME)R. This document was used to inform the inspection approach.

The self-assessment form was returned to HIW within the agreed timescale and was comprehensive. Where we required additional information or clarification in respect of the responses within the self-assessment, senior staff provided this promptly.

### Requirement to hold a licence

Under IR(ME)R 2017, employers must hold a valid licence for each department where radioactive substances are given. Similarly, practitioners are also required to hold a licence to administer such substances.

Senior staff confirmed that valid licences were held in respect of the radiotherapy department and provided documentation to support this. However, there appeared to be uncertainty as to the arrangements relating to the application and reviewing of such licences. Senior staff accepted that the governance arrangements in this regard needed to be confirmed and clarified.

#### Improvement needed

The employer is required to provide HIW with details of the action taken to improve governance arrangements with regards to licences.

### Duties of the employer

#### *Entitlement*

As previously described, the employer had a procedure for the entitlement and identification of practitioners, operators and referrers (known as duty holders) as required under IR(ME)R 2017.

The employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department clearly described the arrangements for entitlement and

identified duty holders by staff group. Appendices to the policy provided details of each duty holder's entitlement and scope of practice.

### *Procedures and protocols*

The chief executive of the Trust was designated as the employer. This is usual practice. The Trust's Ionising Radiation Safety Policy clearly set out that the Chief Executive carried overall responsibility for implementing the requirements of IR(ME)R 2017 across the Trust. This was reiterated within the employer's policy on how IR(ME)R 2017 is implemented within the radiotherapy department

We saw that clear written procedures and protocols had been developed and implemented in accordance with IR(ME)R. We saw that these were up-to-date and review dates were clearly stated.

### *Significant accidental or unintended exposures*

The employer had a written procedure for reporting and investigating significant accidental or unintended exposures<sup>17</sup> (SAUE) within the department. This is required under IR(ME)R 2017.

This clearly set out the procedure staff should follow should they suspect that a SAUE has occurred. The procedure correctly guided staff to inform Healthcare Inspectorate Wales (HIW) of such incidents in a timely manner.

Details of SAUEs and other non-exposure incidents were recorded and reported via the Trust's electronic reporting system. Senior staff confirmed that learning from SAUEs and non-exposure incidents would be shared amongst staff within the radiotherapy department to help prevent similar incidents happening again. They also provided an example of where practice had been changed in response to a SAUE to promote patient safety.

Staff we spoke to were aware of the correct reporting procedure to follow in the event of the occurrence of a SAUE or other no-exposure incident. They confirmed that they were encouraged to report incidents. This demonstrates an open reporting culture that helps promote patient safety and make improvements where necessary.

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<sup>17</sup> <https://hiw.org.uk/notifying-irmer-incidents>

## Staff and resources

### Workforce

Senior staff confirmed long term vacancies (i.e. over three months) existed for medical physics and clinical oncology staff. There were no long term vacancies reported for therapeutic radiography staff. However, senior staff explained that staffing levels were below current professional recommendations across the three staff groups above.

Senior staff described arrangements to minimise the impact of vacancies on the delivery of the service. In addition, a number of initiatives were explained to help address the vacancies and meet the increasing demands on the service.

During the course of our inspection, staff demonstrated they had the appropriate skills and confirmed they were supported to perform their respective roles within the department.

As described earlier, the employer had arrangements in place for the entitlement of practitioners, operators and referrers.

Senior staff described an induction process for new and agency staff.

We looked at a sample of training records for practitioners and operators working within the department. These demonstrated that staff had received relevant training and had their competency assessed in relation to carrying out exposures. The records also clearly identified each individual's scope of practice. However, consideration needs to be given to improving training records for clinical oncologist operator functions. These should be available at a task level as for other staff groups (i.e. clearly demonstrating the elements of an individual's scope of practice). It was reported that work had already commenced to address this.

Radiography staff confirmed they had access to training and were supported by senior staff to meet their continuing professional development needs in their chosen field of work.

In addition to training required under IR(ME)R 2017, senior staff confirmed that staff were required to complete a range of training as part of the Trust's mandatory training programme. Topics included infection prevention and control, moving and handling, resuscitation and safeguarding. Senior staff regularly monitored and reported on compliance with training as part of the overall governance arrangements. Information provided by senior staff showed that overall compliance was less than the Trust's standard. This had been identified by senior staff who described this was being actively managed to improve the department's compliance.

### Improvement needed

The employer is required to provide HIW with details of the action taken to improve the training records for clinical oncologist operator functions so that they clearly demonstrate the elements of their scope of practice.

## 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:** Velindre Cancer Centre  
**Ward/department:** Radiotherapy Department  
**Date of inspection:** 26 and 27 November 2019

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 improvement plan required.	-	-	-	-

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:** Velindre Cancer Centre  
**Ward/department:** Radiotherapy Department  
**Date of inspection:** 26 and 27 November 2019

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
<b>Quality of the patient experience</b>				
The Trust is required to provide HIW with details of the action taken to promote the availability of Welsh speaking staff working in the department to help deliver the 'Active Offer'.	3.2 Communicating effectively	A review of the Radiotherapy departments delivery of 'Active offer' to be undertaken in conjunction with the Trusts Welsh Language officer	Bernadette McCarthy, Radiotherapy Services Manager	Completed December 2019
		Velindre Cancer Centres register of Welsh language speakers and learners to be updated	Bernadette McCarthy, Radiotherapy Services Manager	29th February 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		All Radiotherapy staff name badges / Uniforms to include identification of welsh language speakers/ learners	Bernadette McCarthy, Radiotherapy Services Manager	31st March 2020
		A Review and update of current signage/ signposting within the Radiotherapy department to be undertaken highlighting availability of Welsh language speakers throughout the patient's radiotherapy pathway	Bernadette McCarthy, Radiotherapy Services Manager	31st March 2020
		Availability of Welsh language services to be printed on patient appointment letters and appointment cards.	Bernadette McCarthy, Radiotherapy Services Manager	31st March 2020
The Trust is required to provide HIW with details of the action taken to better inform patients visiting the department of current waiting times.	5.1 Timely access	Radiotherapy reception staff to inform each patient of any wait on relevant machine / treatment area on arrival during the standard check-in process.	Bernadette McCarthy, Radiotherapy Services Manager	29th February 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		Process to be implemented whereby if any changes to waiting times occur within any part of the radiotherapy department and announcement is made within local and general waiting area	Bernadette McCarthy, Radiotherapy Services Manager	29th February 2020
		A process for putting radiotherapy waiting times on an electronic information display board to be worked through	Bernadette McCarthy, Radiotherapy Services Manager	31st March 2020
		Pre-treatment planning refurbishment taking place during 2020, a digital solution regarding live notification of radiotherapy waiting times to be factored into this work.	Bernadette McCarthy, Radiotherapy Services Manager	31st December 2020
The Trust is required to provide HIW with details of the action taken to better inform those patients using the department of the Trust's complaints procedure.	6.3 Listening and Learning from feedback	NHS Wales Putting Things Right Posters & leaflets to be made available in easy to visualise areas within the main radiotherapy waiting room and all sub waiting areas	Bernadette McCarthy, Radiotherapy Services Manager	31st January 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale	
		A notice of who is in charge within the department each day and how they can be contacted if anyone wishes to discuss anything to be placed at the main booking desk	Bernadette McCarthy, Radiotherapy Services Manager	29th February 2020	
		A 'You Said We Did' Board to be erected within Radiotherapy public area and kept live outlining what actions have been taken / changes made following feedback from patients / loved ones	Bernadette McCarthy, Radiotherapy Services Manager	31st 2020	March
		All Radiotherapy Senior Staff and Management Team to receive Putting Things Right Complaints training (that maintains a nipping in the bud focus)	Bernadette McCarthy, Radiotherapy Services Manager	30th 2020	June
Delivery of safe and effective care					
The employer is required to provide HIW with details of the action taken to include within the employer's procedures details of how	2.1 Managing risk and promoting health and safety Regulation 11	Full review of Velindre Cancer Centre's IR(ME)R documentation to be undertaken and be signed off through the Cancer Centre's Quality & Safety Group	Bernadette McCarthy, Radiotherapy Services Manager / Arnold	31st 2020	March

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
authorisation is demonstrated for each type of exposure undertaken.		that includes: Radiotherapy, Medical Physics; and Clinicians	Rust, Head of Radiation Protection	
		The guidelines for justification of all exposures including radiotherapy planning scans, rescans and on set imaging etc. will be expanded where necessary following the above review	Tony Millin Head of Radiotherapy Physics	31st March 2020
Quality of management and leadership				
The employer is required to provide HIW with details of the action taken to improve governance arrangements with regards to licences.	Governance, Leadership and Accountability  Regulation 5	A Procedure detailing the maintenance of ARSAC licences has been produced that states that the licenses will be held within the radiation protection quality management system who will contact the license holder and relevant Medical Physics Experts (MPEs) 6 months before expiry. The Nuclear Medicine Lead MPE and Brachytherapy Lead MPE will maintain responsibility that appropriate licenses are held by appropriate staff. The roles of MPEs, and practitioners are clarified within this document. This	Tony Millin, Head of Medical Physics	31st January 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		document is currently being reviewed by the trust radiation protection committee prior to approval.		
The employer is required to provide HIW with details of the action taken to improve the training records for clinical oncologist operator functions so that they clearly demonstrate the elements of their scope of practice.	7.1 Workforce Regulation 17	Benchmarking of process undertaken across UK Cancer Centres to be undertaken	Eve Gallop-Evans, Clinical Director, Velindre Cancer Centre	Completed January 2020
		Directory of all Velindre Cancer Centre Consultants & Trainees, detailing parameters of scope of practice, training requirements, training undertaken to date and any training / competency gaps to be completed.	Eve Gallop-Evans, Clinical Director, Velindre Cancer Centre	31st March 2020
		A clear plan to address any training / competency gaps to be developed and action taken to address all training / competency requirements	Eve Gallop-Evans, Clinical Director, Velindre Cancer Centre	31st July 2020
		Formalised induction for all Medical Staff commencing in Velindre Cancer Centre to be introduced to ensure that all training	Eve Gallop-Evans, Clinical Director, Velindre Cancer Centre	31st March 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		/ competency gaps required as part of role are addressed during induction		

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):** Bernadette McCarthy  
**Job role:** Radiotherapy Services Manager  
**Date:** 24/01/2020