

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

Radiotherapy Department, South  
West Wales Cancer Centre,  
Singleton Hospital. Abertawe Bro-  
Morgannwg University Health  
Board

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

## **Our purpose**

To check that people in Wales are receiving good care.

## **Our values**

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

## **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 Radiotherapy Services within the South West Wales Cancer Centre (SWWCC) located at Singleton Hospital on the 14 and 15 November 2017. The service is operated by Abertawe Bro Morgannwg University Health Board (ABMU). The following areas were visited during this inspection:

## Radiotherapy Department

- Radiotherapy-all service areas
- Radiotherapy physics areas

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

We met with senior managers, superintendent radiographers, oncologists, radiographers, medical physics experts and radiotherapy physics staff.

We adopted a 'patient journey' approach to our inspection, seeking evidence from written procedures most of which had been provided in advance of the inspection, and from discussions with staff and patients over a period of two days. We therefore examined how procedures, processes and practice from patient referral through to diagnosis, treatment and clinical evaluation, met the requirements of IR(ME)R. In particular, we explored the identity and responsibilities of the various duty holders, the nature of radiotherapy referral criteria and how radiotherapy planning verification and treatment was justified<sup>1</sup>, authorised and delivered.

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<sup>1</sup> Justification is the process of weighing up the potential benefit of an exposure against the potential detriment for that individual. It must include considering the possibility of using techniques which do not use ionising radiation.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011)
- 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

The service provided us with evidence and assurance that it had procedures in place that were in line with regulatory requirements and that duty holders were identified, trained, entitled to carry out their roles and understood their responsibilities. We were also able to confirm that medical physics expertise and support was in place.

Although we had no concerns about safe working practice or risks to patients, we did identify some areas for improvement.

This is what we found the service did well:

- Patients expressed a high level of satisfaction with the care, treatment and support they received at this service
- Staff clearly demonstrated their confidence and competence relating to their duties under IR(ME)R
- We some good examples of staff training records

This is what we recommend the service could improve:

- The health board must review staffing levels within the radiotherapy department to ensure that it can sustain safe and effective care to patients
- There is a need to replace ageing equipment. This is to ensure that the department is able to provide sufficient and contemporary treatment to patients
- Patients need to be provided with a suitable area where sensitive discussions can be held in private within the radiotherapy department

We identified regulatory breaches, where improvement was required during this inspection, some of which are shown above. Further details can be found in Appendix C of this report. Whilst we did not issue a non compliance notice on this occasion, there is an expectation that the health board takes meaningful action to address these matters.

## 3. What we found

### Background of the service

Abertawe Bro Morgannwg University Health Board was formed on 1 October 2009 as a result of a re-organisation within the NHS in Wales. The Health Board consists of an amalgamation of the former Local Health Boards (LHBs) for Swansea, Neath Port Talbot and Bridgend and also the Abertawe Bro Morgannwg University NHS Trust. The Health Board covers a population of approximately 500,000 people.

The Health Board has four acute hospitals providing a range of services; these are Singleton and Morriston Hospitals in Swansea, Neath Port Talbot Hospital in Port Talbot and the Princess of Wales Hospital in Bridgend. There are also a number of smaller community hospitals and primary care resource centres providing clinical services outside of the four main acute hospital settings.

The South West Wales Cancer Centre (SWWCC), based at Singleton Hospital, Swansea, has patients referred for radiotherapy treatment from hospitals across the South West Wales Cancer Network: Neath Port Talbot, Singleton, Morriston, Prince Phillip, West Wales General, Withybush and Bronglais hospitals. It serves a population of approximately 974,678 people.

The radiotherapy department at Singleton Hospital treats approximately 2,150 new patients per year and the number of treatments in a radiotherapy course can vary from 1 up to 37. Most patients attend daily for treatment.

A total of 10.1 consultant clinical oncologists and 5.6 specialist registrars support the radiotherapy department. This is complemented with 31.8 radiographers, 5.4 medical physics experts, 8.4 registered clinical scientists (of which 5.4 relate to the medical physics experts), 2 trainees, 10.2 dosimetrists and 4.5 medical technical officers.

## 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.*

During this inspection, we received many positive comments from patients in the form of completed HIW questionnaires, in writing and via face to face conversations.

It was evident that staff were professional and compassionate; a significant emphasis being placed on ensuring that patients were well supported and informed prior to, and during, their care and treatment.

Improvements identified related to aspects of patients' dignity and privacy and the need for the health board to record verbal concerns.

During the inspection we distributed HIW questionnaires to patients, to obtain their views on the services provided. A total of 31 were completed. We also spoke to a number of patients during the inspection. Patient comments included the following:

*"Everything I've experienced with my treatment has been perfect"*

*"High quality service, very satisfied"*

*"The atmosphere generated by all in this department is second to none"*

*"I have had excellent care from diagnosis until present date"*

HIW received a letter from a patient ahead of the inspection. The letter contained multiple references to, and a detailed description of, the compassion, empathy, knowledge, care and support the person had experienced during the course of their radiotherapy treatment. Such positive comments were extended to all members of the NHS and ambulance transport staff involved in the patient's care.

In addition to the above, we saw many thank you cards received by the department from patients and their families, all expressing their gratitude and appreciation of the care and treatment received from staff working within the radiotherapy department.

## **Staying healthy**

There was a range of MacMillan information booklets available to patients and their families within the main waiting area of the radiotherapy unit. These provided information about a large number of healthcare conditions and procedures. This meant that patients had easy access to information on how to care for themselves following their procedures and who to contact for further advice.

We saw a variety of posters and leaflets on display within the department for patients and their families to read and/or take away with them. This included information about people's right to raise concerns about their NHS care and treatment, ambulance transport, the MacMillan Cancer Rehabilitation Club and invitations to participate in setting up a South West Wales cancer forum.

No smoking signs were displayed within the department. This was in keeping with legislation to ban smoking in enclosed public places to protect people<sup>2</sup>.

We also saw patient information provided by Golau<sup>3</sup>, the recognised charity associated with cancer services and Maggie's<sup>4</sup> Centre located at Singleton Hospital.

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<sup>2</sup> <http://gov.wales/topics/health/improvement/smoking/legislation/ban/?lang=en>

<sup>3</sup> The GOLAU Cancer Foundation supports the work of the NHS, by helping to provide facilities, equipment, training and research above and beyond the normal scope of the NHS.

<sup>4</sup> Maggie's centre offers free practical, emotional and social support to people with cancer and their families and friends. Help is offered freely to anyone with any type of cancer.

## Dignified care

Without exception, all patients who completed a questionnaire told us that the staff working in the department were excellent, professional, and made them feel welcome. Patient comments included:

*“The staff in the department are excellent. The atmosphere is always friendly and welcoming as well as professional and technically competent”*

*“I can't fault any of them, always courteous, respectful and how the utmost compassion”*

*“I found them helpful, considerate and reassuring. Excellent”*

We saw staff treating patients with respect, dignity, compassion and kindness and heard them call individuals for their treatment, using their full names.

There were two changing cubicles located on the periphery of the main patient waiting area. The cubicles were fitted with curtains and patients provided with dignity gowns. However, they then needed to walk across that main area to the treatment rooms. Whilst we did not see any patients in ill-fitting gowns and found that patients were encouraged to bring a dressing gown to appointments, we advised that the cubicles be relocated adjacent to the treatment rooms in the future, as the service develops.

Patients were able to speak with staff ahead of their treatment in two areas which were adjacent to the main waiting area. However, those areas were only segregated by means of a wooden partition which did not permit sufficient privacy at such times when sensitive conversations were held. Discussions with staff indicated that this matter had been raised with the health board estates department during 2016. However, no remedial action had taken place since that time.

### Improvement needed

The health board is required to provide HIW with details of the action to be taken to relocate the patient changing rooms away from the main waiting area.

The health board is required to inform HIW of the action to be taken to provide patients with a private area to speak with staff prior to the start of treatment, or at other times when sensitive information needs to be shared.

## Patient information

The HIW questionnaire asked patients whether they felt that they had been given enough information about their treatment. All patients agreed that they had received enough information, from the initial appointment process through to receiving treatment in the department. Specific patient comments included:

*“My radiotherapy appointments were planned out and I received a list at my first session”*

*“Yes everyone has been very honest and have answered all my questions”*

*“Yes, I felt well aware of what was ahead”*

As described earlier, we saw that a comprehensive range of information leaflets was available to patients and their families.

## Communicating effectively

Patients attending for radiotherapy treatment, were able to announce their arrival via a self check-in facility; assistance given by staff, if required.

We spoke with a number of patients, all of whom told us that staff had answered all their questions and queries. Patients also told us that they had been given sufficient information about their care, treatment and support services available in the community.

Staff described the efforts made to tailor the care to be provided to individual patients, the nature of which was established during the treatment planning stage, recorded on the radiotherapy information system and within paper held medical records.

We were informed that the department held an open evening on the first Wednesday of every month, to help provide patients and their families with a good understanding of radiotherapy services. The meeting was attended by a variety of voluntary healthcare and third sector professionals, including radiographers and representatives from MacMillan Cancer Care and Maggie's Centre. The service was commended for this approach to supporting people.

We found that there were very well established, effective working relationships between the SWWCC, North Wales Cancer Centre and Velindre Cancer Centre. There were also representatives from other cancer centres present at the HIW feedback session as a result of the direct invitation extended to them from staff at the SWWCC. This demonstrated a willingness to collaborate and

share good practice across the radiotherapy community for the benefit of patients.

## **Timely care**

The majority of people who completed a HIW questionnaire indicated that they had not experienced any delays when receiving treatment in the department; those patients who had experienced delays, stating that they were minimal, (that is, less than an hour). Two patients specifically said that the delays they experienced were because the equipment needed for their treatment was not working. Further references are made to the ageing equipment present at the service, in the next section of this report.

A small number of patients told us that they were collected from their home by ambulance services much earlier than their treatment appointment time (but were unable to receive their treatment any earlier).

We were provided with notes and identified actions associated with a multidisciplinary (MDT) meeting held in response to a radiotherapy incident which occurred in Edinburgh (September 2015). The notes demonstrated the department's commitment to learn from radiotherapy events reported across the United Kingdom. The action taken related to a revision of out of hours treatment procedures, to ensure that patients received the same standard of care at all times.

We held conversations about patients' cancer waiting times and found that the percentage of patients seen at the SWWCC alongside other Cancer Centres in Wales was considerably lower, (in the region of 60 to 70 per cent). This was reported as being due to a combination of factors which included the consequences of using ageing equipment. Specifically, patient's treatments were taking longer to complete due to the continued use of equipment that should have been replaced a number of years ago. In addition, the ageing equipment present within the department required significant maintenance.

This, together with the need for essential stringent quality assurance checks resulted in the loss of 45 days per year across the four radiotherapy treatment machines. There followed, a need for staff to organise, and extensively rearrange, radiotherapy schedules to ensure there was no break in patients' planned treatment pathway.

The matters in the paragraph above are also highlighted within the remaining two sections of this report because of their significance and the need for improvement.

## Listening and learning from feedback

Discussions with staff demonstrated that they made every effort to address any patients' concerns on the spot. This was in-keeping with the 'Putting Things Right' arrangements which is the name given to the process for responding to concerns about NHS care in Wales.

We saw a Friends and Family interactive pad in the main reception waiting area that could be used by people to offer their views on the services provided. We also saw blank questionnaires on display for patients' and families' use. In addition, we were informed that the newly appointed MacMillan Review Radiographer would be inviting comments from patients about their treatment, in the near future.

We were provided with a copy of the analysis of a patient survey conducted by the radiotherapy department during September 2016. This showed that 20 patients, who completed a questionnaire, were very satisfied with services provided.

However, we found that there was no process for recording verbal concerns raised by patients. We therefore advised that a system be developed. This was in order to assist the service to easily identify any themes or trends that arise from verbal concerns and to take any necessary remedial action accordingly.

### Improvement needed

The health board is required to inform HIW about how it will ensure that all verbal concerns are recorded and monitored in the future.

## 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 there was a clear emphasis on the provision of safe and effective care and compliance with IR(ME)R Regulations.

Improvements identified related to the continued use of ageing equipment and aspects of infection prevention and control.

## Compliance with Ionising Radiation (Medical Exposure) Regulations

### Duties of employer

We were able to confirm that the clinical practice adopted by staff, reflected that which was set out in the employer's written procedures. The duties of the employer are described in more detail within the next section of this report.

#### *Patient identification*

The employer<sup>5</sup> had a written procedure to correctly identify individuals who were about to be exposed to ionising radiation. This set out that operators<sup>6</sup> were responsible for ensuring the correct identification of individuals prior to undergoing medical exposures.

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<sup>5</sup> The employer is a duty holder under IR(ME)R and is responsible for providing a framework within which professionals undertake their functions.

<sup>6</sup> An operator is defined in IR(ME)R as any person who is entitled, in accordance with the employer's procedures, to carry out technical and practical aspects of a medical exposure. They do not have to be a registered healthcare professional.

The procedure required operators to conduct a three point identification check (to confirm the individual's name, date of birth and address) to positively identify individual patients prior to a medical exposure. The procedure also described what staff needed to do, if patients were unable to confirm their identity.

Conversations with staff also resulted in clear and consistent descriptions of the procedure to follow. It was therefore evident that the service placed a strong emphasis on correctly identifying patients to promote their safety and wellbeing. We did however, advise, that the service should ensure that the identification of patients is recorded electronically as the department progresses further with the use of electronic systems.

#### *Females of child bearing age*

The employer's Pregnancy Procedure described what operators were required to do, to identify potentially pregnant women prior to medical exposures. For example, the procedure provided detailed instructions for staff to follow depending on the outcome of verbal enquiries. It also referred to the need for referrers to advise women of child bearing age, not to become pregnant immediately prior to, or during a course of, radiotherapy due to associated risks.

The current procedure also required operators to re-check pregnancy status halfway through an individual's treatment. However, we were told that the procedure was due to be revised in the near future; and would guide staff to undertake one check only- prior to radiotherapy treatment (if relevant). This was in-keeping with practice in other radiotherapy departments in Wales, as stated. As with patient identification, we advised that patient's pregnancy status would need to be recorded electronically in the future, as a result of the drive toward a reduction in paper held records.

We saw that information for the attention of female patients was displayed within the radiotherapy department, advising them to inform operators if they were, or may be, pregnant.

#### *Medical research*

We looked at the research procedure in place and advised staff of the need to alter some of its content. Specifically, the document needed to delete any

reference to the former National Research Ethics Services (NRES); replacing it with reference to the current Health Research Authority for accuracy purposes. In addition, we saw reference to the provision of Brachytherapy<sup>7</sup>, although we were told that patients were referred to Velindre Cancer Centre for such treatment.

The procedure, therefore, needed to be revised to provide clarity on the above, and to describe instances where patients might be included in clinical trials (under Velindre Cancer Centre's governance and IR(ME)R arrangements). Senior staff indicated their willingness to address this issue.

#### *Referral criteria*

We were able to confirm that all patient referrals were received by the department in writing or via the electronic system and authorised prior to medical exposure. We were also able to confirm that clear site specific referral criteria for the range of exposures undertaken in radiotherapy, were included within clinical protocols. In addition, a comprehensive procedure for handling patient referrals was in place. Examples of appropriately completed referral forms were seen during the inspection.

#### *Exposure Protocols*

We were provided with documents which set out the guidelines for the management of patients with cancer. The protocols included reference to dose levels (per fraction<sup>8</sup>) consistent with the latest clinical evidence base and treatment.

During the inspection, we heard, and saw, how treatment doses of radiation were recorded. No issues of concern were identified.

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<sup>7</sup> Brachytherapy involves placing a radioactive material directly inside or next to a tumour. Brachytherapy, also called internal radiation therapy, allows a physician to use a higher total dose of radiation to treat a smaller area and in a shorter time than is possible with external beam radiation treatment.

<sup>8</sup> The full dose of radiation required by an individual patient is usually divided into a number of smaller doses called fractions.

## Duties of practitioner, operator and referrer

### Entitlement

We observed from documentation and confirmed through discussion, the entitlement of Consultant Clinical Oncologists (CCOs), within the department. As a result, we were satisfied that there were appropriate arrangements in place in that regard. We were also able to confirm that CCOs acted as referrer<sup>9</sup> and practitioner<sup>10</sup> in prescribing and authorising radiotherapy exposures.

In addition, the employer had written procedures for the entitlement<sup>11</sup> and identification of the role of operators, referrers and practitioners (known as duty holders). These clearly described the arrangements for entitlement and identified duty holders by staff group. The procedures set out the expected level of training for each entitled staff group together with their scope of practice.

During the inspection, we took the opportunity to discuss roles and responsibilities with operators delivering care in treatment planning and delivery. Without exception, staff demonstrated their confidence and competence relating to their duties under IR(ME)R. The service was commended for this.

### Justification of Individual Medical Exposures

Arrangements were in place for the range of medical exposures undertaken in the radiotherapy department to be justified and authorised by healthcare professionals, acting as appropriately entitled practitioners. This was evidenced in written procedures, via discussions with staff.

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<sup>9</sup> A referrer is a registered health care professional who is entitled in accordance with the employer's procedures to refer patients for medical exposures.

<sup>10</sup> An IR(ME)R practitioner is a registered health care professional who is entitled in accordance with the employer's procedures and whose primary responsibility is justification and authorisation of individual medical exposures.

<sup>11</sup> Entitlement is the process of defining duty holder roles and tasks that individuals are authorised to undertake.

## Optimisation

Optimisation is one of the three basic principles of radiological protection and is defined as, the process to keep the magnitude of individual doses of radiation as low as reasonably practicable.

Overall, patient treatments were individually planned in accordance with locally agreed evidence based clinical protocols. Planning and verification imaging exposures were also undertaken in accordance with locally agreed protocols. However, we advised senior managers of the need to have clear procedures to support staff in checking all treatment plans and calculations, at all times. This is because the use of a single treatment planning system would reduce the amount of software upgrades, maintenance, staff training and supporting documentation required.

We were informed that a nominated Medical Physics Expert (MPE)<sup>12</sup> formally supported the radiotherapy department on all matters relating to optimisation. This was in-keeping with MPE requirements.

We were provided with a demonstration of individually planned target (radiotherapy) volumes which confirmed that radiation doses to non-target body tissues were as low as reasonably practicable (ALARP), while achieving the intended radio therapeutic purpose of the exposure.

We also found that there were appropriate quality assurance measures in place to ensure the safe and effective delivery of treatment to patients.

In addition, there was a separate in-vivo dosimetry<sup>13</sup> protocol in place.

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<sup>12</sup> An MPE is a suitably experienced medical physicist having the knowledge and training to give advice on all aspects of radiation protection of patients involving ionising radiation when used for medical exposures.

<sup>13</sup> In vivo dosimetry (IVD) is used in external beam radiotherapy (EBRT) to detect major errors, to assess clinically relevant differences between planned and delivered radiation doses, to record the dose received by individual patients, and to fulfil legal requirements.

## *Paediatrics*

Staff confirmed that the radiotherapy department at the hospital did not provide treatment for children.

## *Clinical evaluation*

The employer had arrangements in place for the clinical evaluation of all types of medical exposures administered.

Clinical evaluation processes were described as an operator function carried out by appropriately entitled staff. Clinical evaluation focussed on a range of medical exposures undertaken in radiotherapy services including computerised tomography (CT)<sup>14</sup> scanning simulation, treatment and evaluation of verification images<sup>15</sup>, the latter containing appropriate signatures in the medical notes or information system.

## **Clinical audit**

The requirement of clinical audit as set out in IR(ME)R refers to a systematic examination of medical radiological procedures. This seeks to improve the quality and outcome of patient care through structured review with examination of existing practices intended to lead to modification of practices where indicated.

During this inspection, we saw that a comprehensive two yearly audit plan had been reviewed which included specific IR(ME)R audits for compliance. We did though, advise, that the future audit plan could be enhanced by the inclusion of more clinical reviews of practice and medical physics activities.

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<sup>14</sup> A CT scan, also known as computed tomography scan, makes use of computer-processed combinations of many X-ray measurements taken from different angles to produce cross-sectional images of specific areas of the body.

<sup>15</sup> The evaluation of pre-treatment verification exposures is essential to demonstrate that intended patient therapy can be delivered as prescribed.

## Expert advice

Senior staff confirmed that MPEs were involved as appropriate in relation to medical exposures. The responsibilities of MPEs were also well described in the employer's overarching policy on the implementation of, and compliance with, IR(ME)R Regulations.

## Equipment

It was noted (within the radiotherapy equipment inventory) that the department had a total of four linear accelerators (linacs)<sup>16</sup>. One was being commissioned at the time of the inspection as a replacement for an existing linac. Of the remaining three, two were 14 years old and one was seven years old. The recommendation is that linacs should be replaced every 8-10 years because of increasingly limited functionality, reliability, technical support and spare part issues.

The existing linacs had been subject to an upgrade and comprehensive maintenance and quality assurance (QA) checks (estimated to be in the region of 45 days per year, equivalent to nine working weeks). This level of maintenance was found to be essential in order to achieve the operation of the department's ageing equipment and core working days of 95 per cent.

Additionally, on days when the linacs were subject to such QA checks, patients, their treatment sheets and ancillary equipment needed to be transferred to other machines, increasing the opportunity for error.

The level of maintenance described offered assurances around the safety and accuracy of the equipment but also highlighted that the department was constrained from offering higher levels of radiotherapy. This matter is outlined further in the paragraph below.

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<sup>16</sup> A linac is the device most commonly used to deliver external beam radiation treatments for patients with cancer. The linac is used to treat all parts/organs of the body.

We found that the absence of an additional Cone Beam Computerised Tomography (CBCT) scanner<sup>17</sup> was constraining the development of the service and the ability to offer higher levels of radiotherapy treatment such as Intensity Modulated Radiotherapy (IMRT)<sup>18</sup> and Volumetric Modulated Arc Radiotherapy (VMAT)<sup>19</sup>. Such treatments provide the accepted current standards of care which may offer reduced toxicity as part of the patient experience. Reference as to how such matters are to be addressed, should be included in the service's strategic development plan. We also advised that the department's strategic plan include reference to the commissioning of any new equipment, the de-commissioning of old equipment and the plans for ensuring that there are sufficient staff with relevant skills available to deliver and sustain the service in the future.

The department's equipment inventory, (as required by the Regulations), should be expanded to include all auxiliary equipment which can influence medical exposures. Senior staff told us that this would be addressed directly.

## **Safe care**

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

The radiotherapy department was fairly easy to find and seen to be accessible. Overall, the environment was in a good state of repair and free from trip hazards.

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<sup>17</sup> A CBCT enables the production of 3D images of the body to assist with providing safe and effective radiotherapy treatments to patients.

<sup>18</sup> IMRT is a form of treatment that requires the use of equipment known as linear accelerators to safely and painlessly deliver precise radiation doses to a tumour, whilst minimising the dose to surrounding, normal body tissue.

<sup>19</sup> VMAT is a new type of IMRT technique. The radiotherapy machine rotates around the patient during treatment, re-shaping and changing the intensity of the radiation beam as it moves around the body.

At the time of our inspection, a new treatment room together with a range of equipment was being installed. The entire area was at a distance from patients and we saw signs alerting staff to the work taking place to ensure their safety.

We received satisfactory assurance with regard to risk management processes and that learning and remedial action had followed from incidents had occurred. This was because there were well established arrangements in place to ensure that radiation exposures Much Greater Than Intended (MGTI)<sup>20</sup> were fully investigated; notifications being sent to HIW as appropriate.

We were also made aware that the health board had agreed the introduction of an upgraded radiotherapy treatment planning system which would support the delivery of safe and effective radiotherapy treatment to patients.

### Improvement needed

The health board is required to provide HIW with a full and detailed description of the action to be taken to replace ageing radiotherapy equipment that would result in the delivery of a wider range, and increased number of, timely higher dose radiotherapy treatments.

### Infection prevention and control

Arrangements were in place to protect patients and staff from preventable healthcare associated infections.

For example, we saw that all areas within the department were clean and designed to promote effective cleaning. In addition to the personal protective equipment (PPE) to protect staff from ionising radiation, suitable PPE was also available to protect staff and patients from infection (such as aprons and gloves). Staff we spoke with were also aware of their responsibilities in relation to infection control procedures.

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<sup>20</sup> Employers (under IR(ME)R), are obliged to investigate where an incident has occurred or may have occurred in which a person has been exposed to ionising radiation to an extent much greater than intended.

The majority of patients that completed a questionnaire felt that the department was always spotlessly clean and tidy. However, some patients did comment about old stains on the carpet and how the chairs and the waiting room were looking worn. Patient comments included:

*“Carpet dirty in some places and head rests on armchairs require cleaning”*

*“Excellent - perhaps waiting area could be modernised, brightened up”*

We further observed that flooring in toilets needed to be replaced. This was because the areas concerned were worn and difficult to keep clean.

We also found that there were occasions when paper hand towels and soap were not readily available. This meant that housekeeping staff had to borrow such equipment from other hospital departments whilst waiting for delivery and hand washing is a vital component of the prevention of cross infection.

#### Improvement needed

The health board is required to provide HIW with details of the action to be taken to provide patients with clean and hygienic furniture and flooring in the radiotherapy department.

#### Safeguarding children and adults at risk

We found that there were suitable systems in place to promote the safety of adults who may be vulnerable, or at risk of abuse.

#### Effective care

#### Information governance and communications technology

The service provided us with a range of documents in advance of the inspection.

All the employer's procedures required by the Regulations were in place. Whilst we were satisfied overall, that the content of those procedures were sufficiently detailed, we did advise the service of the need for some revision to a small number of documents.

Information management systems were described and demonstrated by various members of staff. This allowed for relevant patient details and information about radiotherapy procedures and treatment performed, to be recorded, and easily accessed by staff.

## 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.*

We found that staff were very knowledgeable about their area of work and were highly dedicated and passionate about delivering high quality care and treatment to patients.

Senior managers were present and visible within the department and were striving to make improvements to the service. However, they had limited control in terms of improvements needed with regard to staffing levels and the replacement of radiotherapy equipment which was past its original decommissioning date.

There were good working relationships between radiotherapy and medical physics clinical engineering staff.

## Governance, leadership and accountability

### Duties of the employer

#### *Entitlement*

As already indicated earlier in this report, the employer had a written procedure for the entitlement of referrers, operators and practitioners (known as duty holders). This clearly described the arrangements for entitlement and set out the expected level of training for each entitled staff group, together with their scope of practice. Discussions with senior managers, consultant clinical

oncologists, and radiographers confirmed their understanding of the duty holder role.

### *Future of the service*

We were informed that the health board had plans in place to move the SWWCC to Morriston Hospital around 2021. This was because of its intention to also move acute medical services to Morriston where frequently unwell and high risk patients would receive their care. It was therefore envisaged that there would be a transitional period of several years, with split site working between Morriston and Singleton for periods until that time. Whilst staff had clearly been involved in relevant discussions, it was evident that they would welcome further clarity about ongoing planning and transition arrangements.

We were provided with an organisational chart which demonstrated that the Medical Physics Clinical Engineering department formed part of the patient support services directorate, whereas the Radiotherapy Department was integral to the cancer services board. Both services, were however, governed by the Medical Director and it was evident, and positive to note, that the radiotherapy medical physics department were co-located within the main radiotherapy department to support effective cross discipline working. Conversations with staff within those departments revealed however, that improvements would be welcomed with regard to agreeing times for essential quality assurance checks, to enable patients to be treated in a timelier way.

We also advised that the department's strategic plan include reference to the commissioning of any new radiotherapy equipment, the de-commissioning of old equipment and the plans for ensuring that there are sufficient staff with relevant skills available to deliver and sustain the service in the future.

### *Procedures and protocols*

The service's completed (HIW generated) self assessment document was very detailed and well presented. We also saw evidence that the document had been shared across relevant healthcare professionals.

The chief executive of the health board was designated as the employer. This is in keeping with the national guidance<sup>21</sup> on implementing IR(ME)R as they apply to radiotherapy services. However, the overarching IR(ME)R document needed to be slightly revised to make clear, that although day to day responsibility for delegating tasks may be delegated to a senior member of the health board, 'the employer' retains overall responsibility for compliance with IR(ME)R Regulations. Senior managers indicated that this matter would be addressed in the near future, at such time that the new Regulations come into force.

The designated Quality Assurance Radiographer within the department was striving to ensure that patient services were underpinned by a series of processes and procedures to guide staff in their work. The individual concerned had also recently introduced a programme of monthly meetings to which all staff were invited. The meetings were designed to promote learning from significant events and patient incidents, as well as wider staff discussion about the day to day operation of the department. This was, with a view to identifying ways of making improvements to patient services.

Radiotherapy documentation and radiotherapy physics documentation could be accessed via the department's computer system and were available to all staff irrespective of their role.

However, we found that radiotherapy physics documentation was not subject to regular review or an agreed programme of audit. This is at odds with IR(ME)R which clearly states that there is a duty on the employer to ensure that the following are in place:

- written protocols for every type of standard practice for each piece of equipment
- a quality assurance programme for all standard operating procedures
- appropriate arrangements to ensure the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as possible

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<sup>21</sup> 'A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy'. The Society and College of Radiographers. The Royal College of Radiologists. Institute of Physics and Engineering in Medicine.

We found that there was an absence of an agreed multi-disciplinary/operational plan for the development of the radiotherapy service. Such a plan would assist with ensuring that each healthcare discipline involved within radiotherapy services, had agreed priorities and were working towards the same goals, within the same time scale.

### *Incident notifications*

We found that service leads and their respective teams were informed of all radiation incidents irrespective of severity, as stated. This meant that appropriate action could be taken and information cascaded to staff to prevent further occurrence.

We were also provided with several examples of radiotherapy incidents that had been subject to full and thorough investigation; remedial action having been taken and the outcome shared with staff to ensure that lessons were learnt.

### **Improvement needed**

The health board is required to provide HIW with details of the action taken/to be taken to ensure that policies and procedures developed by the radiotherapy physics department, and those produced jointly with the radiotherapy department are subject regular review and external accreditation. This is in accordance with the Regulations.

## **Staff and resources**

### **Workforce**

#### *Training*

We were provided with a copy of a comprehensive blank staff induction document, together with a series of blank training booklets associated with radiotherapy services. This showed that there was an emphasis on supporting staff to become competent and confident in all aspects of their work. We were further assured that staff were supervised in working through such workbooks to ensure their proficiency in the use of departmental equipment.

We saw some good examples of radiotherapy staff training records. Such records included reference to refresher training dates which were replicated within the electronically held entitlement grid.

Conversations with a variety of staff and senior managers however, revealed that the department was non compliant in terms of its agreed staff training programme overall. Senior managers described the challenges they faced in releasing staff from their work and there was no-one in a dedicated training role within the department due to insufficient staff levels, as reported above. This meant that necessary staff training in the use of existing and new equipment was very difficult to complete. In addition, there was a reliance on staff volunteering to assist with essential staff training. We advised the health board that this situation was unsustainable.

We were however, assured that MPEs provided some local training on the use of equipment and computer software.

### *Staffing*

We held a number of conversations about the number and skill mix of staff working within the radiotherapy department and found that the service had faced particular challenges during the past twelve months. This was largely due to long term staff sickness and maternity leave. Senior staff working within the radiotherapy department had brought this issue to the attention of the health board in a timely way as it was evident that, in order to prevent disruption to patient care and treatment, staff needed to be moved from the pre-treatment and CT simulator areas of the service, to treatment areas. As a result, it was taking longer for patients to go through the treatment pathway, which also had the potential to have a negative influence on treatment outcomes in some cases.

We therefore found that understaffing, and recruitment issues had a direct negative impact on departmental performance, service development and sustainability. For example:

- Increasing numbers of patients and complexity of treatments were taking longer. Additional specialist resources were required
- There were delays in providing patients with clinic appointments
- Superintendent radiographers were regularly required to book in patients at the main reception desk as a result of insufficient staffing in that area

- There had been a reduced availability of patient appointments for CT simulation as staff needed to work elsewhere in the department

The health board had made an effort to fill the gaps created by this situation; through the use of an external agency and by offering staff short term contracts (albeit we were told that there was a delay in the use of agency employees). However, those short term contracts were due to come to an end early in 2018, staff were still absent for the reasons already stated. In addition, a small number of vacancies that existed in the department had not yet been filled.

We were informed that the Head of Radiotherapy Physics had been a 0.5WTE appointment for three years Whilst we were informed that efforts had been made to reconfigure the existing Head of Radiotherapy Physics responsibilities, we advised the health board of the need to review this role, together with overall staffing levels in the department to support staff in the delivery of safe and effective services now, and in the future.

#### Improvement needed

The health board is required to inform HIW of the action to be taken to ensure that staff receive relevant, regular training associated with their work and responsibilities under IR(ME)R.

The health board is required to provide HIW with a full description of the action it intends to take to ensure that staff levels within the radiotherapy department and reviewed and improved. The health board is also required to provide details of how it intends to ensure that the radiotherapy service is fully supported by an appropriately resourced radiotherapy physics department. This is, in order to sustain existing services and address the improvements identified at this inspection.

During the inspection, we received descriptions of how well staff worked collaboratively which provided us with assurance that there was cooperation between duty holders across the various professional disciplines. It was also evident that staff offered their time voluntarily to support patients, and each other, outside of normal working hours in order to sustain and improve radiotherapy services.

The openness, compassion and dedication of staff were commended at this inspection.

However, given the areas for improvement identified during this inspection, particularly in relation to the continued use of ageing equipment and aspects of Quality of Leadership and Management, consideration should be given to ensuring that there are more effective and proactive arrangements in place at the service to monitor compliance with relevant regulations and standards. Whilst no specific recommendation has been made in this regard, the expectation is that there will be evidence of a notable improvement in this respect at the time of the next HIW inspection.

## 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, measureable, 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 service who use ionising radiation

HIW are responsible for monitoring compliance against the [Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) 2000](#) (and its subsequent amendments [2006](#) and [2011](#)).

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
We did not identify any immediate concerns during this inspection.			

## Appendix B – Immediate improvement plan

**Hospital:** Singleton Hospital  
**Ward/department:** Radiotherapy Department-SWWCC)  
**Date of inspection:** 14 and 15 November 2017

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	Service action	Responsible officer	Timescale
We did not identify any immediate assurance issues during 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:** Singleton Hospital  
**Ward/department:** Radiotherapy Department-SWWCC  
**Date of inspection:** 14 and 15 November 2017

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	Service action	Responsible officer	Timescale
<b>Quality of the patient experience</b>				
<p>The health board is required to provide HIW with details of the action to be taken to relocate the patient changing rooms away from the main waiting area.</p> <p>The health board is required to inform HIW of the action to be taken to provide patients with a private area to speak with staff prior to the start of treatment, or at other times when sensitive information needs to be shared.</p>	4.1 Dignified Care	<p>The Radiotherapy section has engaged with ABM-UHB Estates to provide appropriate advice on the relocation of the existing changing rooms.</p> <p>The Radiotherapy section has engaged with ABM-UHB Estates to provide appropriate advice on the construction of private consultation rooms for staff-patient discussion prior to start of treatment</p> <p>Negotiations are currently in hand, and</p>	Radiotherapy Service Manager (RSM)	<p>Immediate ongoing action. Decision to be in place by 01.06.18</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
		working towards completion of the project described above.		
The health board is required to inform HIW about how it will ensure that all verbal concerns are recorded and monitored in the future.	6.3 Listening and Learning from feedback	<p>The ABM-UHB form - "Notification of a Verbal Concern" has been redistributed to all members of Radiotherapy Staff with an accompanying description of its purpose and intent. Furthermore when the forms are appropriately completed (and submitted to senior staff) the details will be entered into Datix as a method of (both) recording and monitoring. The responsibility of the Datix entry will be assigned to the member of staff that takes receipt of the completed form.</p> <p>The monitoring of Datix incidents is carried out by means of existing pathways such as 1. Robust incident investigation 2. Quarterly reports to monitor incident trends, 3. Staff sessions, inviting discussion, on Datix incident review and 4. Review of concomitant image related incidents by</p>	QA Radiographer, Radiotherapy/ RSM	Completed 23.01.18

Improvement needed	Standard	Service action	Responsible officer	Timescale
		The Radiotherapy Image Group		
<b>Delivery of safe and effective care</b>				
<p>The health board is required to provide HIW with a full and detailed description of the action to be taken to replace ageing radiotherapy equipment that would result in the delivery of a wider range, and increased number of, timely higher dose (contemporary) radiotherapy treatments.</p>	<p>2.1 Managing risk and promoting health and safety</p>	<p>1. A replacement linear accelerator capable of advanced treatment techniques was installed during the second half of 2017; this equipment is undergoing clinical commissioning and is scheduled to enter service on 20/03/18.</p> <p>2. A business case to replace an existing linear accelerator with one capable of a wide range of advanced treatment techniques is in an advanced state of preparation and will be submitted to the Health Board and Welsh Government in Q1/2 of 2018. If the capital and revenue are funded during 18-19 then this accelerator will enter clinical service during 2019.</p> <p>3. A further business case (essentially identical to point 2) will be submitted during 18-19 to provide a third state-of-the-art linear accelerator for funding</p>	<p>Service Group Manager Cancer Services</p>	<p>20-03-18</p> <p>20-10-19</p> <p>31-12-20</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
		<p>during 19-20. If the capital and revenue are funded during 19-20 then this accelerator will enter clinical service during 2020.</p> <p>4. An advanced treatment planning system, with the capability to support the advanced techniques to be introduced by equipment noted in points 1-3 above, is currently being commissioned and will enter clinical service in Q1 2018.</p> <p>5. The business case for a replacement CT-Simulator will be prepared during 18-19. If funded, then the equipment will be procured and installed during 2019.</p> <p>6. An upgraded treatment head will be retrofitted to an existing linear accelerator during 2018 to enhance the flexibility of the treatment unit and support advanced treatment options. The target for completion of this work is Q3 2018.</p>	<p>Head of Radiotherapy Physics</p> <p>Service Group Manager Cancer Services</p> <p>Head of Radiotherapy Physics</p>	<p>20-03-18</p> <p>31-12-19</p> <p>23-07-18</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>The health board is required to provide HIW with details of the action to be taken to provide patients with clean and hygienic furniture and flooring in the radiotherapy department.</p>	<p>2.4 Infection Prevention and Control (IPC) and Decontamination</p>	<p>RSM has sought quotes for new flooring and new chairs.</p> <p>In the interim, waiting room carpets and chair upholstery have undergone a cleaning service</p>	<p>RSM</p>	<p>Carpets and chair upholstery cleaning service completed.</p> <p>Additional restructuring work to be undertaken in the waiting area prior to the laying down of new flooring.</p> <p>Decision on new flooring and new chairs to be in place by 01.09.18</p>

**Quality of management and leadership**

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>The health board is required to provide HIW with details of the action taken/to be taken to ensure that polices and procedures developed by the radiotherapy physics department, and those produced jointly with the radiotherapy department are subject regular review and external accreditation. This is in accordance with the Regulations.</p>	<p>Governance, Leadership and Accountability  Regulation 4(2) (b) and Schedule 1- Employer's Procedures</p>	<p>New funding to establish robustly a part-time Radiotherapy Physics (RTP) Quality System Manager (QSM) and on-going fees will be sought from the Health Board as a prerequisite to establishing an externally audited quality system. Funding will be sought during 18-19.</p>	<p>Head of Radiotherapy Physics (and below)</p>	<p>31-03-19</p>
		<p>2. The RTP QSM when funded will oversee a procedure and monitor a plan of regular internal review. This will take 12 months to complete the cycle, given that various documents are scheduled for renewal in Q1-2 associated with the introduction of a new treatment planning system (and these will be given priority).</p>		<p>31-03-19</p>
		<p>3. An existing member of staff will provide additional hours on a temporary basis to review treatment planning patient pathways. This work will be completed during Q3 2018.</p>		<p>30-09-18</p>
		<p>4. RTP will explore using the accreditation scheme known as</p>		

Improvement needed	Standard	Service action	Responsible officer	Timescale
		<p>'MPACE' when the scheme (being developed by UKAS from BS70000) has reported the pilot studies currently underway and a procedure is published. This is externally driven and consequently a local timescale cannot be given.</p> <p>5. The Radiotherapy Department has an existing QMS subject to regular review and external certification - ISO9001:2015.</p>		
<p>The health board is required to inform HIW of the action to be taken to ensure that staff receive relevant, regular training associated with their work and responsibilities under IR(ME)R.</p> <p>The health board is required to provide HIW with a full description of the action it intends to take to ensure that staff levels within the radiotherapy department and reviewed and improved.</p> <p>The health board is also required to provide</p>	<p>7.1 Workforce and Regulation 11</p>	<p>1. Radiotherapy. Currently, staff are trained prior to the introduction of new equipment/new practice and changes to practice. New documentation produced specifically for the introduction of new equipment/new practice and changes to practice are read and the date recorded. In addition, this is documented/recorded in staff CPD Folders, and within the training Matrix held within the QMS. The addition of specialist training</p>	<p>RSM</p>	<p>Decision on the appointment of specialist radiographers to meet the training needs of staff will be in place by 31.12.18</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>details of how it intends to ensure that the radiotherapy service is fully supported by the radiotherapy physics department. This is, in order to sustain existing services and address the improvements identified at this inspection.</p>		<p>radiographers would make this less challenging to deliver with less disruption to service. New funding for highly specialised radiographers will be sought from the Health Board. Funding will be sought for 2018.</p> <p>2. To achieve parity with the other Welsh Radiotherapy Centres new funding for highly specialised radiographers will be sought from the Health Board.</p> <p>Velindre 7/8 Linacs approximately 84 Radiographers</p> <p>NWCTC 4 Linacs 39 Radiographers. SWWCC 4 Linacs 31.8 Radiographers</p> <p>Bid for more staff to be requested as follows:</p> <p>5 WTE Specialist Radiographers 2 WTE Senior Radiographers 4 WTE Support Staff</p> <p>Funding will be sought for 2018.</p>	RSM	<p>Decision on the appointment of additional specialist radiographers /support staff will be in place by 31.12.18</p> <p>Post 1</p>



Improvement needed	Standard	Service action	Responsible officer	Timescale
		time.		

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):** Jan Worthing  
**Job role:** Unit Service Director, Singleton Unit  
**Date:** 15.02.2018