

**Ionising Radiation  
(Medical Exposure)  
Regulations Inspection  
(announced)**

**Public Health Wales NHS Trust:**  
Breast Test Wales, Cardiff

**Diagnostic Imaging Department**

2 – 3 November 2016

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## 1. Introduction

A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and regulation amendments 2006 and 2011 was undertaken between 2 and 3 November 2016. The inspection considered the diagnostic imaging (radiography) department at the Breast Test Wales Centre in Cardiff which forms part of Public Health Wales NHS Trust.

HIW is responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011). We achieve this through a programme of assessment and inspection of services in the NHS and independent sectors that use ionising radiation.

The regulations place responsibilities on practitioners, operators, those who refer patients for medical exposures and the employers of these three groups. The employer is required under the regulations to create a framework for the safe, efficient and effective delivery of ionising radiation by the provision of written procedures and protocols. A breach of regulations can result in the issue of prohibition notices, improvement notices or criminal proceedings.

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 (justification)
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology (optimisation)
- Practitioners and operators do not undertake any medical exposure without being adequately trained. Employers ensure adequate training is provided and records of this training are maintained.

We publish our findings within our inspection reports under four themes:

- Quality of the Patient Experience
- Compliance with IR(ME)R
- Quality of Management and Leadership

## 2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Information provided by the department in the HIW Self Assessment Form
- Discussions with staff (where appropriate) and senior management
- Conversations with patients, relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of treatment rooms and the environment
- HIW patient questionnaires

At the end of each inspection, we provide an overview of our main findings to representatives of the service.

The inspection captures a snapshot of the standards of care patients receive; the extent to which services are meeting essential safety and quality standards and regulations. It may also point to wider issues about the quality and safety of services provided.

### 3. Context

#### Background

Breast Test Wales provides a breast cancer screening service to the women of Wales. It is part of the screening Division of Public Health Wales NHS Trust.

Breast screening by mammography involves the use of x-rays.

#### Activity

Each year, the diagnostic imaging department at Breast Test Wales in Cardiff carries out approximately the following number of digital mammography and biopsy procedures.

#### Mammography (during 2015/16)

- Screening – 55, 835 woman
- Assessment – 3,335 woman

#### Core/ Vacuum Biopsy (during 2015/16)

- Stereotactic- 644
- Ultrasound- 683 (non-ionising)
- unknown- 26

The department also carries out breast medical ultrasound scanning procedures.

#### Equipment

The department has digital mammography equipment and ultrasound scanning equipment. The Cardiff centre has 4 digital mammography units within the department and 5 mobile digital mammography units, visiting sites in south east Wales.

#### Environment

The department consisted of a general designated waiting area (screening patients to one side and assessment patients to the other). For screening patients, an x-ray room with a sub waiting area was situated separately from the general waiting area. For assessment patients, a further waiting room was provided where patients were taken through to further x-ray rooms within the department.

## Staffing

In terms of staffing the following staff worked within the department:

- 2.1 whole time equivalent (WTE) Consultant Radiologists
- 11.89 WTE Radiographers (plus 2 WTE radiography managers of which 0.3 WTE is clinical time)
- 1 WTE Associate specialist/ 0.65 WTE speciality doctor
- 0.9 WTE Consultant Radiographer
- 1 WTE Trainee Clinical Specialist Radiographer
- 7.83 WTE Advanced Practitioner Radiographers (of which 2.7 WTE and 1 WTE trainee are Image Interpreters)
- 5.53 WTE Assistant Practitioners
- 1 WTE Medical Physics Expert
- 0.5 WTE Speciality Doctor- Trainee Breast Clinician
- 2.2 WTE Clinical Imaging Support Workers

The department currently has a 0.34 WTE medical vacancy and a 0.5 WTE Band 6 Radiographer (currently on career break).



## 4. Summary

This is the first IR(ME)R inspection by HIW of the diagnostic imaging department at Breast Test Wales which forms part of Public Health Wales NHS Trust. HIW focussed their inspection on the Cardiff centre only.

The inspection was well received by both management and staff and all required documentation was completed and received within timescales specified.

The team within the department approached the inspection in a very positive way and they were keen to receive constructive feedback to support their approach to maintaining high standards of care and continuous improvement. We also received a positive welcome from patients who provided feedback on their experiences via HIW's patient questionnaires.

We found strong and effective leadership being provided by senior departmental staff. It was clear from our conversations with all levels of staff involved during the inspection that there was a strong commitment to learn from the inspection and to make improvements as appropriate.

Across the department, we saw staff treating patients with respect and courtesy. Positive comments were also made by patients regarding the approach and attitude of the staff team. We saw that the department was clean and tidy and efforts had been made to make waiting areas comfortable and welcoming.

The Chief Executive Officer for Public Health Wales NHS Trust was the employer under IR(ME)R and had ultimate responsibility for ensuring IR(ME)R was implemented within Breast Test Wales, Cardiff.

The employer had written procedures in place as required by IR(ME)R and with the aim of delivering a safe and effective service to patients. There was a written procedure for the entitlement and identification of referrers, practitioners and operators as defined under IR(ME)R. It became apparent, however, that there were individuals performing operator functions and who, according to the written procedure, were not entitled by the employer to do so.

At the end of the inspection we provided feedback on our main findings and areas for improvement. The management team will be submitting an improvement plan in response to our findings. The details of this can be seen within Appendix A of this report.

## 5. Findings

### *Quality of the Patient Experience*

**Across all the departments we visited, we saw staff treating patients with respect and courtesy. Positive comments were also made by patients regarding the approach and attitude of the staff team. We saw that the department was clean and tidy and efforts had been made to make waiting areas comfortable and welcoming.**

Prior to the inspection, we asked that the department distribute HIW questionnaires to patients to obtain their views on the services provided. In total, 31 questionnaires were completed and returned.

All patients/carers who provided comments told us they were very happy with the service they had received and praised the approach and attitude of the staff team, the cleanliness of the departments and timeliness of being seen. Comments included:

*“Very quick and professional service, kind, caring staff. I was made to feel comfortable and put at ease as soon as I entered the suite”*

“Wonderful service”

“Staff very helpful”

“Very nice, helpful and friendly (just what you need!)”

“Very grateful to have this service available”

“Knitting in waiting room very nice to see. It has been traumatic but staff have made it as easy as possible”

“Everyone very nice- introduced themselves”

“Thank you for explaining what and why I had been called back for and the continued support throughout my visit”

**It was evident from patient’s comments that, across the department, the attitude, approach and delivery of the service was of a high standard.**

Aside from HIW’s questionnaire, Breast Test Wakes also had their own questionnaire to capture their patients’ experiences. We saw patients being treated with respect and kindness by departmental staff teams and this was reflected in the comments we received from patients. Changing cubicles were

available within each of the departments we visited. These offered patients privacy should they need to change into/out of dignity gowns.

We were provided with a tour of the department. We saw that all areas were clean and tidy. Patients who completed questionnaires also told us that they were satisfied with the cleanliness of the department.

Efforts had been made to make waiting rooms pleasant areas where patients could wait, for example we saw pictures were being displayed and reading material was available. Information leaflets were readily available within waiting areas. Patients who provided comments told us they felt they had been provided with enough information about their screening or assessment treatments.

Patients told us that they had not experienced any delays when attending for their treatment. Some patients added their own positive comments about the timeliness in which they had been seen.

All patient and clinical areas were well presented, clean, and tidy and portrayed a calm atmosphere due to the well thought out layout to the patients pathway. It was evident that a lot of thought had gone into lessening patients' anxiety by providing patients with puzzle books and a knitting box in the waiting areas. Picture monitors were also installed in the x-ray rooms for patients to view while undergoing their procedure. We were told that staff within the department had contributed to this by providing their own photos.

HIW also saw evidence of patient literature throughout the department, however this was not overbearing for patients.

We noted that CCTV was in operation in the department. Although it was not in operation in clinical areas, we didn't see any signs to inform patients that CCTV was in operation.

### ***Improvement needed***

***Signs to inform patients that CCTV is in operation must be clearly displayed in the department***

## ***Compliance with IR(ME)R***

**We found that Breast Test Wales had identified an employer under IR(ME)R. The self assessment form submitted to HIW prior to our inspection clearly identified the employer as the Chief Executive Officer of Public Health Wales NHS Trust.**

At the time of our inspection there were two vacancies within the department, a Band 6 radiographer vacancy due to a career break and a medical vacancy. Staff explained that considerable efforts had been made to recruit to the medical position however recruitment into this post had been problematic due to the low number of qualifying radiologists interested in this field of expertise. We were told that this was a Wales wide issue.

The employer had written procedures and protocols in place as required by IR(ME)R with the aim of delivering a safe and effective service to patients. We identified that the Patient Identification and the Females of Childbearing Age procedures and the protocols were being reviewed and revised to promote further clarity for departmental staff. There was a written procedure for the entitlement and identification of referrers, practitioners and operators as defined under IR(ME)R.

Arrangements were in place to ensure medical exposure doses are kept as low as reasonably practicable.

### **Duties of Employer**

***The employer is defined in Regulation 2(1) as any natural or legal person, who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.***

Through discussion with staff, we were told that the Chief Executive Officer of Public Health Wales NHS Trust was designated as the employer. This is commonly seen and is in keeping with the national guidance on implementing IR(ME)R legislation as it applies to diagnostic and interventional radiology.

However, Breast Test Wales' 'Radiation Safety Procedures' document did not explicitly identify the Chief Executive Officer as the employer under IR(ME)R. This document should describe that the Chief Executive Officer was legally accountable for the safe delivery of ionising radiation used within Breast Test Wales. The document must also set out the employer's responsibilities in order to make it clear to all staff working at Breast Test Wales who the employer is.

We were provided with Breast Test Wales' organisational structure showing the lines of reporting, accountability and delegation in respect of IR(ME)R.

We saw that written procedures and protocols had been developed in accordance with IR(ME)R legislation.

We also saw that the arrangements were in place for quality assurance activity (including documentation), for the adequate training of practitioners and operators and for investigating and reporting incidents. These are all duties of the employer as required by IR(ME)R.

### ***Improvement needed***

***The Employers 'Radiation Safety Procedures' document should explicitly state who the employer is and what their responsibilities are***

### **Procedures and Protocols**

***Regulation 4(1) and 4(2) requires the employer to have written procedures and protocols in place.***

Prior to our inspection visit we were provided with a copy of the employer's Radiation Safety Procedures.

Generally, the operating procedures were very detailed and included those employer's procedures required under IR(ME)R. Senior departmental staff described the process for reviewing written procedures and protocols and the system for informing staff of any changes made. Departmental staff we spoke to also confirmed they were made aware of changes by the system described.

Version control for all documentation that we reviewed was clear, making it easy to identify the current procedure staff should be adhering to.

Through our review of the employer's 'Radiation Safety Procedures' document it became apparent that the Patient Identification procedure was under review and awaiting approval to ensure that it fully reflected current practice and promote further clarity for the staff that use them. Our specific findings on this can be found further on in this section of the report.

All further procedures that were referenced within the 'Radiation Safety Procedures' need to be clearly cross-referenced to the Quality Management System to enable staff to quickly access a procedure if necessary.

### ***Improvement needed***

***All procedures from the Quality Management System that are highlighted in the 'Radiation Safety Procedures' document must be clearly referenced***

### **Incident notifications**

***Regulation 4(5) states that where an incident has occurred in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation much greater than intended, this should be investigated by the healthcare organisation and reported to the appropriate authority.***

The employer had a written procedure for reporting, recording and investigating incidents under IR(ME)R.

The written procedure described the circumstances when an incident must be reported and how this should be done, together with the information that needs to be submitted via the Trust's electronic reporting system (DATIX). Certain incidents need to be reported to HIW and the written procedure reflected this.

### **Diagnostic reference levels**

***Regulation 4(3)(c) requires the employer to establish diagnostic reference levels (DRL) for radio diagnostic examinations. These are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.***

The employer had a written procedure for monitoring diagnostic reference levels (DRLs) and we saw that the employer had established DRLs for examinations performed within the department.

As well as national DRLs being available, we saw that local (LDRLs) had also been established to take account of the local population and equipment used. We identified this as noteworthy practice. Local DRLs were available and visible within the department.

We looked at a sample of a number of patient records and saw that exposure doses had been recorded for audit and monitoring purposes. Staff were aware of the employer's procedure to follow should a DRL be regularly exceeded for an average sized women.

### **Entitlement**

***Regulation 2(1) requires that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake. Regulations 11(1) and 11(4) states that practitioners and operators must also be***

***adequately trained and the employer must keep up to date training records of this training.***

IR(ME)R defines four duty holders, namely the employer, referrer, practitioner and operator.

The employer had a written procedure for the entitlement and identification of referrers, practitioners and operators as defined under IR(ME)R. These duty holders were identified by staff group and the procedure set out the scope of practice and expected level of training for each staff group by the use of an entitlement matrix.

The entitlement matrix that was in place was clear and easy to understand. Entitlement was by staff group. It was suggested that the referrer, practitioner and operator heading in the tables in the '*procedure to identify individuals entitled to act as referrer or practitioner or operator*' (Procedure B) be amended to read 'entitled by' rather than 'approved by' for clarity.

The use of individual entitlement sign off sheets clearly identified each member of staffs' scope of practice training and entitlement. These sheets were kept in one folder on site which made them easily located should staff need to access them.

Through discussions with senior staff and review of the entitlement matrix it became apparent that there were individuals performing operator functions and who, according to the written procedure, were not entitled by the employer to do so. For example, interventional procedures such as biopsies were included in the practitioner entitlement matrix but were not included in the operator matrix. The example was discussed of performing biopsies. Whilst being executed by advanced practitioners and consultant radiologists these were operator tasks associated with the exposure and as such these staff groups need inclusion in the operator entitlement table.

We saw a sample of training records for **all** staff grades working within breast screening department. These records demonstrated that these duty holders had successfully completed the appropriate training and been deemed competent to undertake these tasks by a suitably experienced member of the clinical team. They had then been entitled as a duty holder to perform the tasks required.

Whilst not a requirement of IR(ME)R but in line with the department's manually maintained mandatory training matrix, it was suggested the department produce a clinical training matrix which would provide a clear record and overview of the training status for all clinical staff in one document. This could

include individual's scope of practice, a record of completed training/competencies and include training dates, trainer and trainee sign off.

We also saw evidence of continuing learning within individuals' continuing professional development (CPD) files.

Through discussions with staff we understood that the Electronic Staff Record (ESR) system which should, on successful completion of mandatory training, automatically update and record staff training, did not accurately reflect current training status.

We saw the senior radiography management team had maintained a mandatory training matrix for all staff which was identified as noteworthy practice. However, through the review of this mandatory training matrix it became apparent that staff have yet to complete or indeed update their manual handling training. In discussions with the management team at Breast Test Wales it was explained that despite numerous requests for manual handling training dates to be provided these had not been delivered. This needs to be addressed to ensure the safety of the staff working within the department.

#### ***Improvement needed***

***The employer's written procedure concerning entitlement and identification of duty holders should be reviewed to clearly set out staff groups, scope of practice and training requirements for entitled referrers, practitioners or operators.***

***Whilst not a requirement of IR(ME)R Mandatory Manual Handling Training should be provided to all staff to ensure their safety while working in the department***

***A clinical training matrix should be devised to provide a complete overview of staff training including clinical and equipment training, competencies, scope of practice and when updates are required/undertaken***

#### **Referral Criteria**

***Regulation 4(3)(a) states that the employer shall establish recommendations concerning referral criteria for medical exposures, including radiation doses and shall ensure that these are available to the referrer***



The employer had a written procedure concerning referrals for medical exposures. The written procedure clearly set out how referrals for medical exposures were to be made.

All residential women in Wales are eligible for breast screening by Breast Test Wales from the year in which their 50<sup>th</sup> birthday occurs. Referrals for screening takes place by obtaining details of eligible woman from the National Breast Screening Computer System. An invitation letter is subsequently sent out inviting them to attend a breast screening appointment. Asymptomatic woman aged 50-70 years are automatically invited for screening every three years.

Women, whose screening mammograms are reported as requiring further investigation, are referred to attend one of the four assessment centres across Wales. The Image reader acting as arbitrator or consensus lead is identified as the referrer and this information is recorded on the Breast Test Wales computer system.

For localisation mammography, where the insertion of a biopsy needle or guide wire under mammographic control is required, the referrer is the member of the medical or surgical team.

Women aged 35 and over whom the Genetics service has identified as being at moderate or high risk of breast cancer according to family history can be eligible for breast screening. Consultant Geneticists entitled under the Trusts entitlement procedure act as the referrer in these cases and must provide adequate and accurate information in order for the procedure to be justified.

Women aged 30 and over whom the Haematologist or Oncologist has identified as being at high risk of breast cancer according to the Hodgkin's group screening may be eligible for breast screening. The Consultant Haematologist / Oncologist described in the entitlement matrix is acting as the referrer in these cases and must provide adequate and accurate information in order for the procedure to be justified.

Referrals for other mammography such as follow up require the completion of a Breast Test Wales Imaging request form. These referrals must include patient's name, address, date of birth, adequate clinical information, name of referrer and their signature. The referrer in these cases must provide adequate and accurate information in order for the procedure to be justified.

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

***Regulations 6(1)(a) and 6(1)(b) require that all medical exposures should be justified and authorised prior to the exposure. The practitioner is responsible for the justification of the medical exposure. Authorisation is***

***the means by which it can be demonstrated that justification has been carried out and this may be undertaken by an operator, where justification guidelines are used.***

Breast Test Wales described that all radiographers working in the department once trained and deemed competent were entitled to act as operators working to guidelines to justify and authorise exposures.

However, it was difficult to identify the justification guidelines mentioned as they were embedded in the 'Radiation Safety Procedures' document. These justification guidelines need to be more explicit, clear and more easily accessible for staff.

The justification guidelines also need to state who the author is and be signed by that person as they are the practitioner taking responsibility for the exposure. The operator authorising the exposure should know who the practitioner is for that exposure. These guidelines need to be dated, signed by the practitioner and reviewed regularly. Staff were clear they were operators justifying to guidelines but could not identify where the guidelines were or who the practitioner was.

#### ***Improvement needed***

***An employer's procedure concerning justification and authorisation should be reviewed and revised as appropriate to clarify the arrangements when justifying under guidelines. This needs to be made available and explicitly explained to staff***

#### **Identification**

***Schedule 1(a) states that written procedures for medical exposures should include procedures to correctly identify the individual to be exposed to ionising radiation***

The employer had written procedures concerning the identification of patients. However, at the time of our inspection, the patient identification procedure was in the process of being revised. We were provided with the revised copy which better reflected current practice. Although the procedure had not yet been approved and disseminated to all staff, we were told that this would be done imminently.

The revised procedure clearly stated those staff groups responsible for confirming the identity of patients and described in detail the procedures to follow. The written procedures set out the arrangements where two operators were involved in conducting a procedure. The written procedures also

described the action to be taken where patients were unable to confirm their identity, for example, due to sensory loss or those without mental capacity.

Departmental staff we spoke to were able to describe the procedures to follow and we were assured that they were aware of the action to take in the event of any discrepancies being identified.

We were also able to check a number of completed referral forms and noted that the identification process was recorded.

We suggested a copy of the procedure was placed in the 'Radiation Safety Procedures' rather than just a reference to the Breast Test Wales quality manual.

### ***Improvement needed***

***The revised employer's procedure concerning identification needs to be approved and disseminated to all staff and a copy placed in the 'Radiation Safety Procedures'***

### **Females of child bearing age**

***Schedule 1 (d) states that written procedures for medical exposures should include procedures for making enquiries of females of child bearing age to establish whether the individual is or maybe pregnant.***

The employer had a written procedure concerning the making of enquires of females of childbearing age. The purpose of this is to establish whether the individual is or may be pregnant or breastfeeding.

However, at the time of our inspection, the Females of childbearing age procedure was in the process of being revised. We were provided with the revised copy which better reflected current practice. Although the procedure had not yet been approved and disseminated to all staff, we were told that this would be done imminently. However, the inspection team were satisfied the procedure was being followed and the process of how to check whether a female of childbearing age may be pregnant was clarified with radiographers during the inspection.

Again we suggested a copy of the procedure was placed in the 'Radiation Safety Procedures' rather than just a reference to the Breast Test Wales quality manual. Staff were asked to show us the copy in the Breast Test Wales quality manual and were unable to find it.

### ***Improvement needed***

***The revised employer's procedure concerning females of childbearing age needs to be approved and disseminated to all staff and a copy placed in the 'Radiation Safety Procedures'***

### **Medico-Legal Exposures**

***Schedule 1 (c) states that written procedures for medical exposures shall include procedures to be observed in the case of medico-legal exposures***

The employer had a written procedure concerning Medico- Legal exposures.

However, we were told that medico-legal exposures were not undertaken at the department and this was clearly stated in the procedure.

### **Optimisation**

***Regulation 7(1) requires that doses for all diagnostic medical exposures are kept as low as reasonably practicable (ALARP) consistent with the intended purpose.***

The employer had a written procedure concerning the optimisation of exposures.

This set out the arrangements for ensuring that medical exposures are kept as low as reasonably practicable (often referred to as ALARP). We found that opportunities had been taken to optimise medical exposures and this was reflected in the records we saw.

During discussions, Breast Test Wales described a number of optimisation processes which could be reflected on and expanded in the procedure to demonstrate their good practices.

### **Clinical evaluation**

***Regulation 7(8) states that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with the employer's procedures.***

The employer had a written procedure concerning evaluation of exposures.

This set out the arrangements and the staff group that were entitled to assess and record the outcome of medical exposures. However, when we spoke with the clinical staff reading the images (clinically evaluating) they explained the process which made the process much clearer. The procedure could therefore be expanded to explain who does the clinical evaluation and how they double

blind report all images (which is noteworthy practice) and what happens when a set of images goes to arbitration.

All screening images are read by at least two Image Readers who produce and record a clinical report on the National Breast Screening Computer system.

The department has a system in place that ensures that all screening images have a clinical report which is mentioned in the 'Right Results Protocol'. However, this could also be expanded on and included within the procedure.

Clinical evaluation is an entitled operator function and this was clearly identified in the entitlement of operator's matrix.

### ***Improvement needed***

***The employer's procedure concerning clinical evaluation should be revised to include who does the clinical evaluation, how they double blind report all images and what happens when a set of images goes to arbitration***

### **Medical Research Programmes**

***Schedule 1(h) requires there to be a procedure in place for medical exposures undertaken as part of research programmes.***

The employer had a written procedure concerning medical research programmes.

However, we were told that medical exposures as part of research programmes were not undertaken at the department at the time of our inspection.

Further discussions revealed that patient data from BTW was until recently (the trial is finished) used for the FH02 national family history trial. These women would have been called for family history screening as part of BTW processes and then the data only was used in the trial.

The research procedure will require review/ updating should Breast Test Wales be included in future research trials to reflect details of the trial and the processes

### **Clinical audits**

***Regulation 8 states that employer's procedures shall include provision for carrying out clinical audits as appropriate.***

Information provided to HIW prior to our inspection referred to a number of clinical audits that had been carried out across the department.

During our inspection we saw evidence of a comprehensive audit programme performed on a regular basis, required to ensure compliance with the strict quality standards for the NHS Breast Screening Programme. In particular the 'Performs' educational self-assessment and training scheme for breast screening professionals and process of 'Double Blind reporting' carried out by Breast Test Wales were identified as noteworthy practice.

The department also operates a peer review system whereby staff observe and assess the clinical practice of their colleagues including assistant practitioners annually. This involves assessing patient care, technical and clinical practice and the information delivered to the individual undergoing examination.

Technical recalls and repeat mammogram statistics for each individual staff member are also reviewed monthly and used as a trigger for refresher training or further development. We identified this as noteworthy practice.

### **Expert advice**

***Regulation 9(1) and 9(2) states that the employer shall ensure a Medical Physics Expert (MPE) is available in standardised therapeutic nuclear medicine practices, in diagnostic nuclear medicine practices and involved as appropriate in every other radiological medical exposure.***

A full time Medical Physics Experts (MPE's) was available for advice on all diagnostic exposures conducted within the department and across Breast Test Wales. The MPE also oversaw the mammography equipment within the department and provided input with regard to optimisation, installation, acceptance testing and ongoing QA as appropriate.

### **Equipment**

***Regulation 10 requires that the employer has an up to date inventory of equipment that contains the name of manufacturer, model number, serial number, year of manufacture and the year of installation.***

The employer provided up to date inventory of the radiological equipment used within the department. The inventory contained all the information required under IR(ME)R.

## *Management and Leadership*

**We found strong and effective leadership being provided by senior clinical departmental staff and excellent multidisciplinary team working was evident.**

It was clear from our conversations with all levels of staff involved during the inspection that there was a strong commitment to learn from the inspection and to make improvements as appropriate.

During our verbal feedback meeting we spoke to senior departmental staff, a member of the Trusts executive team and the Chief Executive Officer of Public Health Wales NHS Trust. All were receptive to our comments and demonstrated a strong commitment to learn from the inspection and to make improvements as appropriate.

## 6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan to address the recommendations identified during this inspection. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state when and how the findings identified within the diagnostic imaging department at Breast Test Wales, Cardiff will be addressed, including timescales. Public Health Wales NHS Trust should ensure that the findings from this inspection are not systemic across other Breast Test Centres in Wales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.



**Appendix A**

**IR(ME)R: Improvement Plan**

**Organisation: Public Health Wales NHS Trust**

**Department: Breast Test Wales, Cardiff**

**Date of Inspection: 2 and 3 November 2016**

<b>Page Number</b>	<b>Improvement needed</b>	<b>Service Action</b>	<b>Responsible Officer</b>	<b>Timescale</b>
<b>Quality of the Patient Experience</b>				
8	Signs to inform patients that CCTV is in operation must be clearly displayed in the department	Display appropriate signs.	Dean Phillips	January 2017
<b>Compliance with IR(ME)R</b>				
10	The Employers 'Radiation Safety Procedures' document should explicitly state who the employer is and what their responsibilities are	Add an explicit statement about the employer as part of 2017 review of BTW Radiation Safety Procedures.	Anna Burch	June 2017

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
11	All procedures from the Quality Management System that are highlighted in the 'Radiation Safety Procedures' document must be clearly referenced	Include references and hyperlinks to relevant procedures in Quality Manual as part of 2017 review of BTW Radiation Safety Procedures.	Anna Burch	June 2017
13	The employer's written procedure concerning entitlement and identification of duty holders should be reviewed to clearly set out staff groups, scope of practice and training requirements for entitled referrers, practitioners or operators.	Add explicit operator functions relating to stereotactic biopsy to entitlement procedure as part of 2017 review of BTW Radiation Safety Procedures.	Anna Burch	June 2017
13	Whilst not a requirement of IR(ME)R Mandatory Manual Handling Training should be provided to all staff to ensure their safety while working in the department	Manual handling training delivered in December 2016 and Trust training plan being developed.	Helen Moore	February 2017
13	A clinical training matrix should be devised to provide a complete overview of staff training including clinical and equipment training, competencies, scope of practice and when updates are required/undertaken	Develop clinical training matrix.	Helen Moore & Liz Edwards	June 2017
15	An employer's procedure concerning	Summarise justification guidelines for screening from Quality Manual, get signed off by relevant	Anna Burch	June 2017

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
	justification and authorisation should be reviewed and revised as appropriate to clarify the arrangements when justifying under guidelines. This needs to be made available and explicitly explained to staff	IRMER practitioners and make available to staff. Document this process as part of 2017 review of BTW Radiation Safety Procedures.		
16	The revised employer's procedure concerning identification needs to be approved and disseminated to all staff and a copy placed in the 'Radiation Safety Procedures'	Get revised procedure approved for inclusion in Quality Manual, then disseminate to staff and include a copy and/or hyperlink as part of 2017 review of BTW Radiation Safety Procedures.	Dean Philips	June 2017
17	The revised employer's procedure concerning females of childbearing age needs to be approved and disseminated to all staff and a copy placed in the 'Radiation Safety Procedures'	Get revised procedure approved for inclusion in Quality Manual, then disseminate to staff and include a copy and/or hyperlink as part of 2017 review of BTW Radiation Safety Procedures.	Dean Phillips	June 2017
18	The employer's procedure concerning clinical evaluation should be revised to include who does the clinical evaluation, how they double blind report all images and what happens when a set of images goes to arbitration	Add an explicit summary of clinical evaluation procedures (extracted from Quality Manual) as part of 2017 review of BTW Radiation Safety Procedures.	Anna Burch	June 2017
<b>Management and leadership</b>				

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
-	No improvement plan required			

**Service Representative:**

**Name (print):** Dean Phillips.....

**Title:** Head of Programme for Breast Test Wales.....

**Date:** 28 December 2016.....