Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Ionising Radiation (Medical Exposure) Regulations Inspection Report (Announced)

Breast Test Wales, Swansea, Public Health Wales

Inspection date: 8 and 9 April 2025
Publication date: 10 July 2025

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

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

In writing:

Communications Manager
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ

Or via

Phone: 0300 062 8163
Email: hiw@gov.wales
Website: www.hiw.org.uk

Digital ISBN 978-1-80633-163-5

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

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

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

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile, and we carry out our work where it matters most.

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Contents

1. What we did 5

2. Summary of inspection 6

3. What we found 8

- Quality of Patient Experience 8
- Delivery of Safe and Effective Care 11
- Quality of Management and Leadership 22

4. Next steps 25

Appendix A – Summary of concerns resolved during the inspection 26

Appendix B – Immediate improvement plan 27

Appendix C – Improvement plan 28

1. What we did

Full details on how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of Breast Test Wales, Swansea, Public Health Wales on 8 and 9 April 2025. During our inspection we looked at how the department complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and two Senior Clinical Officers from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. A Senior Healthcare Inspector led the team.

During the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of 28 questionnaires were completed by clients or their carers and 20 were completed by staff. Feedback and some of the comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

Note the inspection findings relate to the point in time that the inspection was undertaken.

2. Summary of inspection

Quality of Patient Experience

Overall summary:
Clients provided positive feedback about their experiences of attending Breast Test Wales, Swansea. We found staff provided individualised care and treated clients with courtesy, respect and kindness. We also found staff provided care in a way that protected and promoted client's rights.

This is what the service did well:

- Delivering a flexible service for women and providing additional screening capacity within the department when mobile screening vans were out of action
- Clients provided positive feedback and comments about the attitude and approach of the staff looking after them
- Commitment to Welsh language information and provision of Welsh language care
- Provision of a wide range of health promotion information.

Delivery of Safe and Effective Care

Overall summary:
We found arrangements in place to provide people with safe and effective care. We reviewed extensive documentation including Employer's Procedures that had been reviewed, updated, ratified and disseminated to staff.

The setting was clean, tidy and free from clutter. Rooms were modern, well-appointed and equipment was in good working order.

This is what we recommend the service can improve:

- Continue to refine and update Employer's Procedures in line with recommendations from the inspection, best practice, staff feedback and IR(ME)R amendments
- Review and update clinical and IR(ME)R audit planning and processes to include an audit schedule, appropriate compliance targets and standardised reporting, learning and re-audit processes.

This is what the service did well:

- Updated Employer's Procedures that were document controlled and available to all staff, including staff working on mobile screening units

- IR(ME)R training videos have been developed by medical physics for all staff
- Communication of benefits and risks of mammography exposures for users of the service
- Staff understanding of IR(ME)R and continued training around the regulations
- Commissioning and testing of new equipment
- Quality assurance programme for equipment
- Well maintained, clean, modern and welcoming environment free from obvious hazards to those visiting the setting
- Safeguarding arrangements.

Quality of Management and Leadership

Overall summary:
We received the completed Self-Assessment Form (SAF) and associated documentation in a timely manner.

The Chief Executive of Public Health Wales was the designated employer under IR(ME)R. The trust was able to demonstrate improved structure for lines of reporting and accountability under IR(ME)R during the inspection.

We met with a dedicated management team who have worked hard in a short period of time to update documents and processes appropriately, to ensure IR(ME)R compliance in Breast Test Wales was in place and consistent across the three Breast Test Wales sites.

This is what the service did well:

- Passionate, engaged and dedicated team of staff that cared about the clients and Breast Test Wales service
- Policies, procedures and documentation were detailed and well written, ratified, version controlled and accessible to staff
- IR(ME)R awareness training for all duty holders
- Training compliance for mandatory training.

3. What we found

Quality of Patient Experience

Patient feedback

HIW issued online and paper questionnaires to obtain the views of clients that used this service. In total we received 28 responses from clients at this setting. Responses were mostly positive across all areas, with all who answered rating the service as 'very good' or 'good.'

Patient comments included:

> ***"Excellent service, amazing staff, very friendly and informative."***

> ***"Very friendly staff. Informative. Lovely and clean setting."***

Person-centred

Health promotion
There were bilingual (English and Welsh) posters displayed that provided information to those attending for screening, to advise staff if they may be pregnant or breastfeeding. We saw health promotion material displayed in the waiting areas within the department. This included information on the benefits of not smoking, reducing risks of breast cancer, as well as being breast aware.

Dignified and respectful care
There were suitable arrangements in place to promote client privacy. All respondents who answered the questionnaire confirmed that:

- Staff treated them with dignity and respect
- Measures were taken to protect their privacy
- They were able to speak to staff about their procedure without being overheard by other patients
- Staff listened to them.

Individualised care
All respondents felt they were involved as much as they wanted to be in decisions about their treatment and that staff explained what they were doing.

All confirmed that they were provided with enough information to understand the benefits and risks of the exposure. Everyone we spoke with were also complimentary about their care.

One commented on the care that they received:

> ***"The Radiographers who looked after me were extremely professional and caring. The Doctor explained everything and made me feel very comfortable. The department was very clean and welcoming. Great team, thank you!"***

Timely

Timely care
Staff we spoke with explained the arrangements in place for communicating screening appointments, timings and any delays to appointments. Staff would let clients know if there was a delay to their appointment time.

Clients attended for screening throughout our inspection and no delays to appointments were seen. Staff we spoke with explained that there was flexibility in the department to add additional screening capacity for clients in the event of mobile screening vans undergoing repair or servicing. **This was seen as notable practice.**

Equitable

Communication and language
The Welsh language was well promoted within the department. We saw bilingual posters in Welsh and English with information clearly displayed. We saw clear bilingual signage in place to direct visitors to the department. Some staff members told us that they were Welsh speakers, and these were identified by wearing the 'Iaith Gwaith' logo.

Staff we spoke with described some of the arrangements in place to help people with hearing difficulties and those whose first language was not English. There was a hearing loop available in the main reception. All staff that we spoke with were aware of how to access translation services, if needed to support clients using the service. Staff confirmed that a mobile device was available to support translation for patients whose first language was not English or Welsh.

'Putting Things Right' notices in both Welsh and English were displayed within patient areas and there was a bilingual poster displayed, asking for client feedback about the department. Llais information was displayed and a "you said, we did"

board detailed actions that staff had taken following client feedback. Staff members that we spoke with were able to confirm how they would deal with feedback, both positive and negative.

Rights and equality

We found client rights were protected and promoted in the department. Staff explained the arrangements in place to make the service accessible to all. The department was accessible with wide doors, clear corridors and spacious screening rooms. Breast screening equipment was adjustable to examine those that were unable to stand at breast screening appointments. Staff members confirmed that longer appointments were available for those clients that needed extra support. There was a stair lift available for anyone with mobility requirements to access offices on the upper floors of the building.

We were told that equality and diversity training for all staff was mandatory, and we saw training records that indicated a high level of compliance. All staff we spoke with confirmed they had completed this training online. Staff had a good awareness of their responsibilities in protecting and promoting client rights when attending the department. They were able to confirm the arrangements in place to promote equality and diversity in the organisation.

Delivery of Safe and Effective Care

Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017 (as amended)[1]

Employer's Duties: establishment of general procedures, protocols and quality assurance programmes

Procedures and protocols
Documentation was provided in advance of the inspection as part of the completed Self-Assessment Form (SAF).

We reviewed all IR(ME)R documentation submitted in advance of the inspection and spoke to duty holders and senior management to confirm understanding of processes and practice. Overall, we found that policies and procedures were:

- Greatly improved from our last inspection and now compliant with IR(ME)R
- Recently reviewed and updated, ratified and accessible to all duty holders (including those working on mobile units)
- Dated and version controlled with review dates noted.

Recently updated Employer's Procedures (EPs) reviewed provided clear, detailed instructions of how and when a process should be carried out and identified who was responsible for carrying out these tasks. Staff that we spoke with, confirmed that these revised EPs were much improved, easy to find and follow, as well as being available to all staff. Documentation largely reflected the clinical practice within the setting.

Staff members that we spoke with were able to confirm, when questioned, where the EPs were available for their reference.

Some specific improvements and amendments were recommended as part of the inspection, these were shared with departmental leads throughout the SAF evaluation meeting and inspection.

Referral guidelines
EPs were reviewed ahead of the inspection, this document identified individuals entitled to act as IR(ME)R referrer, practitioner and operator for exposures.

[1] As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 and the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024

Referral guidelines had been made available during the process of IR(ME)R entitlement.

Documents reviewed confirmed that EPs had been circulated to all duty holders and staff have confirmed that they had read the documents.

The SAF indicated that the Radiography Manager issued new referrers with the document “Information for Referrers” which includes referral criteria and dose indicators. However, it was not possible to review this document during the inspection.

An arbitration form has been developed and is being further developed and implemented. This is a positive development, and the inspection team shared some suggestions for improvements for this form.

The employer must

- **Review the referral guidelines available that may be located within the ‘information for referrers’ document mentioned above, to ensure that the information is up to date and matches current EPs and IR(ME)R guidance**

- **Update the procedure on referrals to add additional detail around the arbitration form as the referral form for assessment clinic. Currently the procedure is focused on breast screening referrals.**

Referral pathway documents that were reviewed included the IR(ME)R pathways for standard screening, high risk cohorts, assessment clinic and individuals over 70 years. It was positive to see improvements in referral documentation since the previous inspection in August 2024. Of note was the updated arbitration form, this served as the referral. It was positive to see recorded evidence to identify the referrer, (with an electronic signature) practitioner and operator. Additional sections for additional exposures evidencing the operator and practitioner were noted on the back of the arbitration form. The SASP2 form that we reviewed also clearly identified IR(ME)R duty holders who carried out each task. These changes represented positive improvements.

As the department now have an increasing amount of completed referral documentation available for audit purposes, the employer should consider broadening IR(ME)R compliance audits to look at the referral process.

The employer must ensure that IR(ME)R compliance audits have a 100% target.

Diagnostic reference levels (DRLs)
Staff we spoke with were able to confirm that they were using local diagnostic reference level (LDRL) for screening mammography and tomosynthesis. DRL charts were displayed on the notice boards in the mammography rooms.

We reviewed the Employer's Procedure for DRLs. Staff that we spoke with confirmed that they were aware of the DRLs in place and the process to follow where DRLs are consistently exceeded. The MPE told us that local DRLs are below national DRLs and film readers (IR(ME)R operators performing clinical evaluation) were content with the current image quality. LDRL charts were available in all the rooms which included the newly established tomosynthesis DRL. MPEs confirmed that they had recently completed annual dose audits, and no changes were required to the local DRLs.

Medical research
We were told that there were no medical research trials related to mammography exposures involving the department currently.

Entitlement
Public Health Wales had delegated the task of entitlement to the Chief Executive Officer of Public Health Wales. Responsibility had been delegated to the National Director of Health Protection and Screening Services/Executive Medical Director. This responsibility was then delegated to the Director of Screening Division who entitled the Head of Programme at Breast Test Wales to act as the referrer for initial screening mammography. The Head of Programme entitled the MPEs. There was a competency matrix that was shared with Breast Test Wales. This matrix was used as assurance during the process of entitlement specifically for the MPEs.

EP2 identified the staff groups entitled to act as referrer, practitioner or operator for exposures. It described clearly who carried out the entitlement on behalf of the Director. We were told that all duty holders held a certificate of entitlement.

Examples of entitlement records and scope of practice documentation were reviewed during the inspection. This included clinical scientists and MPEs entitlement. We reviewed past patient records and confirmed that there was a consultant breast surgeon performing clinical evaluation on one record. It was not possible to determine if the surgeon was entitled as an operator.

The employer must review and update entitlement records and the supporting EP to confirm that operators performing clinical evaluation (e.g. assessment clinic) are appropriately entitled to perform this task. This must be reflected in

the relevant EPs and the individual must be aware of their responsibilities and scope of practice in relation to this.

Competency forms and a competency matrix were shared with the inspection team to evidence training and competency for IR(ME)R duty holders. Whilst we recognised that these documents represented recent significant improvements, some additional suggestions were made to make the competency process more robust.

The employer should review and update:

- **The competency forms to ensure that there is sufficient evidence of training to underpin competency**

- **The competency matrix to reflect review dates of competency and entitlement.**

Patient identification
We reviewed the EP relating to patient identification (EP 3). This was sufficiently robust and clear. It was positive to note that this procedure included how to deal with discrepancies.

All staff we spoke with confirmed their awareness of the processes listed in EP3 and confirmed appropriate actions to identify patients that may not be able to identify themselves. All patient records reviewed consistently documented who had identified the patient and included three unique identifiers.

Individuals of childbearing potential (pregnancy enquiries)
The evidence provided in the SAF submitted by the setting, showed that there was an EP in place for making enquiries of individuals of childbearing potential. We reviewed the procedure and discussed this with relevant staff. The EP included most of the process related to how and when to make pregnancy enquiries. Some improvements to the EP were discussed with management during the inspection. There were some discrepancies noted in documentation reviewed as part of the SAF. This included participants upper age of 49 rather than the recommended 55 included in the pregnancy questioning for Hodgkin's surveillance. Also, the EP did not state where the answer to a pregnancy question was recorded.

The employer must review and update the EP related to pregnancy enquiries to ensure that the ages are correctly listed and ensure that the EP comprehensively details where to document client responses.

Benefits and risks
As part of the evaluation of the SAF, it was confirmed that every client invited for routine breast screening received a copy of the NHS Breast Screening leaflet 'Helping You Decide.'

Every client invited for screening within the family history programme received a copy of the Breast Test Wales leaflet 'Breast screening explained.' These leaflets set out the benefits and risks of breast screening, including the risks from radiation.

We reviewed the related EP, which detailed how benefit and risk information associated with radiation in mammogram was shared with clients. We saw that clients, on arrival for their screening appointments, were given a laminated card to read, fully detailing benefits and risks associated with mammography.

Clinical evaluation
We reviewed the SAF and EP 10 relating to clinical evaluation. This was a comprehensive procedure.

Details confirmed how each reader for screening mammograms uses a double blind read method. The reader categorises the findings and the evaluation is recorded on the breast screening computer system (NBSS). Breast Test Wales Swansea uses arbitration, which looks at both readers results and makes the decision if a recall is necessary.

Quality assurance (QA) in relation to clinical evaluation was undertaken in several ways, including at performance appraisal and development reviews (PADR), at multi-disciplinary team (MDT) reviews and the false negative assessment process. The evaluation was recorded on the breast screening computer system (NBSS).

Assessment images were evaluated during the assessment clinic and recorded in the clinic notes.

Practical aspects of clinical evaluation
There were two separate pathways in Wales; breast screening and the symptomatic service and they use two separate IT systems. There continued to be a potential risk of duplicate referrals, where a client would receive an invite for screening, despite being on the symptomatic pathway which would not be documented in the breast screening administrative systems. The service stated that whilst operators did not have access to previous imaging undertaken by symptomatic services in Health Boards, significant improvements had been made to the process of checking with clients to mitigate this risk whilst a more permanent IT solution was implemented. Staff confirmed that if the client had any

doubt about previous imaging, the exam does not proceed until it is confirmed exactly when the last mammogram was performed. This may involve the radiographer contacting the local hospital or base unit to establish the date. This was now a more established practice to pause proceedings and seek further information.

The employer must work towards a more comprehensive solution in relation to evidencing previous imaging whilst continuing to mitigate the risks of duplicate imaging.

Non-medical imaging exposures
The service confirmed they did not carry out non-medical imaging exposures.

Employer's duties: clinical audit
The newly ratified EP for clinical audit programme was shared along with examples in the completed SAF. It was positive to see that there was a link within this EP and the "Quality and clinical audit procedure" which was comprehensive and clear.

We were told that the QA leads led the annual general meeting which took place in March 2025 and included separate breakout sessions for radiographers and radiologists. There was a lot of discission at the event around clinical audits and the plan for the next year. We did not review the specific detail around this and no clinical audit schedule was available for review.

The employer must document a clinical audit schedule to ensure that themes are audited appropriated with learning outcomes in place.

Some of the clinical audits reviewed during the inspection were found to be inconsistent in how audit findings were presented and lacked evidence of in-depth analysis of the results.

The development of a consistent process for audit and carrying out in-depth analysis would assist staff in closing the feedback loop to drive service improvements.

The employer must ensure that there is a standardised approach to the reporting of audits, the learning actions to be implemented in the audit results and whether there is a need for reaudit.

The department performed some IR(ME)R compliance audits and a sample of these were reviewed.

The employer should aim to keep reaudit timeframes short until 100% compliance is achieved for IR(ME)R compliance audits.

Employer's duties: accidental or unintended exposures

We reviewed evidence that confirmed incidents and near misses were brought to the annual meeting of the radiation protection group (RPG) by the MPEs as members of the Technical Quality Assurance group. Datix incidents were also discussed at the programme board. At the annual RPG meeting, the MPEs presented a summary of incidents that had occurred, and these were listed by theme.

We reviewed a summary report of accidental and unintended exposures over a four-year period (2020-2024) issued by medical physics. Retrospective analysis showed that one trend affecting multiple patients was observed, and this was appropriately reported to HIW in line with SAUE guidance. Senior staff confirmed incidents and near misses were also discussed in minuted meetings.

We were told that any radiation incidents were logged on the Datix system and reported to the medical physics team, who would offer advice and confirm if the incident was notifiable to HIW. All learning was shared initially with the individual involved in the incident through an informal conversation and feedback via the Datix system. Senior staff in the department confirmed that all incidents, near misses, compliments and complaints were discussed at staff meetings. We did not review documentation that confirmed that the IR(ME)R employer was informed of non-notifiable incidents near misses or trends.

Duties of practitioner, operator and referrer

We reviewed the EP and Radiation Safety Procedure which included the entitlement of referrers, practitioners and operators to carry out their duties. This EP included the following:

- How duty holders were made aware of their roles and responsibilities under IR(ME)R
- How training and competencies were assessed and signed off, although some additional work was needed around this
- How staff evidenced their entitlement and scope of practice
- A review period for entitlement across all duty holders.

Staff that we spoke with, at all levels, were mostly aware of their duty holder roles and responsibilities under IR(ME)R and the general understanding of IR(ME)R across all levels was found to be good.

Justification and Authorisation of individual exposures
We reviewed the document 'Authorisation Guidelines' to support staff understanding of authorisation.

Our discussions with staff showed there was some confusion around the use and purpose of the authorisation guidelines that were in place. Recording of authorisation needs to be separate to the evidence of carrying out the exposure. Staff may benefit from further training in this area to improve levels of understanding.

Some suggestions around improvements to the 'Authorisation Guidelines' document was shared during the inspection. These included

- **Adding an introduction to the guideline**
- **Confirming that recording of authorisation needs to be separate to the evidence of carrying out the exposure**
- **Exemptions**
- **Criterial and necessary actions if the criteria are not met.**

The employer must review and update the authorisation guidelines. Also ensuring staff have a clear understanding of the process for justification and authorisation. Evidence of authorisation must be recorded and audited to ensure compliance with IR(ME)R.

Optimisation
We were told that practitioners and operators ensured doses were as low as reasonably practical (ALARP) via a number of factors. The SAF confirmed that mammography techniques followed national standards.

The medical physics service performed annual patient dose surveys, to confirm that doses received by the client on each piece of equipment were in line with local and national DRLs.

We reviewed evidence that confirmed a Quality Assurance (QA) programme and planned maintenance were in place to ensure that equipment performance met national standards.

Equipment was commissioned with support from the manufacturer to optimise exposures from the outset. Exposure protocols were displayed in each room to guide operators.

Carers or comforters
An EP was in place to provide advice and guidance on exposures to carers and comforters. Whilst this was a well written EP some suggested improvements were shared during the inspection. These included

- Adding an introduction to the procedure
- Exemptions
- Criteria and what to do if the criteria are not met
- Adding detail around the signing of the carers and comforter form.

The employer must review and update the carers and comforter EP with a view to making it more robust.

Expert advice
We confirmed the employer had appointed and entitled a Medical Physics Experts (MPEs) to provide advice on radiation protection matters and compliance with IR(ME)R 2017.

Staff we spoke with said they could access expert advice, when required. It was positive to note the involvement of the MPEs, who were clearly engaged with the department despite not being on site daily. This was evidenced by their involvement in a range of groups and committees, as well as advising staff when required. MPEs were an integral part of QC testing, procurement and commissioning of equipment at Breast Test Wales. They had also been responsible for the establishment of a local DRL for tomosynthesis.
Of note were the MPE developed training videos based on IR(ME)R schedule 3. These were available to all staff on SharePoint.

Equipment: general duties of the employer
We reviewed an equipment inventory that was shared along with the SAF. The equipment inventory did not include date of manufacture and date of installation, nor did it reflect requirements of the software inventory as a requirement following the IR(ME)R 2017 amendments.

The employer must update the equipment inventory to include all requirements within IR(ME)R regulations.

The commissioning and testing of new equipment was described, and appropriate forms and processes were reviewed. It was confirmed that medical physics commissioned the equipment. During commissioning, medical physics and radiographers performed consecutive testing over three days. The readings from these tests were used to establish baselines for future quality testing. The

baselines were reviewed following installation of a new tube or detector, recalibration or software updates.

During the commissioning of new equipment, MPEs ensured that the systems were optimised in conjunction with engineers and application specialists.

The Quality Control (QC) manual that inspectors reviewed was comprehensive and the QC records were sufficiently detailed. MPEs had good oversight of QC testing and escalation where required.

Safe

Risk management
During a tour of the department, we noted there was new equipment, and the environment appeared well maintained, modern and in a good state of repair. It offered a bright, clean, clear and welcoming environment for patients. We did not identify any obvious hazards to the health and safety of patients and other individuals visiting the department.

Signage was clearly displayed to alert patients and visitors not to enter controlled areas where ionising radiation was being used.

Infection prevention and control (IPC) and decontamination
We found suitable IPC and decontamination arrangements in place. All areas accessible by patients were visibly clean and free of clutter. The equipment was also visibly clean, and all staff described suitable cleaning and decontamination procedures.

Personal protective equipment (PPE) was available within the facility and staff we spoke with confirmed they had access to suitable PPE and this was readily available. We also saw cleaning wipes to decontaminate shared equipment, and staff demonstrated a good understanding of their role in this regard.

All clients who completed the questionnaire said that, in their opinion, the department was clean, and IPC measures were being followed.

All staff who responded to the questionnaire thought there were appropriate IPC procedures in place, that appropriate PPE was supplied and used, and that the environment allowed for effective infection control. All staff agreed there was an effective cleaning schedule in place.

We checked a sample of five staff records and these confirmed that staff had completed mandatory IPC training.

Safeguarding of children and safeguarding adults
Staff we spoke with were aware of the Public Health Wales safeguarding policies and procedures and where to access these. They were also able to describe the actions they would take if they had a safeguarding concern.

We checked a sample of five staff records and these confirmed that the appropriate level of safeguarding training had been completed.

Effective

Patient records
We reviewed arrangements for the management of records within the department. We were able to review current and past referral documentation of ten clients. We confirmed improvements in the SASP2 forms that were used and these included checks to confirm pregnancy, breastfeeding, previous history and cardiac devices.

We reviewed evidence of appropriate audits taking place on patient records with a view to making improvements.

Efficient

Efficient
All staff we spoke with confirmed that systems and processes in place at Breast Test Wales, Swansea were consistent across the three Breast Test Wales sites and that improvements made to processes and procedures at one site would be reflected in the other sites. It was positive to note that improvements required in Breast Test Wales, Llandudno related to the IR(ME)R inspection in August 2024, had been largely implemented in Breast Test Wales, Swansea.

The Employer must continue to ensure that improvements are consistently implemented throughout Breast Test Wales.

Quality of Management and Leadership

Staff feedback

HIW issued an online questionnaire to obtain staff views on services carried out by Breast Test Wales and their experience of working there. In total, we received 20 responses from staff. Not all respondents completed the questionnaire to the end, and questions were skipped throughout.

Responses from staff were generally positive. All but one of the respondents were satisfied with the quality of care and support they gave to patients, and all agreed that they would be happy with the standard of care provided by their hospital for themselves or for friends and family. All but one of the respondents recommended their organisation as a place to work.

Staff comments included:

> ***"I'm very proud to work in this team. We're very hardworking and put our patients first. It's a privilege to care for the ladies and deliver a really high standard of care."***

> ***"I'm fortunate to work in an environment of trust and respect as per the values of PHW not only in respect of my colleagues but more importantly for the ladies accessing our service."***

Leadership

Governance and leadership

It was confirmed that the Chief Executive of Public Health Wales was the designated employer under IR(ME)R and had overall responsibility for ensuring the regulations were complied with. Where appropriate, the employer had delegated tasks to other professionals working in the NHS Trust to implement IR(ME)R.

We were provided with details of the organisational structure for both Breast Test Wales and Public Health Wales in the documentation supplied in advance of this inspection. Clear lines of reporting and responsibilities under IR(ME)R were confirmed in the completed SAF and in conversations with staff, at all levels.

Senior staff confirmed updated informal and formal processes in place to consider, review, update and ratify policies and procedures through the Quality Safety Improvement Committee as well as immediately following the previous Breast Test Wales IR(ME)R inspection, through a cross organisational working group.

Workforce

Skilled and enabled workforce

IR(ME)R duty holders that we spoke with had an adequate understanding and knowledge of IR(ME)R and how the regulations applied in clinical practice. The IR(ME)R framework provided support for staff and ensured the safety of clients. Staff were not always aware of the framework within which they were working. Staff confirmed that IR(ME)R training in a variety of forms had been rolled out to all staff and processes were in place to confirm competency and understanding.

Management confirmed the process for managing the training matrix. We were also told that when EPs were updated, staff understanding was confirmed following the appropriate training. Feedback from staff on this process was very positive.

Mandatory training compliance was over 84% for the department. There was an appropriate system in place for the monitoring of the training compliance.

All staff that we spoke with and those that completed the questionnaire confirmed that in the last 12 months, they had an appraisal, annual review or development review of their work. Senior staff confirmed that the compliance with appraisals was over 70% and that dates were booked for those who had not completed their appraisal.

All staff we spoke with confirmed that they knew and understood the Duty of Candour. This was also confirmed in the questionnaire where all staff agreed that they knew and understand the Duty of Candour and understood their role in meeting the Duty of Candour standards.

All staff we spoke with, and those that completed the questionnaire, confirmed that they felt that there were enough staff for them to do their job properly and that they were able to meet the conflicting demands on their time at work.

Culture

People engagement, feedback and learning

Feedback from staff we spoke with about the culture in Breast Test Wales, Swansea was positive. Individual staff members confirmed that Breast Test Wales was a positive place to work in and that the support of their peers and direct line managers was supportive. Staff stated that they were proud to work for Breast Test Wales.

All staff we spoke with confirmed that senior staff were approachable and visible. Senior staff confirmed a wide range of processes and meetings in place to

disseminate information and updates to staff. These include team meetings, email bulletins and via online applications

4. Next steps

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.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

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.

Appendix A – Summary of concerns resolved during the inspection

The table below summarises the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection			

Appendix B – Immediate improvement plan

Service: Breast Test Wales, Swansea, Public Health Wales

Date of inspection: 8 and 9 April 2025

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.

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	No immediate assurance / non-compliance issues were identified on this inspection					

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative:

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Breast Test Wales, Swansea, Public Health Wales

Date of inspection: 8 and 9 April 2025

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.

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Safe and effective care						
1.	**Referral guidelines** Information for Referrers document was not available to review during inspection. We were told that this document included referral criteria and dose indicators	Review the referral guidelines available that may be located within the 'information for referrers' document mentioned above, to ensure that the information is up to date and matches current EPs and IR(ME)R guidance	**Regulation 6 (5) (a) Regulation 10(5)**	The service will review information provided to referrers on entitlement to ensure that information matches the current EPs and IR(ME)R guidance	DP	4 months
2.	**Referral guidelines** Current referral procedure reviewed	Update the procedure on referrals to add additional detail around the	**Regulation 6 (5) (a) Regulation 10(5)**	The service will update the procedure on referral to add	DP	4 months

	focussed on breast screening referral, additional detail is required around the use of the arbitration form as a referral form for assessment clinic	arbitration form as the referral form for assessment clinic.		detail on the arbitration form (referred to as the recall form) as this is the referral form for assessment clinic		
3.	**Referral guidelines** The department have an increasing amount of completed referral documentation which is available for audit purposes	The employer review current IR(ME)R audits and consider broadening IR(ME)R compliance audits to look at the referral process. The employer must ensure that IR(ME)R compliance audits have a 100% target.	**Regulation 6 (5) (a)** **Regulation 10(5)**	The IR(ME)R compliance audits will include the referral process in the audits undertaken in the future All compliance audits will include 100% targets in future.	Radiography Regional Managers	6 months
4.	**Entitlement** On review of past patient records, it was not possible to determine from entitlement documentation, if the breast surgeon was	The employer must review and update entitlement records and the supporting EP to confirm that operators performing clinical evaluation (e.g. assessment clinic) are appropriately entitled to perform this task. This must	**Regulation 6 (1)** **Schedule 2 (1) (b)**	The programme will review the entitlement records and supporting EP. To note the breast surgeon is not entitled as an IR(ME)R operator as they do not have these duties within	DP	4 months

	entitled as an IR(ME)R operator	be reflected in the relevant EPs and the individual must be aware of their responsibilities and scope of practice in relation to this.		the assessment clinic as this role is undertaken by Radiologist/ Radiographer in the assessment clinic.		
5.	**Entitlement** IR(ME)R staff competency form and competency matrix needed some additional information to make the process more robust	The employer should review and update: • The competency forms to ensure that there is sufficient evidence of training to underpin competency • The competency matrix to reflect review dates of competency and entitlement.	**Regulation 6 (3) (b)** **Regulation 17 (4)** **Schedule 3**	The programme will review and update the competency form and competency matrix with the additional information as detailed.	Regional Radiography Managers	6 months
6.	**Pregnancy enquiries** Some discrepancies were noted in documentation, ages and within the EP	The employer must review and update the EP related to pregnancy enquiries to ensure that the ages are correctly listed and ensure that the EP comprehensively details	**Regulation 6 (8)** **Schedule 2 (C)**	The programme will review and update the EP related to pregnancy to ensure the ages are correctly listed and ensure that the EP comprehensively	DP	4 months

		where to document client responses.		details where to document client responses.		
7.	**Practical aspects of clinical evaluation** Breast screening and the symptomatic service use separate systems to record imagine. There is a potential risk of duplicate referrals, where a client would receive an invite for screening, despite being on the symptomatic pathway which would not be documented in the breast screening administrative systems.	The employer must work towards a more comprehensive solution in relation to evidencing previous imaging whilst continuing to mitigate the risks of duplicate imaging.	**Regulation 10 (5)** **Regulation 11(4)**	To mitigate the risk of a screening participant having a mammogram within 6 months of a previous symptomatic mammogram the process around checks was reviewed and strengthened. This has been undertaken with the employer procedures and also the work instructions. It is clear to staff that not to proceed with mammogram if the participant is unsure if they had a previous symptomatic mammogram in the previous 6 months. The participant will be asked if can check or if feasible the staff on the mobiles will	SH	Mitigations in place until new PACs is implemented across Wales – 2 year timescales

				make attempt to check by phoning back to site or phoning HB service but that will depend on available time within the clinic. This work has included reaching out to other breast screening programme in UK to explore their processes to mitigate this risk. Fact finding showed that there was variation across the UK breast screening services with access to live IT systems on the mobiles and processes. Discussions have been held with IT colleagues and PACs manager to discuss feasibility of live access. This is not currently feasible due to:		

				Set up of live connections on mobiles is complex and would need to address method, connectivity, cyber security, support costs and financial resource. This would be a significant work plan which is not resourced to take forward currently. The current PACs system in place in Wales does not allow access for radiographers to view history across Wales. Therefore if live access was available now then the information would not an improvement from the current information on NBSS. There is an All Wales project established to change the current PACS system and		

				Radiology Information System across Wales. One of the benefits of this will be to improve cross Health Board access of the PACS and Radiology Information System. PHW went live on the new PACS system in March 2025 but this will need the Radiology Information System to be fully implemented before full access across Wales is possible. Full implementation will take at least two years. Live connectivity on the mobiles will be kept as an aspirational aim and this will have most benefit once the All Wales PACS and Radiology Information System in fully implemented.		

8.	**Clinical audit** No annual clinical audit schedule was available for review	The employer must document a clinical audit schedule to ensure that themes are audited appropriated with learning outcomes in place.	**Regulation 7**	The Programme will collate the planned audits into an audit schedule and share learning from the outcomes.	DP and Regional Radiography Managers	4 months
9.	**Clinical audit** Some clinical audit report findings were not consistently reported and some lacked evidence of in-depth analysis and re-audit schedules.	The employer must ensure that there is a standardised approach to the reporting of audits, the learning actions to be implemented in the audit results and whether there is a need for reaudit. The employer should aim to keep reaudit timeframes short until 100% compliance is achieved for IR(ME)R compliance audits.	**Regulation 7**	The programme will ensure that all clinical audits are completed using the standardised approach and be clearer on the learning actions and if need to reaudit. The reaudit timeframes will be kept short until 100% compliance is achieved for IR(ME)R compliance audits.	Regional Radiography Managers	4 months
10.	**Authorisation Guidelines** The review of the document along with discussions with some staff indicated that	The employer must review and update the authorisation guidelines. Also ensuring staff have a clear understanding of the process for justification and	**Regulation 10 (4) , 11(5)** **Schedule (1) (b)**	The programme will review and update the authorisation guidelines as detailed to ensure it is clear the process for	DP	4 months

	there were some improvements needed to the guidelines to make them more robust.	authorisation. Evidence of authorisation must be recorded and audited to ensure compliance with IR(ME)R.		justification and authorisation. Authorisation will be recorded and audited.		
11.	**Carers or comforters** Suggestions for improvements were made to make the EP more robust.	The employer must review and update the carers and comforter EP in line with inspection feedback, with a view to making it more robust.	**Regulation 6 Schedule 2 (1)(n)**	The programme will review and update the carers and comforter EP in line with inspection feedback.	DP	4 months
12.	**Equipment** The equipment inventory did not include all the information required within IR(ME)R.	The employer must update the equipment inventory to include all requirements within IR(ME)R regulations.	**Regulation 15 (2)**	The programme will update the equipment inventory to include all requirements within IR(ME)R regulations	DP	4 months
13.	**Efficient** We were not able to review all sites of BTW but were advised that systems and processes are consistent across Wales.	The Employer must continue to ensure that improvements are consistently implemented throughout Breast Test Wales.	**Regulation 6**	To confirm that the systems and processes that were inspected in Swansea are the same processes in place throughout Breast Test Wales.	Complete	Complete

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):  **Dr Sharon Hillier**

Job role: **Director Screening Division**

Date: **27 May 2025**