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

Diagnostic Imaging Department, Singleton Hospital, Swansea Bay University Health Board

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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

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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.



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1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulation (IR(ME)R) inspection of the Diagnostic Imaging Department at Singleton Hospital, Swansea Bay University Health Board on 11 and 12 February 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, Diagnostic Imaging from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity.

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 66 questionnaires were completed by patients or their carers and 38 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:

Patient responses to our questionnaire all rated the service as 'very good' or 'good'. Bilingual posters informed patients about X-rays and to advise staff if they might be pregnant or breastfeeding. Health promotion materials were displayed in waiting areas, covering topics like healthy lifestyles and smoking cessation.

Staff were observed being kind and courteous, going out of their way to support patients. Privacy and dignity were generally respected, with gowns and screens provided, although some changing cubicles were across a public corridor, posing potential dignity issues. The waiting area in CT2 was clean and newly refurbished, while other areas had peeling paint.

Patients told us they were treated with dignity and respect, with staff listening and answering questions. Most patients were involved in decisions about their care and received information on post-examination self-care. Waiting times were communicated effectively and the department had processes to assist patients with hearing, sight and reading difficulties. Bilingual appointment letters were sent, though they lacked information on procedure risks and benefits. Accessibility features included wheelchair access, translation services, and advocacy support.

This is what we recommend the service can improve:

• Include benefits and risk of procedures in the appointment letters.

This is what the service did well:

- Treating patients with dignity and respect
- Ensured the department was accessible.

Delivery of Safe and Effective Care

Overall summary:

Employer's procedures were in place as required by IR(ME)R with regular reviews and updates. Updated documents were uploaded to iPassport, a cloud-based system and staff were sufficiently informed via email and meetings. Staff electronically signed to confirm they had read the updated documents, ensuring compliance was monitored.

Based on conversations with the department, the self-assessment form completed and comparison with documents to the regulations, we noted that various updates to documentation were being introduced to reflect the recent amendments to the relevant regulations. Specific feedback in relation to individual employer's procedures and documentation was shared as part of the review of the SAF during the inspection.

Local Diagnostic Reference Levels (DRLs) were established and monitored, with national DRLs appropriately used where local ones did not exist. Staff were aware of DRLs and the process to follow where DRLs were persistently exceeded.

The entitlement process for referrers, practitioners, and operators was described, with annual reviews during appraisals. Procedures for patient identification and pregnancy checks were in place, though some additional details needed to be included.

The procedure for clinical evaluation required additional detail regarding responsibility and the recording of clinical evaluation. Appropriate entitlement must support this role.

Accidental or unintended exposures were reported and discussed. Near misses were recorded and discussed internally at the Medical Exposure Group (MEG).

The employer's procedures for operating the mini C-arm in theatres required further review and documentation updates.

This is what we recommend the service can improve:

- Update employer's procedures and associated documents with the areas identified
- Relevant process needed to be amended to reflect the information in the various procedures.

This is what the service did well:

- Documents were kept in iPassport and staff were updated through this system of changes to documents
- Local DRLs were established where there was sufficient dose information.
- Good clinical audits noted
- Medical Physics Expert support was good.

Quality of Management and Leadership

Staff members who completed the questionnaires responded positively about the quality of care and support provided to patients. Most recommended the hospital as a good workplace.

The Chief Executive was designated as the employer under IR(ME)R 2017, with delegated tasks to other professionals. The management team was committed to learning from HIW's findings and making necessary improvements. Clear lines of leadership and responsibility were noted.

Staff were aware of the policies relevant to their practice and understood their roles under IR(ME)R and the health and care quality standards. Regular monthly meetings and online platforms facilitated information sharing.

Management engaged with staff through an open-door policy and regular presence in the department. Staff felt supported in raising concerns and reporting issues.

Induction and training programs were tailored to individual staff members, with competency assessments and mentorship. Staff understood the Duty of Candour standards, with training provided. Compliance with mandatory training was generally high, but online oxygen cylinder training needs improvement.

The department offered an out-of-hours service and staff were trained on all equipment before participating in night shifts.

Positive actions on health and wellbeing were noted, with low sickness levels and a good work-life balance.

This is what we recommend the service can improve:

- Ensure that training records and competency assessment records are clear and evidenced
- Engaging with staff with less favourable comments on the service.

This is what the service did well:

- Staff understood their roles under IR(ME)R
- Positive management engagement with the inspection process
- Compliance with mandatory training requirements
- Making the main department a positive place to work.

3. What we found

Quality of Patient Experience

Patient feedback

HIW issued online and paper questionnaires to obtain patient views on services carried out by Singleton Hospital to complement the HIW inspection in February 2025. In total, we received 66 responses from patients at this setting. Responses were mostly positive across all areas, with all respondents rating the service as 'very good' or 'good'. Some comments we received about the service and how it could improve, included:

"Overall, everything was perfect no complaints."

"Fantastic service provided by the staff in CT for my mother's recent scan. The staff treated my 94-year-old mother with the upmost dignity & respect. They kept her informed during the entirety of the scan, ensuring she had understood the procedure."

"I was very nervous coming in for my appointment today, but the staff members were so lovely and helpful they made me feel at ease."

"Reception area was very open, and other patients were able to hear my personal details. Scan room was very clean, but the toilet area was in desperate need of a refurbishment. Clean, but in need of urgent refurbishment. Staff were always courteous and treated me with respect from the moment I entered to the moment I left the department. Was amazing! The NHS staff are superb and need more recognition."

"Signage was very poor in the hospital in comparison to nearby Prince Philip Hospital. There was a mix of old out of date signage and paper signage stuck up with sticky tape. Looks very unprofessional and does not inspire confidence in the quality of the service. Also, saw the staff in radiology using paper forms. I saw completely paperless systems being used in Bristol, over 10 years ago."

Person-centred

Health promotion

Bilingual posters, in Welsh and English, were displayed that provided information to patients about having an X-ray and also to advise staff if they may be pregnant

or breastfeeding. Relevant information was made available to patients about the associated risks and benefits of the intended exposure on various posters.

Health promotion material was displayed in the waiting areas within the department. This included information on the benefits of adopting a healthy lifestyle and smoking cessation.

Dignified and respectful care

During our time at the location, staff were seen to be kind and courteous to patients. Staff went out of their way to support patients; we noted examples such as staff looking for a phone and walking someone back to their car. Staff spoke to patients in a reassuring and kind manner. Patient privacy and dignity was respected, there were gowns for patients to wear in all rooms and screens were used. However, the layout of the department meant that some changing cubicles were across a corridor from the imaging rooms. This was a potential dignity issue for patients that needed to change into gowns and walk across and along a public corridor. We also noted one patient waiting to go in for imaging in a gown with a moveable screen but they could still be seen from the corridor.

The health board should continue to review the arrangements in place to protect patient privacy and dignity, particularly regarding the location of the changing rooms compared to the examination rooms.

That being said we heard staff ensuring that patient changing cubicles were locked to protect dignity. When patients were late to appointments due to patient transport delays, they were always seen by staff and reassured before during and after the imaging.

The waiting area for patients waiting to receive their imaging examination in the room known as CT2 was clean, bright and tidy, and had been newly refurbished. Other waiting areas were not in the same condition with some peeling paint on walls. However, there were new high-backed chairs with arms in the waiting areas, which assisted patients with limited mobility. There were areas where staff could have sensitive conversations with patients where they could not be overheard by others. The imaging examination room doors were seen to be closed when in use, with signs on the doors when the imaging occurred.

All patients in the questionnaire felt they were treated with dignity and respect and felt staff listened to them and answered their questions. All patients agreed that measures were taken to protect their privacy. Almost all patients were able to speak to staff without being overheard by other patients or service users. All but two respondents thought patients' privacy and dignity was maintained and agreed patients were informed and involved in decisions about their care. Many respondents felt there were enough staff for them to do their job properly and said they had adequate materials, supplies and equipment to do their work.

Individualised care

All but one patient in the questionnaire felt they were involved as much as they wanted to be in decisions about their examination and all patients said that staff explained what they were doing. Most patients said they were given information on how to care for themselves following their examination. Some comments we received on patient care were:

"Staff were so kind and helpful to me when I was anxious."

"The staff were very friendly and kind. They seemed happy in their work. They made sure that I was okay and that I understood what was happening."

"Staff were lovely and friendly throughout my scan. I was very nervous and was re-assured by multiple staff members, which made the whole examination a lot nicer that I was expecting. She calmed and made me feel at ease. I was grateful to sit in the little room beforehand whilst she put a needle in my arm. She also spoke Welsh, which made my care lovely to have in my first language. Lots of chances to ask questions, of which I am grateful, I didn't feel rushed at all..."

"The staff were very nice and friendly helped me complete the X-ray. Made me feel at ease. It would be nice to know how long it will take to be seen. Although nobody seemed to wait very long. The monitor could be used intermittently for wait times or calling names."

"I was treated with respect and dignity and staff were very polite and friendly. My hearing wasn't brilliant so I felt that a visual monitor for name calling for appointment would be very helpful."

Timely

Timely care

Staff we spoke with explained the arrangements for communicating waiting times to patients within the department, including verbally informing the patient of any delay. During the inspection, patients were being seen at the arranged appointment time. Radiographers we spoke with said they would let staff in reception know if there was a delay.

All respondents to our questionnaire agreed that the wait between referral and appointment was reasonable, 77 per cent(%) of patients said that at the department, they were told how long they would likely have to wait to be seen.

Equitable

Communication and language

The department had a number of processes to help people with difficulties with hearing, sight and reading signs and information leaflets, these included bilingual posters. Staff said they would adapt their technique to provide clearer instructions to patients.

There were arrangements in place for patients unable to communicate in English, via a language line. Staff would normally be aware of the need for a translator through an alert on the radiology information system (RadIS). There were several Welsh speakers in the department and there was a list of staff who were Welsh speakers displayed in clinical areas, who would be available to speak to patients in Welsh. Staff were seen wearing a 'iaith gwaith' badge on their uniform. There were also signs displaying the active offer to patients in the various areas of the department.

The appointment letters sent out by the department were bilingual in Welsh and English. However, the benefits and risks of the procedures were not on the appointment letter sent out, to enable patients to make an informed choice of the need for the examination.

The health board must ensure that benefits and risks are included in the appointment letters.

There were various forms of signage to direct patients and visitors to the radiology department.

Only six patients said that Welsh was their preferred language and two of the four that answered said they were actively offered the opportunity to speak Welsh throughout their patient journey. One patient commented in response to the question "did that make a difference to you?":

"Absolutely! We are in Wales after all. I did notice some signage to say that Welsh was spoken in the hospital, but not many had it on their uniform. So, it was a little difficult to know who could speak Welsh."

Rights and equality

The arrangements in place to make the department accessible to patients included wheelchair access to the department. Whilst the department was accessible and easy to find, we noted patients asking for directions. There were facilities for people with mobility and disabled access. The environment was clean and generally reasonably well maintained. Most patients said they were able to find the department easily. However, patients commented:

"Better signposting for afterhours appointments. Difficult to know where the waiting room was."

"... The signage could be improved, I found it difficult to locate the X-Ray department and had to ask a volunteer for help. Maybe a map on the back of the appointment letter would help. Toilet facilities were in need of improvement, but plenty around. Overall, a pleasant experience, considering I was so nervous and embarrassed of my X-ray."

We were told there when a patient did not attend an appointment, the department would always endeavour to re-book an appointment and contact the patients rather than just returning the form to the referrer.

There were wide corridors with large imaging rooms and disabled toilets. We were also told that the department were sourcing an Auracast hearing loop, a feature that allowed an audio source to broadcast one or multiple audio streams to an unlimited number of receivers, like Bluetooth earbuds or hearing aids.

Staff we spoke with described the arrangements in place to ensure equality and diversity was promoted within the organisation. This included Calon, the health board's lesbian, gay, bisexual, transgender plus (LGBT+) and allies staff network, which aimed to create a safe space and a community for likeminded colleagues to come together. Staff also referred to an equality and diversity policy as well as mandatory training. There were also neurodiversity groups and staff were seen wearing lanyards for 'Pride Cymru', a charity that promoted the elimination of discrimination.

Staff had a good awareness of their responsibilities in protecting and promoting patients' rights when attending the department, as well as staff rights when working in the department.

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

We noted that there was a quality assurance programme for written procedures. The procedures were reviewed every two years and protocols were updated annually or when any changes to practice occurred.

Updated documents such as employer's procedures would be uploaded onto iPassport, a cloud-based system to improve quality management, and assigned to the relevant staff groups. Staff were also informed of updates to employer's procedures via email and staff meetings. This detail was covered in the quality assurance imaging protocol but was not reflected in the employer's procedure. Once staff read the updated document, they would then electronically sign to confirm reading the document. As a result, the department had an electronic record of the duty holders who had read the employer's procedures and could monitor this via a dashboard on iPassport for compliance.

Following review of the self-assessment form (SAF) and discussions with the service, a discrepancy was identified. The self-assessment form (SAF) completed by the department stated that the Radiology Clinical Director would be responsible for authorising the employer's procedures. The employer's procedure stated that the Service Manager would authorise the employer's procedures.

The employer must ensure that employer's procedure on quality assurance programmes accurately reflects the individual responsible for authorising the employer's procedures.

The employer's procedures were well laid out, with version control including issue date, review date and page number. The front page also had a lead author, reviewed by, accountable executive, approved by, signature, approval date and an issue date.

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

The written protocols in place for standard radiological practice (including non-medical imaging procedures) were electronic protocols and were available for imaging patients in general X-ray, mobiles, fluoroscopy, computerised tomography (CT) and the breast unit. The protocols were reviewed bi-annually as per the document version control or if any change in practice was made, the protocols were also available on iPassport. All protocols were signed by the modality lead and site lead radiographer following review. One printed copy was available for staff in the site lead radiographer's office for business continuity.

Within the plain film protocols, some terminology used left it ambiguous regarding who was responsible for justification and authorisation.

The employer must ensure that the department reviews imaging protocols regarding sentences which may be confusing in relation to duty holder's roles

That being said the appendices contained good detail to support staff. Some sections described additional views well. There was good detail included in the fluoroscopy protocols. Regarding the CT protocols, they would benefit from further detail similar to the general radiography protocols.

The relevant employer's procedure for the quality assurance of IR(ME)R employer's procedures and equipment noted that documents must be reviewed every two years. The delegated authorisation guidelines (DAGs) however appeared to be reviewed every four years. The DAGs referenced IR(ME)R 2000. The mammography DAG did not have a listed IR(ME)R practitioner responsible for the exposures authorised under this DAG.

The employer must ensure that the:

- DAGs are all updated to ensure that they refer to IR(ME)R 2017
- DAGs are reviewed in line with the relevant employer's procedure
- Mammography DAG must clearly identify the IR(ME)R practitioner responsible for the exposures.

Referral guidelines

The clinical referral guidelines, iRefer, were available to all healthcare professionals employed in NHS Wales and were also available from the health board intranet. All general medical council (GMC) registered medical practitioners and general dental council (GDC) dental practitioners were entitled to make a referral.

We were told that referrals for most of the diagnostic imaging were made via a paper referral form. The department were currently piloting an e-referral system where selected wards and departments could make electronic referrals for imaging.

The employer's procedure for referral and referral criteria described a process whereby an individual signed the referral on behalf of the surgeon. On discussion with staff, this did not reflect clinical practice. The surgeon completed the referral in advance of the theatre procedure.

The employer must ensure that the employer's procedure is reviewed and amended to reflect the clinical practice as described by the service.

There was a health board document called 'responsibilities when referring for radiological imaging' which included information on availability of referral guidelines, this was considered a good resource for referrers. The process for cancelling referrals including how referrers were made aware was described in the SAF. This included where urgent requests and urgent suspected cancer requests were returned to the referrer and accompanied by a telephone call or email to the referrer or referring speciality team to notify them that the examination would not be performed.

Where insufficient clinical information was provided by the referrer, the practitioner would arrange for the referral form to be returned with a template identifying the additional information required. In the event of urgent referrals, the practitioner would arrange for the referrer to be contacted to obtain the relevant information.

The department described monthly IR(ME)R audits. The results of these audits were reviewed at the clinical governance meeting which was held every three months. These discussions were fed back to the teams via the clinical governance report. If a significant issue was identified regarding referrers, it was fed back to the specific referring team. There were audits on the red alert (urgent unexpected finding) system and whether the referrer had acted on the report findings. However, compliance with referrer responsibilities was not included in this routine audit.

Diagnostic reference levels (DRLs)

The employer had a written procedure describing the process for the setting, auditing and reviewing of DRLs established for imaging examinations performed in the department. There was good detail in the employer's procedure on what to include in the DRL exceeded logbook.

Local DRLs were either at or lower than national DRLs for those rooms where a patient dose audit had been conducted. These DRLs were clearly displayed at control panels within the department for staff reference. Staff we spoke with were aware of the correct DRLs to use and of the process to use when local DRLs were exceeded, including using the exceeded DRL logbook. We were told that the site lead radiographer would ensure that all radiology staff were aware of any new or revised DRLs issued by the MPE through verbal and written communication.

Where the DRLs had been exceeded, the operator would make a record in the DRL exceeded logbook. Staff would escalate any concerns immediately. We were told that the logbook was reviewed every six months as part of the routine audit programme. The logbook had a section which had to be signed by the modality lead to evidence regular review. The medical physics experts (MPEs) would be advised should DRLs be consistently exceeded to support investigation and corrective action. The above process must be detailed within the appropriate procedure.

National and European DRLs were used where local DRLs were not available. The procedure did not detail the process of approving a local DRL where it exceeds a national DRL. For the special care baby unit (SCBU) mobile radiography, local DRLs had been established. To support the development of local DRLs for paediatric CT, the department had recently started recording patient weight. It was anticipated this would support ensuring sufficient numbers to determine local DRLs.

DRLs would be reviewed at regular intervals, the MPE analysed the patient dose data provided. The MPE would recommend DRLs and issue these to the site lead radiographer. Local DRLs had not been established for X-ray room one as it was the most recent equipment replacement. National and European DRLs were used for paediatrics, pending sufficient local patient dose data to establish local DRLs.

Medical research

Medical research was not currently performed at the hospital, although it was performed at other sites within the health board. However, an employer's procedure was available and clearly written.

Entitlement

There was a written employer's procedure in place to identify individuals entitled to act as referrer, practitioner or operator within a specified scope of practice. Staff confirmed the entitlement process described in the employer's written procedure was in place for new referrers, practitioners and operators who joined the department. They also confirmed how they were made aware of their duties and scope of entitlement under IR(ME)R.

The entitlement register was reviewed and updated annually following the annual appraisal and job planning interviews where any changes to previous entitlements would be identified. We reviewed the entitlement register, which was held on Microsoft Teams, and these were up to date. The service had updated the local appraisal documentation to identify any changes to scope of practice or entitlement required. The entitlement register was then updated as required.

Patient identification

The employer had a suitable employer's written procedure in place to correctly identify the individual to be exposed to ionising radiation. This also set out the procedure to follow when patients were unable to confirm their identity verbally or in writing such as patients who were unconscious.

Staff we spoke with also had a clear understanding of the correct patient identification process and how to correctly identify individuals who may not be able to identify themselves.

Individuals of childbearing potential (pregnancy enquiries)

There were information posters in various areas of the department to alert patients to inform radiographers if they suspected they may be pregnant. The posters were in several languages. Information regarding pregnancy and informing the radiographer prior to their appointment, if the patient was pregnant was also included in the appointment letters.

Staff we spoke with described the action they would take to make enquires of individuals of childbearing potential to establish pregnancy or breastfeeding, which was consistent with the employer's procedure. Reference was also made to the pilot currently running at the health board, relating to inclusive pregnancy enquiries, with a positive response to date.

We were informed that the operator responsible for checking pregnancy status in theatres was the radiographer. Additionally, the main part of the procedure would benefit for including detail similar to that in section 5.6 (nuclear medicine) to detail the procedure and responsibilities where there is more than one operator present such as in CT. Where it was decided to perform a human chorionic gonadotropin (hCG) test to determine if a patient was pregnant, the patient would be sent back to the referrer or ward if an inpatient. The procedure would benefit from including detail on responsibilities in relation to pregnancy enquiry and hCG testing.

Benefits and risks

The purpose of the employer's procedure for benefits and risk was to ensure that whenever practicable, the individual to be exposed or their representative was

provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure.

Patient information posters summarising benefits and risks from the available exposure modalities were displayed prominently in radiology patient waiting areas. The sample verbal statement in the procedure was good to ensure consistency in communication.

Staff were able to describe the information provided to individuals or their representatives relating to the benefits and risks associated with the radiation dose from exposures. Where the patient or their representative be unsatisfied or unclear about the benefit and risk information provided, they would inform a consultant radiologist who would provide additional information or discuss the issues with the patient. No specific training was provided to assistant practitioners and radiographers on risk benefit communication.

In the patient questionnaire, all but one of the respondents said they were provided with enough information to understand the benefits and risks of the procedure.

Clinical evaluation

We were told that clinical evaluation was performed by a radiologist, suitably trained reporting radiographer or a surgeon for referrals such as theatre and fracture clinic follow up imaging.

Where examinations were clinically evaluated by the surgeon, a canned report is available on PACS. This canned report stated that a formal radiology report would not be issued and if a radiologist's review was required to contact the department. The canned report did not direct the reader to where the clinical evaluation was recorded. The employer's procedure noted in this scenario the clinical evaluation would be available in the patient notes. It may be beneficial to review the canned report and consider including a statement identifying where the clinical evaluation was available. The department could not confirm if the appropriate surgeons were entitled as operators to perform clinical evaluation.

During the patient record keeping checks, for one theatre imaging procedure a radiology report did not appear to be available. A canned report was also not available for this examination. The department could not indicate if, where and how the clinical evaluation for this procedure was recorded. Assurances were required that clinical evaluation had been performed for all exposures (except those to carers and comforters).

From a review of the procedure, further detail on who was responsible for providing clinical evaluation outside of the radiology department.

The employer must ensure that:

- Clinical evaluation has been performed for all imaging procedures, including those performed in theatre
- Duty holders are appropriately entitled to perform clinical evaluation
- Employer's procedure accurately reflects the different processes for clinical evaluation within and outside the radiology department, including the individuals involved and where this is recorded.

Non-medical imaging exposures

There was a written employer's procedure on non-medical imaging exposures using radiology equipment. Non-medical imaging exposures included those performed for insurance or legal purposes without a medical indication.

The procedure did not outline how the referral was identified as a non-medical imaging exposure. Senior staff told us that the referrer would document on the referral that it was a non-medical exposure. It may be beneficial to reflect this detail in the procedure.

Employer's duties: clinical audit

There were monthly clinical and educational meetings across the health board. Audits were presented at the meetings and the results of the audit were discussed by those present. Any decisions would be shared with relevant staff within the department in the minutes of the meetings.

The minutes of these meeting were good and outlined the audits well. There were also good clinical audits and evidence of robust discussions regarding audit results.

We were told that the department was currently reviewing how they tracked IR(ME)R and clinical audits in terms of processes within the health board. Once the process had been agreed, the relevant procedure would be updated to reflect this. They were previously using an audit management and tracking tool which they were exploring returning to use, for monitoring and audits. The department did not have a clinical audit programme available but they did evidence a clinical audit schedule for nuclear medicine.

The employer must ensure that there is a clinical audit programme for the radiology department.

Examples of clinical audits carried out in the department were seen, including an audit to assess best practice and dose optimisation for a CT scan of the kidneys, ureters and bladder (KUB). The audit findings were shared across all three sites in the health-board to be shared with relevant staff.

Another example was an audit on plain film X-rays to assess compliance of anatomical marker use. As a result of this audit, staff had been reminded of the importance of using a physical anatomical marker. This was then re-audited and there had been an improvement in the overall percentage of images with a marker placed in the primary beam.

Some audits did not contain all aspects as listed in the employer's procedure, such as references to reaudit (for the audit on record keeping) and the target compliance was not clearly identified.

The employer must ensure that the clinical audit report template contains the relevant aspects outlined in the employer's procedure.

Whilst we saw the audit programme evidenced the audit of RadIS and referral forms, there were audits on other IR(ME)R aspects which could be reflected in the programme, such as, clinical evaluation, optimisation, referrer responsibility and entitlement records of duty holders. It may be beneficial to audit compliance in relation to these aspects. The department were regularly auditing the red alert system and monthly turnaround times but the schedule did not reflect this.

The department described the process where discrepancies regarding compliance were identified. The quality assurance (QA) lead radiographer had developed resources to support staff using iPassport, where this document was available. Several clinical governance reports were also visible on iPassport.

The employer must ensure that:

- The audit schedule reflects the audits of the red alert system and monthly turnaround times which are currently being performed
- Where audit findings identify required actions, these actions are carried out.

Employer's duties: accidental or unintended exposures

Staff we spoke with were aware of the procedure for reporting accidental or unintended exposures and described this appropriately. Learning from incidents

would be shared at monthly staff meetings where incidents would be discussed anonymously.

The SAF provided, described how the referrer, practitioner and the individual (or their representative) were informed of a clinically significant unintended or accidental exposure and were provided with the outcome of the investigation into the event.

There was good detail in the employer's procedure about when equipment faults occurred. The procedure was ambiguous in terms of identifying who was responsible for deciding if an incident was a CSAUE. The department confirmed that the radiologist, following discussion with the referrer, determined if an incident was to be considered a clinically significant and accidental or unintended exposure (CSAUE). The procedure defined a CSAUE focusing on the stochastic effects and referenced the professional body guidance in relation to this. The professional body guidance also described psychological harm in terms of CSAUE, which was not covered in the definition in the procedure.

The procedure did not describe the process where a decision was made not to inform a patient, however it was described in the SAF. Additionally, the reference for SAUE criteria was out of date.

The employer must ensure that the employer's procedure:

- Accurately reflects who is responsible for determining if an incident was to be considered a CSAUE
- Reflects the detail described in the SAF and by staff during the inspection
- Includes the full definition of a clinically significant accidental or unintended exposure, including reference to moderate harm or psychological harm in line with the professional body guidance currently referenced
- The reference to the SAUE criteria is updated.

Senior staff we spoke with described the process in place for reporting near misses. The near misses would be recorded on Datix (local incident reporting system) and discussed along with incidents and near misses were discussed at the Medical Exposure Group (MEG). The remit of this group was to identify trends with a view to taking the actions further, trends could also be escalated to the employer via the MEG. The trend analysis was documented within the clinical

governance report. The department had also introduced a reflection statement following an incident.

Duties of practitioner, operator and referrer

The SAF described how entitlement was delegated from the chief executive to the executive medical director. The summary of responsibilities in the policy on implementation of IR(ME)R demonstrated the lines of accountability and noted the medical exposure group (MEG) was authorised by the executive medical director to authorise individual clinical directors and service managers to entitle practitioners and operators.

Training records were maintained and the competency for the scope of practice was assessed by the modality lead or senior radiographer where appropriate. For non-medical referrers, there was a discrepancy in terms of training requirements between the relevant employer's procedure and the policy on implementation of IR(ME)R 2017.

There was good use of tables to demonstrate the responsible individuals for entitlement. However, there were some discrepancies noted between the table in the employer's procedure and the document 'list of individuals authorised by the medical exposure group to entitle IR(ME)R duty holders'. It was unclear who was responsible for entitlement of clinical directors where they acted as a duty holder. The service confirmed the clinical directors were entitled by the executive medical director for duty holder roles.

There were some discrepancies noted between the employer's procedures and the SAF in relation to entitlement of non-medical referrers (NMRs). The service confirmed the clinical director for radiology was responsible for entitling the non-medical referrers (NMRs). Following discussion with the department they felt a revision of the language used would provide clarity between the individual responsible for coordinating the NMR entitlement and the individual responsible for entitling the NMR. On the NMR entitlement form there were several signatures present and it was unclear who was responsible for assessing competency and who was responsible for entitlement.

The employer must review the relevant procedure and:

• Ensure consistency between the relevant procedure and supporting documents regarding individuals responsible for entitlement, including the entitlement of clinical directors where relevant

 Ensure clarity regarding the individuals responsible for assessing competency and entitlement for NMRs, and that this is reflected on evidence of entitlement.

All general medical council (GMC) and general dental council (GDC) registered medical staff were entitled to refer for radiological imaging by the executive medical director. This was communicated to the relevant staff at induction.

We discussed how the employer was assured the referrer was aware of their responsibilities and how the referrer was aware of their scope of practice. The department noted referrers had IR(ME)R training during induction. The medical director sent reminders to the referrers (medical) about their responsibilities.

In terms of scope of referral, the department noted that medical referrers could refer for anything. However, further discussion identified that there were specialist examinations which some medical referrers would not be entitled to refer for. This was not reflected in the scope of referral for medical referrers.

The employer must review the process of entitlement for medical referrers with consideration of how the referrer is notified of their entitlement and scope of referral.

The process by which named individuals or groups of individuals were entitled as practitioners was described in the SAF. This included that newly appointed radiographers as well as locum and agency radiographers underwent a period of training and competency assessment to practice as a practitioner. Radiologists and medical staff were informed at their induction of their entitlement.

The SAF referred to the fact that radiologists were assessed during their training and following competency assessment were entitled by the Radiology Clinical Director. Equipment competency assessment forms reviewed were detailed.

The process by which named individuals or groups of individuals were entitled to act as operators (including locum or agency staff) was described. All newly appointed radiographers including locum or agency radiographers, would undergo a period of training following appointment and would not be entitled as operators until assessed as being competent. Newly appointed and locum radiographers would have access to iPassport to read and confirm they understood the health board employer's procedures, departmental local rules and protocols.

The process by which each operator or group of operators were made aware of their entitlement and scope of practice was explained. The example entitlement and scope of practice review forms provided in the employer's procedures were good. Senior staff told us that the department was currently updating procedure regarding the review of scope of practice. The relevant procedure will be updated to reflect these changes.

The MPEs who performed operator tasks were entitled appropriately. The MPE entitlement matrix was reviewed and categorised scope of practice well, in terms of types of testing.

Justification of individual exposures

There was an employer's procedure for the justification and authorisation of a medical exposure. Staff we spoke with identified what they would consider when justifying exposures and where authorisation of exposures were recorded. Referrals were first vetted by radiographers prior to patients being invited to attend for an appointment. During vetting the urgency of the referral was determined, the referral was not justified at this point. The referral was justified on the day of the appointment. The procedures did not provide clarity on who was the practitioner on the exposure pathway, considering the role of the radiographer performing the vetting task.

The employer must ensure that the procedure for the justification and authorisation of a medical exposure is reviewed to:

- Clarify what aspects come under the task of vetting (for example prioritisation of the referral)
- Clarify who was acting as practitioner and when justification occurs in the patient pathway
- Ensure staff were aware of roles and responsibilities.

Optimisation

Staff we spoke with described how practitioners and operators ensured doses were as low as reasonably practical (ALARP). Staff we spoke with were aware of how to ensure that doses were ALARP, by optimising, ensuring positioning is correct and accurate centring. Also, they referred to using positioning aides, collimation and good positioning.

There were no imaging optimisation teams (IOT) for general x ray, fluoroscopy and mammography currently. However, we were told that mammography was in discussions about establishing an IOT, particularly to support the restructuring of services.

The process of optimising the exposure for individuals in whom pregnancy could not be excluded was described in the appropriate employer's procedure. If the examination could not be deferred, justification could only be performed by a consultant radiologist.

The MPE was involved in optimisation for all radiological practice. MPEs also linked between other hospitals within the health board and assisted with the standardisation of best practice.

Paediatrics

To optimise exposures to children, radiographers would use the digital equipment whenever possible for general X-ray examinations. Paediatric protocols were used for paediatric patients, based on the patient's age. The preset exposure factors would then be optimised to account for body habitus and size. Additionally, suitable collimation would be used to reduce dose and scatter.

We were told that there was a paediatric fluoroscopy list once per week and there was a paediatric radiologist on the site. The only paediatric CT imaging performed on the site was non-contrast CT. The CT lead had been liaising with a paediatric CT lead based in a paediatric hospital to further support staff with paediatric CT imaging.

National and European DRLs were used for paediatrics. To support the development of local DRLs for paediatric CT, with ongoing work towards establishing local paediatric CT DRLs.

Carers or comforters

There was good detail noted in the written employer's procedure for establishing dose constraints and guidance for the exposure of carers and comforters.

The SAF explained the process for the justification of exposures to carers or comforters. The operator initiating the exposure was responsible for ensuring that carers and comforters were advised of the benefits and risks associated with being close to the patient during an exposure prior to the exposure being made. There was a DAG in place for exposures to carers and comforters in CT. It must be clear on the document who was the practitioner responsible for the exposures of carers and comforters under the DAG.

The employer must ensure that the DAG for carers and comforters in CT clearly identifies the practitioner responsible for exposures under the DAG.

The SAF further described the guidance for the exposure of carers and comforters to ensure that they were provided with adequate information on benefit and risk to inform their decision to 'knowingly and willingly' incur their own exposure from remaining close to a patient during an X-ray examination.

Staff we spoke with were aware of the guidance in relation to carers and comforters and described the process including completing the carers and comforters consent form.

Expert advice

The involvement of the MPEs in the department was detailed in the SAF and considered good. There was good MPE support with training workshops, instructional videos and training sessions for staff. We confirmed the employer for the X-ray department had appointed and entitled MPEs to provide advice on radiation protection matters and compliance with IR(ME)R 2017.

The MPEs noted difficulty with recruitment of MPEs as well as training staff to be MPEs. They were currently prioritising high-risk workload such as CT and interventional work as well as dose audits. There was a workforce plan in place.

In terms of quality control testing, we were told that level B X-ray testing, carried out by MPE's, was sitting at 96% compliance. Patient dose audits and DRL reviews were 50% complaint as these required more MPE input. The Medical Exposure Group and Radiation Protection Group were aware of this and it had been escalated further.

Following the amendments to IR(ME)R, the service had an action plan in place with expected timeframes and individuals responsible for actions. The MPE had advised the Director of Allied Health Professions and Health Science (DAPHS), who then informed all responsible managers about the changes required following the amendments.

There was ongoing work in relation to managing compliance with IR(ME)R in the theatre environment, particularly with the mini c-arm. Procedures involving the mini c-arm come under the scope of a separate set of employer's procedures. There had been engagement from theatres on this and this piece of work was ongoing, with focus on identifying appropriate individuals responsible for managing compliance in these areas. The MPE noted they would be reviewing the DRL established for the mini c-arm as it was in an unusual format.

Equipment: general duties of the employer

There was an employer's written procedure in place to ensure a quality assurance (QA) programme in respect of equipment was followed.

The example of the QA spreadsheet seen contained good record keeping, with clear trend analysis and baselines established. The 'handbook for quality assurance in diagnostic imaging' document was also reviewed during the inspection.

There was a modified AXREM² form in place for handover of equipment. We were informed that the core QA team performed the quality control (QC) testing. The team described the QC training provided however training and competency was not evidenced. It would be beneficial to evidence this. The department were currently exploring cascading QC testing training to other team members.

The National Capital Imaging Equipment Priorities Group (NCIEP) was responsible for the process of replacement of high value items of radiological equipment across Wales. This was an independent expert panel scrutiny to ensure that purchases were prioritised appropriately. The MPEs sat on this panel to advise on radiological equipment purchases with regard to existing equipment performance and issues.

Equipment inventory was held within a live database for the health board. The year of manufacture was not currently included in this document.

The employer must ensure the equipment inventory is updated to include the year of manufacture.

Safe

Risk management

The risk assessment process was described, which included escalation as required to the directorate risk register and potentially onto the clinical board risk register.

Senior staff we spoke with described the procedure for reporting accidental or unintended exposures or other incidents. Staff would inform the radiation protection supervisor entered the incident on DATIX and contacted the MPE for a dose assessment. Relevant incidents would be reported to HIW. Staff would also reflect on the incident. Learning from incidents, as well as IR(ME)R incidents was shared at monthly staff meetings as well as discussing the clinical governance report sent via iPassport. We were also told that safety notices, alerts and other communications would be shared with staff and acted upon where required.

² AXREM was formed originally as the Association of X-ray Equipment Manufacturers. However, as technology advances have increased the scope of diagnostic imaging and treatment modalities the Association is now represented by the strap-line - Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care

Imaging rooms were in a good state of repair, with murals and were freshly painted although the corridors needed some attention. There was a plentiful supply of chairs. Whilst some changing rooms were used for storage of cleaning trolleys there were still changing rooms available.

Infection prevention and control (IPC) and decontamination

All areas inspected were visibly clean and tidy and the environment was generally well maintained. Personal protective equipment (PPE) was readily available for staff to use. Suitable handwashing and drying facilities as well as hand sanitiser were also readily available within the department.

Staff we spoke with were able to describe the arrangements for infection control and referenced the cleaning equipment they would use, including the different type of cleaning wipes used for different equipment. They were also able to access the IPC policy on the health board intranet. There was a specific room available furthest away from the waiting room which would be used for any infectious or symptomatic patients who attended for a procedure.

All patients who expressed an opinion in the questionnaire said that IPC measures were being followed and all who answered felt the setting was clean. All but one member of staff thought there were appropriate infection prevention and control procedures in place and that appropriate PPE was supplied and used. All bar one thought there was an effective cleaning schedule in place and most said the environment allowed for effective infection control.

Safeguarding of children and safeguarding adults

Staff we spoke with were aware of their responsibilities around reporting safeguarding concerns and described the process they would follow. This included being able to speak to the safeguarding team where necessary. They were also aware of where to find the relevant information. Senior staff described a suitable process for responding to safeguarding concerns.

A policy with a flowchart listing phone numbers to call was available in staff areas. We examined training information for a sample of three staff and saw that they had all attended safeguarding training at a level appropriate to their role.

Effective

Patient records

A sample of five current patient referral documentation and five retrospective patient referral documentation were examined. The sample showed that the referral records had been completed fully to demonstrate appropriate patient checks had been performed. This included patient identification, sufficient clinical

details, enquiries made of pregnancy status where applicable, justification had been carried out and the referral appropriately signed by an entitled referrer.

During the check of patient referral records, we noted a theatre case which did not have a canned report or a clinical evaluation recorded on the Picture Archiving and Communication System (PACS). Assurance was required that clinical evaluation had been performed for this cohort and was accessible. Following this, ensuring employer's procedures were updated appropriately to reflect this cohort of procedures.

Efficient

Efficient

We spoke with staff about the arrangements or systems in place to promote an efficient service. They referred to the digital rooms producing improved image quality whilst optimising radiation dose and the new shift system implemented. The shift pattern resulted in an extended working day. There was also additional capacity in the department that enabled a 12-hour working day on a Saturday to maintain referral to examination times and reduced the backlog for diagnostic imaging.

Mini C-arm

We noted from the SAF that there was a mini-C-arm being used in theatres. As described earlier in this report, procedures involving the mini c-arm were within the scope of a separate set of employer's procedures. The mini c-arm employer's procedures were reviewed.

Unfortunately, due to the unavailability of relevant staff during the inspection, it was not possible to establish compliance with IR(ME)R in relation to the mini carm. We were unable to review evidence of entitlement, referral, authorisation and clinical evaluation in relation to this. We therefore contacted the employer separately with our concerns about the employer's procedures, the referral for the exposures, entitlement records and audits.

Quality of Management and Leadership

Staff feedback

HIW issued an online questionnaire to obtain staff views on services carried out by Singleton Hospital and their experience of working there. The questionnaire complements the HIW inspection in February 2025. In total, we received 38 responses from staff. We also received responses from six members of staff who worked in the department, but their work was not covered by IR(ME)R. Whilst their comments were not included in this report, we have written separately to the department and directorate with the comments.

The health board is required to reflect on some of the less favourable responses from staff and inform HIW of the actions it will take to address these.

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

We received several comments on the service and how it could improve, some are shown below:

"Our department is so lovely to work in. Our Line Managers go above and beyond to ensure their staff are happy and feel evolved in decisions about our department. It's a pleasure to work with my bosses. We have a great team spirit - when the going gets tough the tough get going.....together!"

"Patient care is paramount in the unit and the high standard of care received is noted with patient's feedback, cards and biscuits for all the team. I feel that we go above and beyond for patients, when one can, compared to other outpatient departments in the hospital. I believe we provide a very high standard of care throughout a patients visit. We do need a bigger unit, and I believe that this is finally being addressed so that we are on one site."

"In my opinion Singleton radiology is excellent at keeping wait times for patients down and being flexible with patients. If a patient is late, we don't turn them away - we will always make room for them to ensure they get seen so. Similarly, if they have a pending X-ray or scan that can be done on the same day as a different appointment, we will try our

best to get that sorted the same day to save them having to come back."

"I feel that we all provide a high standard of care to our patients, we work well as a team, and I am very happy within my department."

"The department successfully identified a need for more staff. It has recently employed more staff so hopefully time for training and development should be possible now new staff are trained and competent. The inspection has been a fantastic motivator to prioritise best practice."

Leadership

Governance and leadership

The Chief Executive was designated as the 'employer' as required under IR(ME)R 2017. Whilst they had overall responsibility for ensuring the regulations were complied with, where appropriate the employer had delegated tasks to other professionals working in the health board to implement IR(ME)R.

The management team demonstrated a commitment to learn from HIW's inspection findings and make improvements where needed. There was a clear governance and management structure demonstrated within the self-assessment, which was completed comprehensively, as well as being provided within the timescale required.

Staff we spoke with were aware of where to find general polices relevant to their practice and had a good understanding of their roles and responsibilities under IR(ME)R as well as the health and care quality standards. They also said there were regular monthly staff meetings with topics discussed based on staff suggestions in addition to the passage of information. Information would also be shared online and thorough a team collaboration platform and an instant messaging platform.

Management described the process to engage with staff on a regular basis, this included an open-door policy at the department, as well as being present in the department on a regular basis.

The reporting lines within radiology were described through to the medical director and the DAPHS. The policy on the implementation of IR(ME)R, showed the lead executive as the Director of Therapies and Health Sciences (DOTHS). However, the relevant employer's procedure on the overview and list of employer's procedures stated the accountable executive was the (DAPHS).

The employer must ensure that the policy is updated to list the new title of the accountable executive.

Senior staff we spoke with about the SAF described the induction and training programmes in place for all newly appointed duty holders under IR(ME)R. This included the induction and training programmes for locum and agency staff. There was no specific timeframe associated with the induction period as the department was eager to tailor it to the individual staff member. Induction included training through modalities and completion of competency assessments. The department used sign-off sheets as evidence of competency assessments. The staff member had a mentor assigned at the start of the induction programme. Assistant practitioners followed the same induction process as radiographers. Radiologists had a similar training process. For equipment competencies, the competency assessment was performed by a senior radiographer.

Health and Care Professionals Council (HCPC) registration was checked prior to adding a staff member to the entitlement register and was checked annually during the appraisal process. The electronic staff record (ESR) also indicated if the staff member had not revalidated registration.

There were also clear lines of leadership and responsibility noted in the department, this was supported by staff comments in the questionnaires. Percentages agreeing with the comments of the organisation were as follows:

- My organisation was supportive --95%
- My organisation supported staff to identify and solve problems 90%
- My organisation took swift action to improve when necessary 84%.

Most staff respondents said their immediate manager could be counted on to help with a difficult task at work, whilst fewer said their immediate manager asked for their opinion before making decisions that affected their work. Many felt that senior management were visible, fewer felt that communication between senior management and staff was effective. Additionally, most staff said that their immediate manager gave them clear feedback on their work and that senior managers were committed to patient care. Some comments we received on management were:

"No management support, no communication and low morale in department."

"Unfairness over what staff perform what tasks. Not every member of staff is asked to work out in every area. Some staff have to work in more areas than others."

"Line managers support staff and are always available to discuss any concerns. They provide an excellent working environment and are supportive in career development."

"Senior Managers at this site work hard to promote a positive working environment and improve general staff morale..."

Workforce

Skilled and enabled workforce

There were a number of advanced practice radiographers in chest and abdomen general X-ray reporting, CT colonography (CTC), gastrointestinal and breast imaging.

The department offered an emergency out of hours service between 5pm and 7am, 24 hours a day, 7 days a week. The radiographers worked three long days a week, we were told that the different rota system helped staff wellbeing.

During the out of hours service the workload typically included ward X-ray imaging including on the SCBU and emergency inpatient CT. All staff on the on-call rota were trained on all pieces of equipment before participating on the night shift rota.

Staff at the department that we spoke with felt that, in general, the number and skill mix of staff was appropriate, but the department would benefit from more band six staff. They believed they had enough time to perform their duties and had recently had their performance appraised.

Senior staff stated that the department were fortunate in having employed newly qualified radiographers recently. The ESR system informed senior staff when appraisals were due (now known as a career discussion) and the department were trying to catch up with overdue appraisals. The ESR system showed that appraisals were at 86%.

Staff said that they were able to report concerns and stated that there was a culture of being open and honest in the department. They said that they would be supported when raising concerns.

Senior staff described the arrangements in place to enable staff to report issues or concerns, with an open-door policy. They described all modality leads as being excellent. They also referred to the guardian service where staff could report anything anonymously, as well as the NHS Wales 'Speaking up safely', to support colleagues to speak up about concerns and issues, no matter how big or small.

A check of the mandatory training of three members of staff showed compliance with mandatory training between 93 % and 100%. Overall staff compliance was good, including basic life support at 96% and IPC at 97%. However, staff had not undertaken online oxygen cylinder training as required by the Welsh Health Circular - Oxygen cylinders: regulation 28 report and patient safety notice 041 reminder. This included making sure guidance and training arrangements were in place for oxygen administration and medical devices, which should be monitored to ensure all staff who had any role in oxygen administration were trained accordingly. In addition to using ESR to monitor compliance with mandatory training, management also kept a matrix of other training such as level two in safeguarding and IPC.

The employer must ensure that all relevant staff complete all their relevant training, including the online oxygen cylinder training.

We reviewed a sample of record keeping, training records, entitlement forms and the entitlement matrix. The entitlement records reviewed matched training records. The training and competency records for CT were detailed. With the general X-ray training and competency records, it was unclear which aspect evidenced competency assessment.

The radiologist entitlement was reviewed along with the electronic recording that they had read the employer's procedures. Training and competency records reviewed during inspection were updated within the three-year timeframe as outlined in the relevant procedure.

The employer must ensure that training records and competency assessment records are clear and evidenced.

In the staff questionnaire, regarding their health and wellbeing at work, 82% of staff agreed that, in general, their job was not detrimental to their health and 89% said that their organisation took positive action on health and wellbeing. More staff, 92% stated that their current working pattern and off duty allowed for a good work-life balance and all but one were aware of the occupational health support available to them.

It was also positive to note that sickness levels in the department were low for radiographic, support staff and administrative staff as of November 2024, it was 3.84%, rates for radiologist were 2.73%. We were told that there was a low turnover of staff, with a waiting list of staff to join the department. The department had won an award for student feedback.

All respondents felt they had appropriate training to undertake their role. Some comments we received on training were:

"More training on resuscitation within the department. Use of the equipment, where it is and how we use it."

"Regular updates from management."

"Opportunity for role extension. Dedicated time for mandatory training and iPassport compliance as well as CPD as part of rota. Not relying on out of hours being quiet or doing in own time."

For the questions asked about the duty of candour in the questionnaire, all but one member of staff agreed that they knew and understand the Duty of Candour and understood their role in meeting the Duty of Candour standards.

All but one respondent said their organisation encouraged them to report errors, near misses or incidents and most felt staff who were involved were treated fairly. Similarly, most staff said they felt secure raising concerns about unsafe clinical practice and were confident their concerns would be addressed. In total 89% of respondents said that:

- Their organisation encouraged staff to raise concerns when something had gone wrong and to share this with the patient
- When errors, near misses or incidents were reported, the organisation took action to ensure they did not happen again
- They were given feedback about changes made in response to reported errors, near misses and incidents.

In total, 76% of staff were able to confirm in the questionnaire that in the last 12 months, they had an appraisal, annual review or development review of their work.

Culture

People engagement, feedback and learning

Any concerns, complaints and compliments would be managed by the patient advice and liaison service (PALS). The department received a monthly PALS report, which was discussed in governance meetings and feedback to staff via the governance report, emailed to staff through iPassport.

Staff we spoke with were able to describe the duty of candour and were aware of their role in meeting the duty. They also stated they had received training on the duty. Senior staff described how they had to exercise the duty of candour.

The log of complaints and compliments was seen and there was nothing specific to diagnostic imaging, neither informal nor formal complaints.

We also noted bilingual information on display on how to provide feedback. There was also a patient feedback board giving comments, but this was not a 'You said, we did' board as such.

The health board must ensure that the results of the feedback received is made known to patients on a "You said, we did" board.

All most all staff, 93%, agreed that patient or service user experience feedback was collected within the department and 84% of staff said they received regular updates on patient or service user experience feedback. Whilst only 68% said that feedback from patients or service users was used to make informed decisions within the department, 29% said they did not know.

In total 75% of patients said they would know how to complain about poor service, if they wanted to.

Other responses in the staff questionnaire were as follows:

- Care of patients was the organisation's top priority 95%
- Overall, staff were content with the efforts of the organisation to keep staff and patients safe 100%
- They would recommend their organisation as a good place to work 92%
- They would be happy with the standard of care provided by the organisation for themself or friends and family 100%

- They were involved in deciding on changes introduced that affected their work area 70%
- They were able to meet the conflicting demands on their time at work 89%
- They were able to access ICT systems needed to provide good care and support for patients 97%.

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: Diagno	stic Imaging Depai	rtment, Singleton Hospital
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Date of inspection: 11 and 12 February 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.

Ris	k/finding/issue	Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	There were no immediate assurance / non-compliance issues in 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	represe	ntative:
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Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Diagnostic Imaging Department, Singleton Hospital

Date of inspection: 11 and 12 February 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
1.	The self-assessment form (SAF) completed by the department stated that the Radiology Clinical Director would be responsible for authorising the employer's procedures. The employer's procedure stated that the Service Manager would and authorise the employer's procedures.	The employer must ensure that the employer's procedure on quality assurance programmes accurately reflects the individual responsible for authorising the employer's procedures	Ionisation Radiation (Medical Exposure) Regulations (IR(ME)R) regulation 6 (5)(b)	The employer's procedure will be amended to show that it is the Radiology Clinical Director that is responsible for authorising the employer's procedures.	Quality Safety and Governance Radiographer	June 2025

2.	Within the plain film protocols, some terminology used left it ambiguous regarding who was responsible for justification and authorisation.	The employer must ensure that the department reviews imaging protocols regarding sentences which may be confusing in relation to duty holders roles.	IR(ME)R regulation 6 (4)	The plain film imaging protocols will be updated to remove any ambiguous language and will reflect the duty holder's responsibility for justification and authorisation.	Site lead/ Deputy Site Lead Radiology Singleton.	June 2025
3.	The relevant employer's procedure for the quality assurance of IR(ME)R employer's procedures and equipment noted that documents must be reviewed every two years a document review every two years. The delegated authorisation guidelines (DAGs) however appeared to be reviewed every four years. The DAGS also referenced IR(ME)R	The employer must ensure that the: DAGs are all updated to ensure that they refer to IR(ME)R 2017 DAGs are reviewed in line with the relevant employer's procedure Mammography DAG must have a	IR(ME)R regulation 6 (5)(b) regulation 11 (5) Schedule 2 (1) (d)	The DAGs will be updated to reference IR(ME)R 2017 and review dates will be amended to two yearly in line with the employer's procedures. The Mammography DAG will be updated to list an IR(ME)R practitioner to take responsibility for exposures authorised under this DAG.	Owners of DAG's/Quality safety and governance Radiographer.	September 2025

	2000. The mammography DAG did not have a listed IR(ME)R practitioner responsible for the exposures authorised under this DAG.	named IR(ME)R practitioner.				
4.	The employer's procedure for referral and referral criteria described a process whereby an individual signs the referral on behalf of the surgeon. On discussion with staff, this does not reflect clinical practice. The surgeon completes the Referral in advance of the theatre procedure.	The employer must ensure that the employer's procedure is reviewed and amended to reflect the clinical practice as described by the service.	IR(ME)R regulation 6 (2) Regulation 10 (5)	A discussion has taken place on amending the employer's procedures to reflect that all referrals must be completed by an authorised referrer in advance of the Theatre procedure. This will ensure that the employers' procedures accurately reflect clinical practice.	Quality Safety and Governance Radiographer/Radio logy service manager/Site Leads/Deputy Site Leads	June 2025
5.	Clinical evaluation was performed by a radiologist, suitably	The employer must ensure that:	IR(ME)R regulation 12 (9)	Under the IR(ME)R policy Clinical Directors or nominated Lead Clinicians	Radiology Site Leads/Deputy Site Leads	July 2025

trained reporting	 Clinical 	Regulation 10	are responsible for		
radiographer or a	evaluation has been	(4)	entitling operators within		
surgeon for particular	performed for all	Schedule 2 (1)	their area to perform		
referrals such as theatre	imaging procedures,	(b)	clinical evaluation.		
and fracture clinic	particularly those		An audit of a sample of		
follow up imaging. The	performed in theatre.		theatre cases will be		
department could not			performed to ascertain		
confirm if the	 Duty holders are 		that clinical evaluation		
appropriate surgeons	appropriately entitled		has occurred.		
were entitled as	to perform clinical				
operators to perform	evaluation.		Employers' procedures	Quality Safety and	July 2025
clinical evaluation.			will be amended to	Governance	
	 Employer's 		reflect the different	Radiographer/Radio	
During the patient	procedure accurately		processes for clinical	logy service	
record keeping checks,	reflects the different		evaluation outside the	manager/Site	
for one particular	processes for clinical		radiology department.	Leads/Deputy Site	
theatre imaging	evaluation within and			Leads	
procedure, the	outside the radiology		All images that are		July 2025
department could not	department, including		acquired outside of	Quality Safety and	
indicate if, where and	the individuals involved		radiology will have a	Governance	
how the clinical	and where this is		record to demonstrate	Radiographer/Radio	
evaluation for this	recorded		that clinical evaluation	logy service	
procedure was recorded.			has taken place and	manager/Site	
Assurances were			where to access the	Leads/Deputy Site	
required that clinical			information.	Leads/Radis	
evaluation had been				Manager	
performed for all					
exposures (except those					

	to carers and comforters).					
6.	The department did not have a clinical audit programme available but they did evidence a clinical audit schedule for nuclear medicine.	The employer must ensure that there is a clinical audit schedule programme for the radiology department.	IR(ME)R regulation 7	A clinical audit schedule will be developed for the department.	Clinical Audit Lead/Quality Safety and Governance radiographer	September 2025
7.	Some audits did not contain all aspects as listed in the employer's procedure, such as references to reaudit (for the audit on record keeping) and the target compliance was not clearly identified.	The employer must ensure that the clinical audit report template contains the relevant aspects outlined in the employer's procedure.	IR(ME)R regulation 7	The clinical audit report template will be amended to include all aspects listed in the employer's procedure.	Quality safety and governance Radiographer/site lead/deputy	July 2025
8.	The department were regularly auditing the red alert system and monthly turnaround	The employer must ensure that:	IR(ME)R regulation 7	The red alert monthly audits and turnaround time audits will be	Clinical Audit Lead/Quality Safety and Governance radiographer	July 2025

		-				
	times but the schedule	The schedule		included in the clinical		
	did not reflect this.	reflects the audits of		audit schedule.		
		the red alert system				
	The department were	and monthly		Where actions are		
	unsure if particular audit	turnaround times which		required, this will be		
	findings had been	are currently being		identified in the audit		
	followed up.	performed		with named person		
	·	·		responsible and relevant		
		Where audit		time period for		
		findings identify		implementation.		
		required actions, these		ptee.reacio		
		actions are carried out.		To ensure that findings		
		actions are carried out.		have been followed up		
				the audit template has		
				been amended to		
				reference 'need to		
				reaudit', immediate		
				action and target		
				compliance.		
	T	T	ID (HE) D			
9.	The procedure was	The employer must	IR(ME)R	Employer's procedure EP-	Medical Physics	June 2025
	ambiguous in terms of	ensure that the	regulation 8 (1)	20 revised to provide	Expert	
	identifying who was	employer's procedure:	Schedule 2 (1)	clarity around	(MPE)/Departmenta	
	responsible for deciding		(l)	responsibility for	l Leads	
	if an incident was a	 Accurately 		determining CSAUE		
	CSAUE. The department	reflects who is				

confirmed that the	responsible for			
radiologist, following	determining if an			
discussion with the	incident was to be			
referrer, determined if	considered a CSAUE.			
an incident was to be				
considered a clinically	 Reflects the 			
significant and	detail described in the			
accidental or unintended	SAF and by staff during			
exposure (CSAUE). The	inspection.			
procedure defined a				
CSAUE focusing on the	 The reference to 	IR(ME)R		
stochastic effects and	the SAUE criteria is	regulation 8		
references the	updated.			
professional body				
guidance in relation to				
this. The professional				
body guidance also				
describes psychological				
harm in terms of CSAUE,				
which was not covered				
in the definition in the				
procedure. It may be				
beneficial to review this				
definition.				
The procedure did not				
describe the process				
where a decision was				

	made not to inform a patient, however it was described in the SAF. Additionally, the reference for SAUE criteria was out of date.					
10.	There were some discrepancies noted between the table in the employer's procedure and the document 'list of individuals authorised by the medical exposure group to entitle IR(ME)R duty holders. It was unclear who was responsible for entitlement of clinical directors were acted as a duty holder.	The employer must review the relevant procedure and: • Ensure consistency between the relevant procedure and supporting documents regarding individuals responsible for entitlement, including the entitlement of clinical directors where relevant	IR(ME)R regulation 6, Schedule 1 (b)	EP 1 to be updated to reflect that the Medical Director entitles the Radiology clinical director. The employer's procedure for NMRs states that it is the Radiology clinical director responsible for entitlement. Documentation will be updated to ensure this is clearly demonstrated.	Radiology Services Manager (RSM) /NMR lead	September 2025
	There were some discrepancies noted between the employer's	 Ensure clarity regarding the individuals responsible 				

			<u> </u>			
	procedures and the SAF	for assessing				
	in relation to	competency and				
	entitlement of non-	entitlement for NMRs,				
	medical referrers	and that this is				
	(NMRs).	reflected on evidence				
	On the NMR entitlement	of entitlement.				
	form there were several					
	signatures present and it					
	was unclear who was					
	responsible for assessing					
	competency and who					
	was responsible for					
	entitlement.					
11	In terms of scope of	The employer must	IR(ME)R	To discuss at the All-	MPE/RSM/Quality	September
11	referral, the department	review the process of	regulation 6,	Wales Imaging Quality	Safety and	2025
	noted that medical	entitlement for medical	Schedule 1 (b)	Forum to look at how	Governance	2023
	referrers could refer for	referrers with	Schedule 1 (b)	other Health Boards	radiographer/Medic	
	anything. However,	consideration of how		review the process of	al Exposures Group	
	further discussion	the referrer is notified		entitlement and how the	(MEG) chair	
	identified that there	of their entitlement		referrer is notified of	(med) chall	
	were specialist	and scope of referral.		their entitlement and		
	examinations which	and scope of referrat.		scope of referral.		
	some medical referrers			scope of referrat.		
	would not be entitled to			The outcome of the		
	refer for. This was not			national discussion will be		
	10101 101. 11113 4443 1100			Hacional discussion will be		

	reflected in the scope of referral for medical referrers.			discussed at Medical Exposures Group (MEG) and action taken as agreed.		
12.	There was an employer's procedure for the justification and authorisation of a medical exposure. Staff we spoke with identified what they would consider when justifying exposures and where authorisations of exposures were recorded. Referrals were first vetted by radiographers prior to patients being invited to attend for an appointment. During vetting the urgency of the referral was determined, the referral	The employer must ensure that the procedure for the justification and authorisation of a medical exposure is reviewed to: Clarify what aspects come under the task of vetting (for example prioritisation of the referral) Clarify who was acting as practitioner and when justification occurs in the patient pathway	IR(ME)R regulation 10 (2) regulation 11	The employer's procedures have been amended to reflect that the initial vetting process is only to determine the urgency of the appointment. Justification and authorisation occur on the day of the appointment. This will consider whether any imaging has been undertaken in the interim between appointing and appointment.	Quality Safety and Governance Radiographer/Radio logy service manager/Site Leads/Deputy Site Leads	June 2025

	was not justified at this	- Enguro staff				
	was not justified at this	Ensure staff Ware aware of release				
	point. The referral was	were aware of roles				
	justified on the day of	and responsibilities.				
	the appointment. The					
	procedures did not					
	provide clarity on who					
	was the practitioner on					
	the exposure pathway,					
	taking into account the					
	role of the radiographer					
	performing the vetting					
	task.					
13.	There was a DAG in	The employer must	IR(ME)R 2017	The DAG has been	CT Superintendent/	Completed
	place for exposures to	ensure that the DAG for	regulation 6 (1)	reviewed and amended to	Quality, Safety and	- as
	carers and comforters in	carers and comforters	regulation 11	clearly document the	Governance	evidenced
	CT. It must be clear on	in CT clearly identifies	(5)	practitioner responsible	Radiographer	in i-
	the document the	the practitioner	Schedule 2 (1)	for the exposure of carers		passport
	practitioner responsible	responsible for	(n)	and comforters under the		
	for the exposures of	exposures under the		DAG.		
	carers and comforters	DAG.				
	under the DAG.					
						_
14.	Equipment inventory	The employer must	IR(ME)R 2017	The equipment inventory	Site Lead/Deputy	September
	was held within a live	ensure that the	regulation 15	will be updated to include	Site Lead Radiology	2025
	database for the health		(2)		Singleton	

	board. The year of manufacture was not currently included in this document.	equipment inventory is completed in full.		information on the year of manufacture.		
15.	We also received responses from six members of staff who worked in the department, but their work was not covered by IR(ME)R. Whilst their comments were not included in this report, we have written separately to the department and directorate with the comments.	The health board is required to reflect on some of the less favourable responses from staff and inform HIW of the actions it will take to address these.	Health and Care Quality Standards - Leadership	The comments from these staff members have been reviewed by the service managers and modality leads, head of HR and Head of Nursing and DAHPHS. An action plan has been agreed to improve the working conditions for these staff members. New equipment has been delivered in March 2025 and steps have been taken to address the gaps in management support for Obstetric Ultrasound.	Radiology service manager/modality leads.	October 2025 Deliver action plan.

16.	The reporting lines within radiology were described through to the medical director and the DAHPHS. The policy on the implementation of IR(ME)R, showed the lead executive as the Director of Therapies and Health Sciences (DOTHS).	The employer must ensure that the policy is updated to list the new title of the accountable executive.	IR(ME)R regulation 6 schedule 2 (1) (d)	The policy on implementation on IR(ME)R has been revised to reflect change in Executive Director title. The policy is due to be approved by the Medical Exposure group at the next meeting in June 2025.	MPE	July 2025
17.	We reviewed a sample of record keeping, training records, entitlement forms and the entitlement matrix. With the general X-ray training and competency records, it was unclear which aspect evidenced competency assessment.	The employer must ensure that training and competency assessment records are clear and evidenced.	IR(ME)R regulation 17	A separate competency framework has been developed for newly qualified radiographers that is in use across the health board. A similar document is being developed for existing staff to evidence competency assessment.	Site Lead/Deputy Site Lead Radiology Singleton	September 2025

18.	There was also a patient feedback board giving comments, but this was not a 'You said, we did' board as such.	The health board must ensure that the results of the feedback received is made known to patients on a "You said, we did" board.	Health and Care Quality Standards - Culture - People Engagement	We will alter the feedback board to ensure that patients can see how any feedback received is acted upon.	Site Lead/Deputy Site Lead Radiology Singleton	July 2025
19.	Staff had not undertaken online oxygen cylinder training as required by the Welsh Health Circular - Oxygen cylinders: regulation 28 report and patient safety notice 041 reminder.	The employer must ensure that all relevant staff complete all their relevant training, including the online oxygen cylinder training.	Health and Care Quality Standards - Skilled and enabled workforce	All staff will complete the e-learning module 'safe use, storage and set up of medical gases and cylinders used in healthcare' A record of their training will be recorded.	Site Lead/Deputy Site Lead Radiology Singleton	September 2025
20.	The appointment letters sent out by the department were bilingual in Welsh and English. However, the benefits and risks of the procedures were not on the appointment letter	The health board must ensure that benefits and risks are included in the appointment letters.	Health and Care Quality Standards - Communication and Language	The appointment letters will be amended to include a statement regarding the benefits and risks of procedures to allow patients to consider these before attending the appointment.	Site Lead/Deputy Site Lead Radiology Singleton/MPE/ Quality Safety and Governance Radiographer	September 2025

	sent out, to enable patients to make an informed choice of the need for the examination.			This will be translated into Welsh for the bilingual appointment letters.		
21.	The layout of the department meant that some changing cubicles were across a corridor from the imaging rooms. This was a potential dignity issue for patients that needed to change into gowns and walk across and along a public corridor. We also noted one patient waiting to go in for imaging in a gown with a moveable screen but they could still be seen from the corridor.	The health board should continue to review the arrangements in place to protect patient privacy and dignity, particularly regarding the location of the changing rooms compared to the examination rooms.	Health and Care Quality Standards - Dignified Care	Site Lead to review with estates the options regarding improving the changing facilities	Site Lead Radiographer	September 2025

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): Victoria Watts

Job role: Radiology Site Lead, Singleton Hospital

Date: 29/04/2025

Service representative:

Name (print): Sue Moore

Job role: Service Group Director, Morriston

Date: 29/4/2025