Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

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

Nuclear Medicine Department, Withybush General Hospital, Hywel Dda University Health Board

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

Our purpose

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

Our values

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

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

Our goal

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

Our priorities

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

Contents

1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department at Withybush General Hospital, Hywel Dda University Health Board on 17 and 18 June 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 healthcare inspectors and two Scientific Advisers, Administration of Radioactive Substances Advisory Committee (ARSAC) 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 62 questionnaires were completed by patients or their carers and eight 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:
Patients were mostly positive across all areas in the questionnaire, with all respondents who answered rating the service as ‘very good’ or ‘good’. Whilst there was a visible commitment to promoting smoking cessation and cancer screening, general health promotion, such as healthy eating, physical activity and mental wellbeing, was lacking. Signage advising patients to disclose medical conditions was also absent, potentially affecting care quality.

Positive practices included multilingual pregnancy-related signage and detailed patient letters for those who were pregnant or breastfeeding. There was a children’s corner with engaging, age-appropriate materials supporting child-friendly care. Staff interactions were consistently respectful and professional, with privacy maintained through a thoughtful layout and a secure nuclear medicine department.

Patients reported timely care, with short waiting times and updates during delays. Nuclear medicine was also excluded from displayed wait time estimates and reporting timelines.

Communication signage and letters included bilingual materials. Accessibility features such as hearing loops and ground-level access were present, but there was a shortage of large print or easy-read materials.

The department demonstrated a commitment to equality and diversity. Staff were trained in cultural awareness and policies considered equality impact assessments. However, gaps remained in menopause-related support and accessible patient materials.

This is what we recommend the service can improve:

- Make information available in accessible formats, including in large print, for patients.

This is what the service did well:

- The children’s corner in the waiting area
- Staff interacted with patients in a polite, friendly and professional manner

- Patient feedback was mostly positive, highlighting respectful treatment and dignity
- Patients agreed they had been given information on how to care for themselves following their procedure or treatment
- Patients were seen to receive timely care.

Delivery of Safe and Effective Care

Overall summary:
Written procedures were accessible in both digital and paper formats. Protocols were generally clear, but nuclear medicine-specific details needed inclusion or enhancement. Communication of updates was effective and staff were required to sign to confirm they were aware of the changes.

Referral and entitlement procedures were in place, but some documents were outdated or duplicated. Clinical audit processes were in place but lacked clarity and structure.

Accidental or unintended exposure procedures were in place, but updates were needed to reflect actual practices and include nuclear medicine equipment. Patient identification and pregnancy checks were consistently applied.

Clinical evaluation was at risk due to a noisy reporting environment, prompting a recommendation for a quieter space.

Equipment concerns centred on an aging gamma camera, identified as a single point of failure. A replacement plan was in progress but faced funding and infrastructure challenges.

Infection control was generally good, though cleaning coverage, especially on weekends, was insufficient. Whilst medical physics support was good, there was a lack of a formal service level agreement (SLA) for medical physics support in nuclear medicine.

This is what we recommend the service can improve:

- Formalise audit schedules and improve documentation
- Provide a quieter space for clinical evaluation
- Resolve the issue with the replacement of the gamma camera
- Ensure there is sufficient cleaning coverage, especially on weekends
- Agree and sign an SLA for medical physics support in nuclear medicine.

This is what the service did well:

- Written procedures were accessible and protocols were generally clear
- Patient identification and pregnancy checks were consistently applied
- Medical physics support was good.

Quality of Management and Leadership

Overall summary:
In the staff questionnaire, with eight responses received, whilst staff agreed that patient care was a top priority and that incident reporting was encouraged, concerns were raised about senior management visibility and communication. Only one member of staff felt the organisation was supportive and none believed it supported problem-solving.

Leadership was described as structured, with accountability through the nuclear medicine head of service. An SLA with Swansea Bay University Health Board for radiopharmaceuticals was in place but required updating. Staff noted limited engagement from senior management, though communication channels such as meetings and emails were in use.

Although 97% compliance with mandatory training was reported, oxygen cylinder training was missing from the electronic staff record (ESR). Training processes lacked formal review systems and IR(ME)R training documentation was incomplete.

While most staff felt adequately trained and supported in their roles, some reported discrimination and unequal access to opportunities. Staff were confident in raising concerns and understood the Duty of Candour.

Overall, the department demonstrated a commitment to patient care and safety, but improvements were needed in leadership visibility, training oversight, equality, and communication of patient feedback.

This is what we recommend the service can improve:

- Introduce an IR(ME)R theoretical training schedule for all staff to complete
- Ensure IR(ME)R training records are fully completed and reviews are documented
- Address the concerns of staff particularly the equality and diversity concerns.

This is what the service did well:

- Mandatory training compliance was good

- The self-assessment form was completed in a timely manner
- A clear management structure was described.

3. What we found

Quality of Patient Experience

Patient feedback

HIW issued online and paper questionnaires to obtain patient views on services carried out at the Nuclear Medicine Department at Withybush General Hospital to complement the HIW inspection. In total, we received 62 responses from patients at this setting. Responses were mostly positive across all areas, with all respondents who answered rating the service as 'very good' or 'good'. Some comments we received about the service and how it could improve were as follows:

> ***"Friendly staff who greet you with respect."***
>
> ***"Wonderful kind and caring staff, they explained everything to my dad and answered our questions with ease. They took their time with my dad, wonderful to see. Fabulous team I am so grateful to them all thank you ever so much."***
>
> ***"Signposts not clearly marked on arrival and no one was present in the reception desk so we could not ask where we had to go."***
>
> ***"At reception lower desk area could be kept clear for communication with wheelchair users."***
>
> ***"Polite helpful staff explained procedures well, very efficient, friendly."***
>
> ***"Staff were very professional, empathetic and kind towards me. Explaining everything clearly regarding the procedure."***
>
> ***"Very helpful, professional and kind team who took very good care of me during a very difficult and worrying time for me."***

Person-centred

Health promotion

There was a commitment to promoting patient health and wellbeing, with visible materials in the waiting area focused on smoking cessation and cancer screening (breast, cervical, bowel). However, general health promotion, such as advice on

healthy eating, physical activity, and mental wellbeing, was underrepresented. Furthermore, there was not clear signage advising patients to inform staff of relevant medical conditions and this message was not included in appointment letters, which may impact safe and effective care.

There was prominent signage reminding patients, in English and multilingual languages, to inform staff if they were pregnant, though breastfeeding was not referenced on the signage. However, patient letters did provide detailed instructions for those who were pregnant or breastfeeding, including preparation guidance. Relevant information was made available to patients about the associated benefits and risks of the intended exposure.

The health board is to ensure the following information is clearly displayed in the waiting areas at the department:

- **General health promotion information on healthy eating, physical activity and mental wellbeing**
- **Information advising patients to inform staff of relevant medical conditions**
- **Advising patients to inform staff of relevant medical conditions.**

This information must also be included in appointment letters sent to patients.

A notable example of good practice was the children's corner in the waiting area, which included engaging activities and scan information presented in a child-friendly format. We were informed that some staff within the department had an interest in improving the experience for children. We were shown a pictorial children's book that had been written for children by a staff member to support and inform children attending. This was seen as notable good practice and award winning from the British Nuclear Medicine Society. This supported patient-centred care and helped reduce anxiety for younger patients.

Dignified and respectful care
Staff were observed interacting with patients in a polite, friendly and professional manner. Patient feedback was overwhelmingly positive, highlighting respectful treatment and dignity. The reception area was positioned away from the main waiting space, allowing for discreet conversations. We saw suitable arrangements in place to promote patient privacy and noted staff made efforts to promote patents' privacy and dignity.

Nuclear medicine patients were seen in a separate, secure suite behind locked doors, ensuring privacy during discussions and treatment. The nuclear medicine suite included a dedicated toilet and changing area with direct access to the gamma camera room, supporting patient comfort and confidentiality. While there was no specific nuclear medicine waiting room, a separate area with beds was available for non-ambulatory patients.

When asked whether staff treated them with dignity, respect and whether measures were taken to protect their privacy, all patients in the questionnaire agreed. All patients stated they were able to speak to staff about their procedure without being overheard by other patients and that staff listened to them.

All staff respondents thought patients' privacy and dignity was maintained and all agreed that patients were informed and involved in decisions about their care, with 75% of respondents agreeing there were enough staff for them to do their job properly and they had adequate materials, supplies and equipment to do their work.

Individualised care
All respondents to the patient questionnaire agreed that they had been given information on how to care for themselves following their procedure or treatment and that staff explained what they were doing. All but two patients said they were involved as much as they wanted to be in decisions about their examination or scan.

Most patients said they were provided with enough information to understand the risks and benefits of the procedure or treatment and they were given written information on who to contact for advice about any aftereffects from their examination.

Timely

Timely care
Patients attending the department were seen to receive timely care. Staff we spoke with reported typical waiting times of five to ten minutes, with verbal updates and refreshments offered during delays. Staff also said patients would be told if there was a delay due to the wait for the arrival of the radionuclide, from the radiopharmacy in Swansea.

Nuclear medicine patients would typically leave the department after injection and return later, as uptake periods could take several hours. However, there was no designated waiting area for patients who had received radiopharmaceuticals.

There was the possibility that, whilst patients would be told not be go near pregnant patients or children, they could sit in the main reception waiting room.

The health board must consider the need for designated waiting areas so that patients who have been injected with a radiopharmaceutical can wait for their scan in an area away from other patients.

A poster in the general X-ray waiting area displayed estimated waiting times for computerised tomography, magnetic resonance imaging, ultrasound and X-ray, but nuclear medicine was not included. Similarly, radiology reporting times excluded nuclear medicine. Another poster advised patients to speak to reception if they had been waiting over 20 minutes, but there was no live or real-time information available, nor consistent verbal communication of expected waiting times.

Most respondents who answered agreed that the wait between referral and appointment was reasonable. The majority of patients agreed they were told at the department how long they would have to wait.

Equitable

Communication and language

A new monthly patient feedback system had been introduced using QR codes, with the first survey conducted in March–April 2025. A summary of results, including a "you said, we did" section, was displayed in the waiting area. However, the system was not accessible to patients without digital access and feedback was currently aggregated across the radiology department and not specific to nuclear medicine. The department should consider the data being gathered and how it could be used usefully to identify themes or actions.

There was a health board 'putting things right' leaflet available at reception, which was out of date, referencing community health councils instead of Llais, the patient voice in health and care. However, the website had the correct information on Llais and we were told that an updated leaflet was in development.

Accessibility features included a hearing loop at reception, pictorial signage, and bilingual posters and letters. The letter sent to patients would benefit from medical physics support to improve the references to radiation risk. Welsh language support was visible, with 'use your Welsh' signage and staff wearing 'Iaith Gwaith' and 'Dysgwr' lanyards. There was one Welsh-speaking member of staff present in the nuclear medicine department, with another staff member learning Welsh. The Welsh language was well promoted within the department, with bilingual signage in both Welsh and English. We saw bilingual posters with information for patients clearly displayed within the department.

The employer with support from medical physics must ensure that appropriate information is included in appointment letters in relation to radiation risks.

Nuclear medicine patient letters included clear pre- and post-treatment advice in both English and Welsh. Staff we spoke with described the arrangements in place for patients unable to communicate in English.

In total 12 patients in the questionnaire said they were Welsh speakers. The majority said they were actively offered the opportunity to speak Welsh throughout their patient journey and felt comfortable using the Welsh language within the hospital. There were three Welsh speakers who completed the staff questionnaire.

Most patients also said that they were given written information on who to contact for advice about any aftereffects from the treatment.

Rights and equality

The service demonstrated good physical accessibility, with a lowered reception desk for wheelchair users, ground-level access, a hearing loop and chairs with arms in the waiting area. Staff had access to telephone translation services, but no large print or easy-read materials were currently available. Staff typically read information aloud when needed. Given the demographic of the patients, greater consideration should be given to providing materials in accessible formats.

The health board must ensure that there is information available in accessible formats, including in large print, for the patients at the department.

Provision for paediatric patients included award-winning, storybook-style materials. using age-appropriate language and visuals to explain the procedures.

Staff described proactive approaches to managing patients who do not attend (DNA), including follow-up calls and personalised support. One example involved staff providing verbal explanations and arranged a one-to-one session to ensure understanding and enable the child's treatment. If a patient missed two confirmed appointments, the case was returned to the clinician for further action. Patients could also be accommodated with their choice of gender radiographer.

Staff we spoke with described how equality and diversity was promoted in the organisation through policies and training. However, staff believed that more work needed to be done relating to menopause. We were told that whilst there was a menopause policy, staff did not believe the necessary adjustments were in place.

Senior staff we spoke with also referenced posters on equality and diversity and input from organisation development about cultural awareness. There were also leads for equality and diversity in the health board. Any policy change had to consider the equality impact assessment. A black and minority ethnic representative was present on the radiology quality standard experience meetings.

Staff said that transgender patients were addressed by their known name, using inclusive language and the name could be changed on the radiology information system (RadIS).

When asked whether they could access the right healthcare at the right time (regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation) the majority of patients who answered this question said they had.

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
Employer's written procedures were accessible by both paper and digital formats, though staff we spoke with preferred using paper copies. These were kept in a dedicated nuclear medicine folder and cabinet. Additionally, staff believed the nuclear medicine-specific detail could be improved in the procedures. Protocols were generally clear and easy to follow, covering full procedure steps, patient aftercare and activity levels.

Updates to procedures were communicated via email, meetings and online channels. Staff were required to read and sign to agree changes and hard copies were updated accordingly. The small team structure supported effective communication and tracking of amendments.

The self-assessment form (SAF) completed in advance of the inspection described how the employer demonstrated they had taken steps to ensure written procedures were complied with by all duty holders. This included that new medical staff and all non-medical referrers were required to complete e-IR(ME)R training and provide evidence of a completion certificate.

Delegated authorisation guidelines (DAGs) were issued by all practitioners for the use of operators. Practitioners contributed to the quarterly nuclear medicine learning from events meetings and presented anonymised cases for shared learning.

Referral guidelines
We were told that the clinical referral guidelines, iRefer, were freely available to all healthcare professions employed in NHS Wales and were available on the intranet.

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

The process of identifying the referrer and accepting the referral was in the employer's procedures. There were two employer's procedures relating to referrals, one (number five) for acceptance of referrals and the other (number 25) for the making amending and cancelling of referrals. There was overlap between the two procedures.

The employer should consolidate the two procedures on the referral process into one.

Diagnostic reference levels (DRLs)
DRLs were available and clearly documented throughout the nuclear medicine area. Staff we spoke with said they checked the correct DRL form based on the practitioner and scan type. If DRLs were exceeded, incidents were reported to the radiation protection supervisor, the Medical Physics Expert (MPE) as well as recording the incident on Datix, with the duty of candour followed.

There was an employer's procedure that described the use and review of DRLs. Senior staff described the process for establishing, using and reviewing DRLs. The DRLs were displayed in the control area for radiographers to reference. Where insufficient data was available to generate local DRLs, national DRLs were provided for reference.

If the CT DRL had been exceeded then the operator would make a record in the DRL exceeded logbook (except for reasons due to body habitus, exam complexity, or need for reasonable repeat for optimisation purposes).

The response in the SAF stated that the practitioners approved the local DRLs as part of the local protocols but this methodology was not stated in the employer's procedure. The employer's procedure stated that DRLs were displayed in the gamma camera suite. However, the local DRLs, which had recently been updated, were on display in the dispensing room. There were three versions of DRLs displayed (each relating to a different practitioner) this is not required and the department should have one DRL on display for each procedure. The DRLs on display had the 10% tolerance range included, which is useful for operators. Paediatric DRLs were also displayed on the wall in the dispensing room.

The employer must ensure that one clear set of DRLs for all procedures are displayed.

There were Image Optimisation Teams (IOT) for individual modalities, but there was not a formal IOT for nuclear medicine. However, optimisation work was conducted by the lead radiographer and the MPE.

Medical research
The department did not participate in research involving nuclear medicine medical exposures.

Entitlement
Staff we spoke with said that they were entitled as operators by the site lead, who maintained an entitlement matrix accessible as a physical copy in the nuclear medicine department or electronically on a shared drive. They also stated that competency for staff undertaking training was tracked, with around 20 tasks required for them to complete. Staff were informed when they were competent and had been signed off for a particular task, with training records and associated protocols available for reference.

The entitlement process was covered in both Annex 1 of the Ionising Safety Policy and the employer's procedure (EP1) to identify individuals entitled to act as a referrer, practitioner or operator. We were told that this approach was consistent across the health board and was previously suggested by the MPE at Swansea Bay University Health Board. However, the department should review the documents for potential duplication and have one document to cover the entitlement process.

The employer must ensure that both Annex 1 of the Ionising Safety Policy and the employer's procedure (EP1) are reviewed for potential duplication and one document is used to cover the entitlement process.

We noted an entitlement document for one member of staff which showed that training was completed in 2021, but the entitlement was only signed in May 2025. The training record had not been signed off by the assessor, only the duty holder. We were told that the member of staff would sign this off, following this inspection. Reference was also noted in the employer's procedure to the previous title of the Executive Director of Allied Health Professions and Health Science (DAHPHS). The department agreed that the employer's procedure would be reviewed to ensure up to date job titles are used.

The employer must ensure that:

- **All IR(ME)R entitlement and training competency documentation is completed in full, with the appropriate signatures, in a timely manner and before entitlement is granted**

- **The employer's procedure contains reference to the correct titles of staff.**

Senior staff in the SAF described how they would confirm the appointment of the MPEs initially and check that all MPEs were named and active on the list of 'Current holders of the RPA 2000 Certificate of Competence to act as a Medical Physics Expert (MPE)'. However, the RPA 2000 list was not checked annually to ensure MPEs were still named. The department agreed that annual checks of the RPA 2000 list would be completed.

The employer must ensure that the list of 'Current holders of the RPA 2000 Certificate of Competence to act as a Medical Physics Expert (MPE)' is checked annually, to ensure that all MPEs appointed remain on the list.

Additionally, the SAF described how duty holders (including staff external to the department) were informed they were entitled to act and made aware of their scope of practice. This included referrers, non-medical referrers, operators, and practitioners. For operators it stated that once the training document was complete, they were informed that they were fit to practice and their name added to the training matrix indicating their scope of practice. The training matrix was available within the department, so staff were aware of and could check any limitations of practice. It was stated in the SAF discussion that an individual's entitlement was reviewed at the annual performance review (PADR) and updated accordingly. The entitlement matrix would then be reviewed annually by the site lead superintendent radiographer. However, the dates in the entitlement matrix had not been updated since initial entitlement. Also stated was that the entitlement matrix would be reviewed as part of the annual IR(ME)R audit. The entitlement reviews need to be updated formally on records.

The employer must ensure thar the entitlement matrix is updated annually when the individual's entitlement is reviewed and that this accurately reflects competency records.

Patient identification

We noted an employer's written procedure in place relating to the identification of individuals to be exposed to ionising radiation. This procedure stated that the operator administering the radiopharmaceutical was responsible for ensuring that a positive patient identity check had been completed before proceeding.

Staff we spoke with consistently describe the use of the three-point check i.e. full name, date of birth and address, to confirm identity. For patients who were unable to identify themselves, identification would be confirmed via guardians, identity badges on the patient's wrist if they were inpatients, or consultation with practitioners. Any support needed would normally be logged on RadIS.

Individuals of childbearing potential (pregnancy enquiries)

Staff we spoke with described the process for confirming whether patients were pregnant, including asking patients aged 12–55 about their last menstrual period and applying the 28-day rule. If patients were uncertain, a pregnancy test would be requested, or the scan rebooked.

Relevant employer's procedure for establishing whether an individual of childbearing potential may be pregnant or breastfeeding, were in place. The procedure stated that if a patient was found to be pregnant or breastfeeding then the exposure would need to be justified by a "senior clinical radiologist". However, for nuclear medicine this should state the "relevant licensed practitioner".

The employer must ensure that the employer's procedure includes the correct duty holder to justify nuclear medicine procedures, for pregnant or breastfeeding individuals.

Benefits and risks
We were told that patients were informed about the benefits and risk of the exposure, with verbal explanations tailored to the procedure (e.g. bone or lung scans). Staff we spoke with stated they would emphasise that the benefit outweighed the risk and if the patient agreed they would confirm the patient's consent. Leaflets and verbal discussions were used to support understanding.

Clinical evaluation
The completed SAF described how clinical evaluation was undertaken and evidenced for each type of exposure. This confirmed that a medical practitioner or other qualified person authorised by the employer had to evaluate the outcome of each medical exposure. A written employer's procedure was in place for carrying out and recording a clinical evaluation of each medical exposure within the department.

There were two nuclear medicine radiographers entitled to refer for radiographs following evaluation of the nuclear medicine images. The mechanism to flag instances where clinical evaluation had not been completed following a procedure was also described.

We noted during a tour of the department and following a conversation with a practitioner licence holder that clinical evaluation was at risk due to the environment in which the reporter was working within. This was because the reporting room was shared with the duty radiologist, we were told this could be noisy when there were queries or many people waiting to speak to the duty radiologist. This could be a potential patient safety issue as ideally there should be a quiet space for reporting, with the potential distraction being an issue.

The employer must consider the environment under which the clinical evaluation is taking place and ensure any risk to the clinical evaluation is minimised.

Employer's duties: clinical audit
Evidence provided showed that all members of the nuclear medicine team were actively involved in clinical audit. This included the nuclear medicine team presenting on data gained from clinical audit at two All-Wales Nuclear Medicine meetings in 2024. The process for clinical audit and how any follow-on actions were identified and completed as part of the audit were described.

Clinical audits were decided and discussed at the clinical errors group meeting. There was a clinical audit template available which could be used for all clinical audits. Outcomes from clinical audits were discussed at bi-monthly meeting (learning and errors meeting). However, it was not made clear which audit results were being presented and when.

The employer must ensure that all audits are discussed at regular meetings, to ensure actions are completed and learning shared.

The employer's procedure for clinical audit relating to IR(ME)R should include further detail on formal process and be clearer on responsibilities. For example, the employer's procedures stated audit findings would be "shared via appropriate channels" this could be more specific. There was also no reference in the employer's procedures to the audit report templates that had been shared. The department said they were aware of this and agreed this procedure should be updated.

The only procedure describing the audit process was the employer's procedure on clinical audit, as a result there may be confusion between the difference of a clinical audit and IR(ME)R audit.

The employer must ensure that the relevant employer's procedure includes:

- **Details on the formal process and responsibilities of identifying and conducting both clinical and IR(ME)R audits**
- **Reference to the audit report templates that should be used**
- **Specific terminology to ensure clarity between clinical and IR(ME)R audits.**

A document called, “WGH Nuclear Medicine Team Audits” was provided. This was not version controlled nor part of the employer’s procedures and referred to both a clinical and IR(ME)R audit schedule. We were told there were ad hoc decisions on the frequency of audits and that audits were based on practitioner interest. A new role of a clinical governance radiographer was described and this role would be ideal to support clinical audit implementation. However, the process could be improved with set meeting dates to discuss the audits at the wider radiology department meetings.

We were provided with examples of three audits, one was an “observational audit of staff compliance with IR(ME)R-2017-Employer Procedures”. It was not clear what was being checked for each task listed, for example for “pregnancy checks” we were told this was the retrospective audit of forms. It was highlighted that the MEG provide an IR(ME)R audit schedule. The frequency was usually six monthly or annually, depending on the audit being carried out. The IR(ME)R audit schedule was due to be ratified at the next MEG meeting.

The employer must improve the audit process for nuclear medicine by:

- **Setting dates in advance to discuss clinical audits at clinical audit meetings**

- **Discussing nuclear medicine audits (IR(ME)R and clinical) at the wider radiology department audit meetings**

- **Reviewing and formalising IR(ME)R audit schedule.**

Employer’s duties: accidental or unintended exposures
Staff we spoke with described a clear procedure for reporting accidental or unintended exposures, including completing a Datix report, informing the Medical Physics Expert (MPE) and notifying the Radiation Protection Supervisor (RPS) where appropriate. We were told that learning from incidents was shared through structured team processes, including monthly “Errors and Excellence” meetings and quarterly or six-monthly reviews. These sessions focussed on both positive and negative outcomes, encouraging reflection on what went wrong, what went well, and how practice could be improved.

Only one nuclear medicine related significant accidental or unintended exposure (SAUE), had been reported in the last two years. This related to an equipment issue that had been resolved and had not since led to any further SAUEs. The SAF submitted described the process for the immediate management, investigation and follow-up actions of SAUE involving ionising radiation.

There was a written employer's procedure relating to the procedure for reporting and investigation of accidental or unintended medical exposures. Whilst the procedure stated that the "clinical decisions on whether to inform the individual or not would be clearly recorded in the patient's case notes" senior staff we spoke with said that they would inform all patients. The patient would only not be informed, in rare circumstances for example where a patient was unconscious s. The procedure did not include information on the circumstances of whether to inform the individual or not and this should be added to the employer's procedures.

Similarly, the employer's procedure stated that "the radiology clinical lead would establish the requirement to inform the referrer, the practitioner and the individual exposed or their representative, of the occurrence of any clinically significant unintended or accidental exposure (CSAUE) and the outcome of the dose and risk assessment". If determined there is a CSAUE the practitioner and referrer should always be informed. The relevant employer's procedure needed to be updated to make clear the practitioner, referrer and operator are informed.

The SAF described the process in place for recording and analysing accidental or unintended exposures including near misses. However, the employer's procedure only stated that incidents were presented to the Medical Exposure Group. The employer's procedure should be updated to reflect what happens in practice.

We also noted that the employer's procedure referred to X-ray equipment only, the procedure should also include reference to nuclear medicine equipment.

The employer must ensure that the relevant employer's procedure is updated to include:

- **Clarity on the circumstances of informing or not informing patient**
- **Making it clear that the relevant practitioner, referrer and operator should always be informed of any CSAUEs**
- **The process in place for recording and analysing accidental or unintended exposures including near misses**
- **References to nuclear medicine equipment.**

All respondents said their organisation encouraged them to report errors, near misses or incidents, but only 25% felt staff who were involved were treated fairly. Whilst all staff said that if they were concerned about unsafe practice, they would know how to report it, only half said they would feel secure raising concerns about

unsafe clinical practice. A similar number felt confident their concerns would be addressed and the remainder responded, 'don't know'. Additionally, further relevant responses were:

- Their organisation encouraged staff to raise concerns when something had gone wrong and to share this with the patient - 100%

- When errors, near misses or incidents were reported, the organisation took action to ensure they did not happen again - 75%

- They were given feedback about changes made in response to reported errors, near misses and incidents - 88%.

Duties of practitioner, operator and referrer
Staff we spoke with demonstrated a good understanding of their duty holder roles and responsibilities under IR(ME)R. The SAF explained how practitioners, operators and referrers were entitled to carry out their duties which was included in an employer's procedure.

There were differing training programmes in place for all duty holders under IR(ME)R and how training records for practitioners and operators were managed. The SAF described the process for non-medical referrers. Medical referrers received training as part of their undergraduate programme. Regarding non-radiology medical staff, responsibility for reviewing images and competency assessments was through their supervising consultant. Practitioners undertook training required to obtain the ARSAC licence.

There was a written employer's procedure for ensuring that quality assurance programmes in respect of written procedures, written protocols and equipment, were followed. The purpose of the procedure was to ensure that regular reviews of all policies, procedures and protocols were followed. The head of radiology approved any proposed changes to employer's procedures and authorised this by signing the front page. Changes were communicated to appropriate staff via internal email and staff meetings. Staff were asked to read and sign to agree their understanding of these revisions.

Justification of individual exposures
Senior staff we spoke with described the processes of how justification and authorisation was performed and where this was recorded. The DAGs supplied referred to ARSAC certification as opposed to the practitioner licence, it also stated that "An appropriately trained Operator working within written guidelines may undertake the task of authorisation" – this terminology related to outdated

Medicines (Administration of Radioactive Substances) (MARS) regulations and needed to be updated to relate to the current IR(ME)R regulations.

The patient information leaflets asked the patient to contact the department prior to their appointment if there was any possibility that they were pregnant or breastfeeding.

Staff we spoke with described how they would use authorisation guidelines and were aware that delegated authorisation guidelines (DAGs) were in place for certain procedures, including for carers or comforters. Carers or comforters completed consent forms, with risks and benefits explained and documented. They used DAGs to authorise exposures, ensuring clinical details aligned with protocols. The staff in training were aware of the process but had not been entitled yet to use the DAGs.

Optimisation
The SAF described how practitioners and operators ensured doses for diagnostic procedures were optimised. This included consideration of exposures to children, high dose exposures, persons who may be pregnant and breastfeeding and any methods for dose reduction. The SAF further explained that the patient information leaflets informed the patient that the amount of radiation was like that of an X-ray examination and that the benefits outweighed the risk. In discussion with senior staff, they agreed to change the description of risk with support from the MPE

Additional pregnancy and breastfeeding patient information leaflets were also provided. We were also told that for all in-patients the nursing team would be issued with a test specific radiation safety advice sheet, detailing the nursing procedure following administration of radioactive material.

There were posters designed for nuclear medicine examinations which were displayed prominently within the waiting areas of the imaging department relating to the benefits and risks associated with examinations using ionising radiation examinations.

Paediatrics
Paediatric administered activities were calculated based on the patient weight and the fraction of the adult administered activity as stated in the ARSAC Notes for Guidance. The relevant weight-based fractions from the ARSAC Notes for Guidance were displayed in the dispensing room next to the local diagnostic reference levels, for operators to reference. The ARSAC notes for guidance and the European nuclear medicine guidelines were referred to when setting the minimum administered activity for paediatric patients.

A play specialist attended on paediatric days and the gamma camera room was changed to be child friendly.

Carers or comforters
A delegated authorisation guideline (DAG) was in place that provided authorisation of carers and comforters exposures for CT and nuclear medicine examinations to be delegated to entitled operators. The DAG stated that the operator initiating the exposure was responsible for advising carers and comforters of the benefits and risks associated with being close to the patient during an exposure and prior to the exposure being made.

There was an employer's procedure for establishing dose constraints and guidance for the exposure of carers and comforters. This listed the procedure for nuclear medicine examinations and included an example of risk and benefit information for the carer or comforter.

The record associated with carers or comforters was linked to the patient record only. Staff confirmed that they asked the person if they have been a carer or comforter previously. We were told that there was an audit planned to investigate if carer or comforter dose constraint (2mSv) was exceeded. It was not clear from the DAG or the procedure if the radiographer was acting as the practitioner or operator. The DAG did not have a criterion for authorisation, this should be included.

The employer must ensure that the authorisation guidelines and the employer's procedure is updated to correctly reflect the process and ensure there is clarity on who is authorising the exposure to carers and comforters.

Expert advice
Staff we spoke with were aware of how to access MPEs for advice. Named MPEs were known to the team and relevant contact details were readily available. Whilst not all staff had personally contacted the MPEs, they understood the process and knew how to seek timely support when needed.

We reviewed the MPE support levels for both MPE and clinical scientist and were told that the MPEs were contactable outside the one day per month on site. There was not an agreed SLA for nuclear medicine MPE support. Therefore, the nuclear medicine specific MPE whole time equivalent (WTE) support was not easily identifiable. An approximate estimate provided by the nuclear medicine MPE was 0.1-0.2 WTE. We were told that the MPE was always available.

The MPE advice listed in the SLA did not include nuclear medicine and referred to X-ray only. Additionally, the equipment quality assurance programme only referred to X-ray, it did include CT as part of single-photon emission computed tomography (SPECT-CT) but there were no other references to nuclear medicine services. Nuclear medicine MPE services should be included in the SLA. Whilst we were told that, historically, a nuclear medicine SLA had never been formally agreed, currently there was a nuclear medicine specific SLA drafted and ready to be ratified. The diagnostic (X-ray) SLA agreement had been approved separately to nuclear medicine. Service and support was provided but there was a risk that this would not be provided or paid for.

The requirement for an SLA was raised at the last inspection in July 2021. An SLA for nuclear medicine would help in defining specific tasks that MPE and medical physics could support the health board within terms of compliance with IR(ME)R. Currently support appeared to be based on local need were identified by the nuclear medicine team.

MPE involvement and availability included:

- IR(ME)R advice
- Optimisation and review of DRLs
- Incident Analysis
- IR(ME)R training and IR(ME)R compliance audits
- Equipment Testing.

The employer must ensure there is a formal SLA in place for nuclear medicine medical physics support.

Equipment: general duties of the employer
We noted that the relevant employer's procedures described the quality assurance for the whole of radiology. The SAF described the quality assurance programme in place for all relevant equipment including testing of any equipment before first use, performance testing at regular intervals and testing following maintenance.

The SAF also described the process for the assessment of patient dose from nuclear medicine exposures and associated hybrid CT exposures. We were told that daily radionuclide calibrator quality control was performed and checks were made these were passed prior to patient radioactivity measurements. The radionuclide calibrator was subject to quality control testing on a daily, monthly and annual basis, with monthly accuracy checks against a regional system and annual accuracy checks against a secondary standard system.

We were provided with a description of the procedure for ensuring accurate verification of the administered activity. This was done in accordance with the employer's procedure for the use and review of DRLs.

There was also an accurate description of the measures to be taken when inadequate or defective equipment was identified. This included corrective actions that may be taken and how equipment issues were communicated to the employer.

Safe

Risk management

The department was accessible and easy to find, including good signage with a map at the main entrance. There were facilities for those with mobility difficulties. The environment was clean and in a good state of repair. No tripping hazards or clutter were noted in the department. All but two patients in the questionnaire said that they were able to find the department easily.

The control room was compact and included acquisition, processing and reporting workstations as well as a booking computer. There was a separate area for stress testing and a specific area with beds should patients need to lie down.

The gamma camera was installed in 2014 and is now over 10 years old. We were told that the gamma camera was the highest priority for replacement in the health board. Currently a task and finish group were looking at the options for replacing the gamma camera. However, there were infrastructure difficulties (related to electric supply). We saw documentation stating that the current funding allocation could not support the preferred option of full replacement and redevelopment of the radiology department to allow expansion of the nuclear medicine department. A full business case would be required and once that was approved by the health board it would be submitted to Welsh Government (WG) for consideration. However, the planned bid to be submitted to the WG to cover a replacement gamma camera at the current site, would take two years to complete (from bid to completion). Then for a new camera installation, it was expected that the nuclear medicine department would have to be shut down for six to nine months, with a need for a contingency plan to send patients to a different hospital. The gamma camera was identified as a single point of failure.

We were also told that the CT component of the current gamma camera had failed regularly. Furthermore, a photomultiplier tube correction had been required on the gamma camera. The version of the computer software used, to process scans, was also no longer supported by the manufacturer. Therefore, if an issue was to occur with patient images, these would have to be sent via the picture archiving

and communication system, (PACS) to another location for processing. This would require a separate agreement with another health board.

The employer must ensure that the replacement of the gamma camera is completed, and contingency plans are put in place as a matter of priority to reduce the risk of this identified current single point of failure.

Senior staff we spoke with described the procedure for reporting accidental or unintended exposures or other incidents. Relevant incidents would be reported to HIW. Quarterly learning from events meetings were held with nuclear medicine radiologists, radiographers and clinical technologists, where anonymised cases and audit findings were discussed.

We were also told that safety notices, alerts and other communications would be shared with staff and acted upon where required. We were also told that in the new structure all Welsh Health Circulars would come into the new Clinical Care Group via quality and safety.

Infection prevention and control (IPC) and decontamination
The nuclear environment was generally clean and well-maintained, with patient feedback confirming high standards of cleanliness. The gamma camera showed signs of wear but remained in good repair and visibly clean. The nuclear medicine suite itself was in a good state of repair and designed to support effective cleaning.

Infection control practices were appropriate. Radioactive sharps were disposed of in designated metal containers and non-radioactive sharps were managed using a separate bin, transported safely between rooms. Personal protective equipment (gloves and aprons) was available and accessible in the injection room, supporting safe clinical practice.

Staff we spoke with said that there was an issue with the cleaning of the department, due to the timings of the availability of cleaning staff when the department was busy. Senior staff we spoke with said that the cleaning audit results produce did not indicate there was an issue with cleaning of the department. Cleaning staff were not available on the weekend, should the department be open. One member of staff in the questionnaire commented:

> ***"With regards to cleaning the cleaners never come into our department this has become worse since we became wipe only. When staff are working till 8pm they ask the cleaners if they will clean and they barley come in. We are having to regularly clean the department ourselves as it is not up to standard."***

All the patients who completed the questionnaire said that the setting was clean and all but two patients who had an opinion said that IPC measures were being followed. Most staff respondents thought the organisation implemented an effective infection control policy and all said that there was appropriate PPE supplied and used. However, only half of respondents felt there was an effective cleaning schedule in place and 88% felt that the environment allowed for effective infection control.

The health board need to ensure that the cleaning of the dept is carried out as required and that this includes weekends when the service is operational.

Safeguarding of children and safeguarding adults
Staff we spoke with said they were aware of the organisations' policies and procedures for safeguarding children and adults at risk. Staff were also aware of the actions to take if they had a safeguarding concern.

Training records inspected showed that staff had completed safeguarding training at a suitable level.

Effective

Patient records
We checked a random sample of five current patient referral documents, including two patient records with childbearing potential. All the required information was present on the referral documents. All referral forms had been completed in full with the relevant information. There were several different types of referral forms noted. Ideally there would be one standardised format with a relevant box for all information and checks to be recorded in a consistent way. Only one inconsistency was found between paper record and the record on RadIS in the sample checked.

Efficient

Efficient
We spoke with staff about the arrangements and systems in place to promote an efficient service. They stated that patients were telephoned prior to the appointment to confirm their attendance and that they had access to a waiting list of patients who could attend at short notice.

Whilst the department was not normally open on the weekend due to the availability of the radionuclides, should the radiopharmacy be open on any weekends they would aim to also sources material to use on those weekends.

Senior staff we spoke with confirmed that the department aimed to maximise flow by filling empty appointments.

We spoke with senior staff about the medicines review that took place which included adjuvant drugs used as part of nuclear medicine exposures. This review was conducted due to findings in other areas of radiology where Patient Group Directions (PGDs) were not in place. Therefore, as part of this review, it was determined that prescriptions were required for all adjuvant drugs used in nuclear medicine.

We saw evidence that during the review senior staff were made aware of the provision in regulation 240 of the Human Medicines Regulations 2012 for IR(ME)R operators to administer prescription only medicines (POM) required as part of nuclear medicine procedures. this was confirmed by the MPE and reflected in the Hywel Dda UHB Injectable and Infusion Therapy Policy. We were told that locally there is a requirement for medicines to be part of a formulary. The adjuvant drugs used as part of nuclear medicine need to be put on the formulary.

We were told that protocols in nuclear medicine had been drafted to ensure compliance with regulation 240 of the Human Medicines Regulations 2012. However, these protocols had not yet been signed off by the head of radiology and this review had taken longer than senior staff would have hoped. We were told that once protocols were signed off, nuclear medicine staff would be able to work under the exemption.

We also received correspondence from one of the nuclear medicine practitioners, who stated that a Myocardial perfusion (MPS) imaging tests, had been in place in Withybush since 2016. They stated that significant progress had been made in reducing the waiting lists of the tests from approximately 11 months to three months. However, since November 2024, there had been a change in protocol that prevented the clinical technologist, from administering the Regadenoson and the radiopharmaceutical. The licence holder stated that whilst they managed the patient's history and completed the necessary forms, the clinical technologist was able to support the service by injecting the Regadenoson and radiopharmaceuticals under their direct supervision. This allowed the streamlining of the sessions.

However, due to the changes which had to be put in place, this resulted in a decrease in the capacity to perform scans and the waiting list had increased back to around 10-11 months. They believed that the service they undertook adhered closely to the protocols set forth by the nuclear medicine department of Singleton Hospital and the practitioner believed that the clinical technologist should be allowed to continue to perform the injections during the MPS which would greatly enhance efficiency and allow more patients to be managed and reduce the waiting

list further. Senior staff we spoke with raised concerns regarding the supervision of the myocardial perfusion stress sessions and stated that the governance of the process was currently being reviewed.

The employer must ensure that:

- **The adjuvant drugs used in nuclear medicine are part of the formulary**

- **The nuclear medicine protocols are ratified and approved to ensure compliance with regulation 240 of the Human Medicines Regulations 2012.**

We also spoke with another practitioner licence holder who was concerned that the clinical services plan consultation recently published by health board included five to six pages dedicated to radiology and diagnostics, with no mention of nuclear medicine. They believed that the nuclear medicine department felt ignored which was frustrating as nuclear medicine was integral to patient care for many patients including those with prostate and bone cancer and should be included in the plan. However, they were pleased to note that the plan gave hope if the principle of developing radiographers to carry out reporting could be delivered.

Quality of Management and Leadership

Staff feedback

HIW issued a questionnaire to staff to obtain their views about the department at the hospital. We received eight responses from staff at this setting. Responses by staff were mixed, with negative comments relating to senior managers being visible and the communication between senior management and staff. However, all staff agreed that the care of patients was the organisation's top priority and that their organisation encouraged them to report errors, near misses or incidents.

Staff we spoke with during the inspection spoke well when interviewed and were friendly and approachable. Staff comments in the questionnaire included:

> *"The modality lead manages the department well and is approachable however senior management lack visibility and approachability. There is also challenges as none of the senior management team have a nuclear medicine background although the site lead has had 2 days within the department to understand our challenges."*

> *"Modality lead sets a good example for leadership and promotes values of the health board creating a good working environment where staff feel supported and heard."*

> *".....When staff speak out they are targeted, this does not align with my values or the health board values yet it is allowed to continue."*

> *"My current line manager is extremely supportive and we are lucky to have her. Unfortunately, though she is under supported and her role has grown too big for her alone to manage. Senior managers do not appreciate this and she often feels undervalued. In fact the whole team feel undervalued and un-supported. The health board do not support progression within the workplace and do not support learning, this is resulting in low staff moral, and staff leaving as they are unhappy.*

> *"My job is really good with a fantastic team, interesting work and lovely patients. The only thing that causes me anxiety is the prospect of interactions with managers. I feel like 'knee-jerk' decisions are made that are not in the best interest of patients and staff and there are no consultation opportunities. The managers do not appear to want to engage with staff and 'sneak in' the side entrance and go straight to their office. Senior managers vary rarely come on site and when they do*

it is kept a secret so they are not disturbed I have witnessed cohersive {sic} tactics and staff not been treated equally. There is a strict hierarchy that prevents staff speaking directly to the head of radiology, as everything has to go through the Site leads, leading to misinformation. There are also rules in Radiology that do not apply to the rest of the hospital and are against HB values and policies."

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

Leadership

Governance and leadership

Senior staff we spoke with told us how all staff involved in delivering nuclear medicine services were accountable via the nuclear medicine head of service, despite being in different departments such as cardiology and radiology. The department had recently moved to the clinical care group structure, including healthcare science, pathology and radiology. It was positive to note the new structure proposed within the wider health board.

We noted that the service level agreement (SLA) for the Provision of Radiopharmaceuticals with Swansea Bay University Health Board support, was reviewed in June 2023 for a period of 12 months, with a review date of March 2024. This was written by the chief pharmacist, who had since left the organisation. Some actions were listed in the SLA such as the purchase of new transport containers which have now been purchased. However, the SLA required review and updates.

The employer must ensure that the SLA for the Provision of Radiopharmaceuticals with Swansea Bay University Health Board is reviewed and updated.

The Chief Executive had overall responsibility for the implementation of IR(ME)R with tasks, but not responsibility, this was delegated through the management structure. Key responsibilities under IR(ME)R for the Chief Executive and duty holders were provided in the Ionising Radiations Safety Policy. The health board Medical Exposure Group (MEG) had been established to oversee compliance with this policy and to consider patient safety matters arising from medical exposures within the health board. This was chaired by the Executive Director of Allied Health Professions and Health Science (DAHPHS) who reported into the Executive Board.

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

Staff we spoke with said that senior management did not visit the department and engage with them on a regular basis. They explained how information was shared between management and staff, this included through emails, online applications and face to face. We were told that there was a modality leads meeting every Monday morning, to raise issues and for the up and down passage of info. There were monthly meetings between the Site Lead Superintendent Radiographer and the Nuclear Medicine Superintendent Radiographer to ensure there was an effective passage of information.

Staff percentages agreeing with the comments of the organisation were as follows:

- My organisation was supportive - 13%
- My organisation supported staff to identify and solve problems - Nil
- My organisation took swift action to improve when necessary - 13%.

Regarding whether their immediate manager could be counted on to help them with a difficult task at work, 88% agreed and the same amount said their manager asked for their opinion before making decisions that affect their work. Additionally, 63% agreed that their immediate manager gave them clear feedback on their work, with 50% agreeing that senior managers were committed to patient care.

Workforce

Skilled and enabled workforce
We were provided with details of the numbers and skill mix of staff working at the department. Staff we spoke with felt that the department would benefit from more staff and that several staff had left recently, with two trainees employed, from the wider radiology team. These new staff were being trained and the team were increased by support staff with rotational support staff.

Records reviewed indicated 97% compliance with mandatory training requirements, including safeguarding and IPC at an appropriate level. 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.

The electronic staff record (ESR) was used to monitor and record training compliance. However, we were told that there was no mandatory oxygen cylinder training on ESR.

The health board must ensure that staff complete the relevant oxygen cylinder training.

Staff we spoke with understood their roles and scope of practice and answered our question well, describing IR(ME)R processes under their roles. Staff worked well together despite the challenging environment.

There was a relevant employer's procedures, relating to the practical training of practitioners and operators which stated that the practitioner or operator would not carry out a medical exposure or any other practical aspect of it unless they had received appropriate training. We spoke to senior staff about how the employer ensured practitioners and operators were adequately trained for their scope of practice. We were told for newly qualified staff, they were issued with an induction and training book that provided a training plan, access to learning materials and a logbook of practical skills and competencies.

We checked a sample of five IR(ME)R training and competency records. There was not an appropriate system to identify when reviews had taken place and there was not a list of training requirements to show IR(ME)R schedule 3 was complied with. A formal review and the recording of the review needed to be established and recorded.

There was not a standard theoretical training list relating to IR(ME)R, that staff should complete. Operators had a detailed practical competency list they needed to complete. Practitioners were required to complete appropriate medical training to obtain a practitioner licence.

The relevant employer's procedure did not refer to the review of training or training records. Senior staff we spoke with stated that the review was conducted as part of performance appraisals. A check of performance appraisal records showed this was not formally recorded.

The employer must ensure that:

- **A document list of relevant IR(ME)R theoretical training is introduced and completed by staff**

- **The relevant employer's procedure states the process for the review of training records and how the review of training records is recorded.**

Regarding training and development staff commented:

> ***"……if a staff member from Radiology attends a HB course everyone else will be allowed to do their on-line learning at home, but this is now prohibited in Radiology. CPD is actively discouraged, and the Radiology managers do not support advanced practice or role development (except for management courses). Requests for flexible working are generally frowned upon. Lots of staff in Radiology have left over the last year and others are considering leaving."***
>
> ***"Lack of opportunity to progress, management are not fourth coming about people improving and helping people further their career"***

In the staff questionnaire, all respondents said they had an appraisal, annual review, or development review of their work. Additionally, regarding their health and wellbeing at work, 75% of staff agreed that, in general, their job was not detrimental to their health, but only 25% said that their organisation took positive action on health and wellbeing. All bar one member of staff stated that their current working pattern and off duty allowed for a good work-life balance and all staff were aware of the occupational health support available to them.

All staff felt they had appropriate training to undertake their role. Some comments received on professional development were:

> ***"Currently in-training/new to post."***
>
> ***"Undergoing training in new role."***
>
> ***"I am new to my post and still undergoing training but the training I have received so far has been excellent."***

There were four members of staff who said they faced discrimination at work in the last 12 months. A similar number said they did not have fair and equal access to workplace opportunities and that the workplace was not supportive of equality and diversity.

The health board must ensure that processes are in place to ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken.

Culture

People engagement, feedback and learning
Staff we spoke with were confident when raising concerns and spoke well when interviewed. Staff understood the meaning of the duty of candour and had received training on the duty. All staff said in the questionnaire that they knew and understood the Duty of Candour and understood their role in meeting the Duty of Candour Standards.

Evidence in the patient questionnaire showed that most of those who answered knew how to complain about poor service if they wanted too.

All staff agreed that patient or service user experience feedback was collected within the department. However, only 25% of staff said they received regular updates on patient or service user experience feedback. Whilst only one respondent said that feedback from patients or service users was used to make informed decisions within the department, three said they did not know. Other responses in the staff questionnaire were as follows:

- Overall, staff were content with the efforts of the organisation to keep staff and patients safe - 63%

- They were involved in deciding on changes introduced that affected their work area – 87.5%

- They were able to meet the conflicting demands on their time at work - 100%

- They were able to access ICT systems needed to provide good care and support for patients - 50%.

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
- YDdraigGoch1
- 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: Nuclear Medicine Department, Withybush General Hospital

Date of inspection: 17/18 June 2025

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

	Risk/finding/issue	Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	No immediate assurances were identified.					

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

Service representative:

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Nuclear Medicine Department, Withybush General Hospital

Date of inspection: 17/18 June 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.	However, general health promotion, such as advice on healthy eating, physical activity, and mental wellbeing—was underrepresented. Furthermore, there was not clear signage advising patients to inform staff of relevant medical conditions and this message was not included in	The health board is to ensure the following information is clearly displayed in the waiting areas at the department: • General health promotion information on healthy eating, physical activity and mental wellbeing	Health and Care Quality Standards (H&CQS) – Health Promotion)	1. • Source general health posters for display in patient waiting areas. • Have general health flyers available for patients to take away. • Display posters to advise patients to	Superintendent Radiographer & Site Lead Superintendent Radiographer Superintendent Radiographer & Site Lead Superintendent Radiographer Superintendent Radiographer	12/09/25 12/09/25 12/09/25

	appointment letters, which may impact safe and effective care. There was prominent signage reminding patients, in English and multilingual languages, to inform staff if they were pregnant, though breastfeeding was not referenced on the signage. However, patient letters did provide detailed instructions for those who were pregnant or breastfeeding, including preparation guidance. Relevant information was made available to patients about the associated benefits and risks of the intended exposure.	• Information advising patients to inform staff of relevant medical conditions • Advising patients to inform staff of relevant medical conditions. This information must also be included in appointment letters sent to patients.		inform staff of relevant medical conditions. • Review and amend (as apprioriate) appointment letters to advise patients to inform staff of relevant medical conditions. To be implemented into new RIS system. • Develop/amend signage to inform staff if patients are breastfeeding and having Nuclear Procedures.	Superintendent Radiographer Superintendent Radiographer & Site Lead Superintendent Radiographer	31/10/25 01/10/25

2.	There was no designated waiting area for patients who had received radiopharmaceuticals. There was the possibility that, whilst patients would be told not be go near pregnant patients or children, they could sit in the main reception waiting room.	The health board must consider the need for designated waiting areas so that patients who have been injected with a radiopharmaceutical can wait for their scan in an area away from other patients.	H&CQS – Safe and Effective Care	2. Develop segregated waiting area for patients who are returning after having been injected with a radiopharmaceutical. This will be raised at RPG and an appropriate location will be allocated.	Superintendent Radiographer & Site Lead Superintendent Radiographer	31/12/26
3.	The letter sent to patients would benefit from medical physics support to improve the references to radiation risk.	The employer with support from medical physics must ensure that appropriate information is included in appointment letters in relation to radiation risks.	H&CQS – Communication and Language	3. Develop patient information in appointment letter to contextualise radiation risk. This will be incorporated into the new RIS system.	Superintendent Radiographer/ Medical Physics (SBUHB)	01/10/25

4.	Staff had access to telephone translation services, but no large print or easy-read materials were currently available. Staff typically read information aloud when needed. Given the demographic of the patients, greater consideration should be given to providing materials in accessible formats.	The health board must ensure that there is information available in accessible formats, including in large print, for the patients at the department.	H&CQS – Rights and Equality)	4. Develop large read print and easy read patient information to be offered to patients at the time booking and prior to the procedure.	Superintendent Radiographer	01/12/25
5.	There were two employer's procedures relating to referrals, one (number five) for acceptance of referrals and the other (number 25) for the making amending and cancelling of	The employer should consolidate the two procedures on the referral process into one.	Ionisation Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 Regulation 6 (5) (a) and Schedule 2(1)(p)	5. Review relevant Employers Procedures to amalgamate EP5 and EP25.	Deputy Head of Radiology	01/01/26

	referrals. There was overlap between the two procedures					
6.	There were three versions of DRLs displayed (each relating to a different practitioner) this is not required and the department should have one DRL on display for each procedure.	The employer must ensure that one clear set of DRLs for all procedures are displayed.	IR(ME)R 2017, Regulation 6 (5) and Schedule 2(1)(f))	6. Amended DRL has been issues, following advice from MPE.	Superintendent Radiographer/ Medical Physics (SBUHB)	Completed (13/08/2025)
7.	The entitlement process was covered in both Annex 1 of the Ionising Safety Policy and the employer's procedure (EP1) to identify individuals entitled to act as a referrer, practitioner or operator. We were	The employer must ensure that both Annex 1 of the Ionising Safety Policy and the employer's procedure (EP1) are reviewed for potential duplication and one document is used to cover the entitlement process.	IR(ME)R 2017, Schedule 2(1)(b)	7. Review of Ionising Safety Policy and Employers Procedure 1. Discussion with Medical Physics to decide which document is most appropriate for the entitlement process to remain.	Deputy Head of Radiology / Radiation Physics (SBUHB) & Medical Physics (SBUHB)	12/09/25

	told that this approach was consistent across the health board and was previously suggested by the MPE at Swansea Bay University Health Board. However, the department should review the documents for potential duplication and have one document to cover the entitlement process.					
8.	We noted an entitlement document for one member of staff which showed that training was completed in 2021, but the entitlement was only signed in May 2025. The training	The employer must ensure that: • All IR(ME)R entitlement and training competency documentation is completed in full,	IR(ME)R 2017, Regulation 10(3) and Schedule 2(1)(b)	8. • Ensure all entitlement documentation is completed prior to the duty holder being able to perform the task unsupervised.	Clinical Director	01/10/25

	record had not been signed off by the assessor, only the duty holder. We were told that the member of staff would sign this off, following this inspection. Reference was also noted in the employer's procedure to the previous title of the Executive Director of Allied Health Professions and Health Science (DAHPHS). The department agreed that the employer's procedure would be reviewed to ensure up to date job titles are used.	with the appropriate signatures, in a timely manner and before entitlement is granted • The employer's procedure contains reference to the correct titles of staff.		• Develop new entitlement document which reflects all duty holders under IR(ME)R. • Review all job titles within Employers Procedures.	Site Lead Superintendent Radiographer Deputy Head of Radiology	01/01/26 01/01/26
9.	However, the RPA 2000 list was not checked annually to ensure MPEs were still	The employer must ensure that the list of 'Current holders of the RPA 2000 Certificate of	IR(ME)R 2017, Regulation 14	9. Entitlement documents for all MPEs will be added to the IR(ME)R audit cycle by	Site Lead Superintendent Radiographers/	01/10/25

	named. The department agreed that annual checks of the RPA 2000 list would be completed.	Competence to act as a Medical Physics Expert (MPE)' is checked annually, to ensure that all MPEs appointed remain on the list.		Site Lead Superintendent Radiographers. Overseen by MEG.	Deputy Director of Health Science	
10.	The dates in the entitlement matrix had not been updated since initial entitlement. Also stated was that the entitlement matrix would be reviewed as part of the annual IR(ME)R audit. The entitlement reviews need to be updated formally on records.	The employer must ensure thar the entitlement matrix is updated annually when the individual's entitlement is reviewed and that this accurately reflects competency records.	IR(ME)R 2017, Schedule 2(1)(b)	10. The entitlement matrix will be updated on a three-monthly basis and will be added to the IR(ME)R audit cycle by Site Lead Superintendent Radiographers. Overseen by MEG and/or when the individual's entitlement is reviewed as part of annual PADR process or when they have additional tasks added.	Site Lead Superintendent Radiographers	01/10/25
11.	Relevant employer's procedure for establishing whether an individual of	The employer must ensure that the employer's procedure includes the correct duty	IR(ME)R 2017, Regulation 11 (b) and Schedule (2)(1)(c))	11. Review Employers Procedure 8 to amend the duty holder required	Deputy Head of Radiology	01/01/26

	childbearing potential may be pregnant or breastfeeding, were in place. The procedure stated that if a patient was found to be pregnant or breastfeeding then the exposure would need to be justified by a "senior clinical radiologist". However, for nuclear medicine this should state the "relevant licensed practitioner".	holder to justify nuclear medicine procedures, for pregnant or breastfeeding individuals.		to justify Nuclear Medicine procedures.		
12.	We noted during a tour of the department and following a conversation with a practitioner licence holder that clinical evaluation was at risk due to the	The employer must consider the environment under which the clinical evaluation is taking place and ensure any risk to the clinical evaluation is minimised.	IR(ME)R 2017, Regulation 12 (9) and Schedule2(1)(j)	12. Alternative reporting office locations have been offered. In addition, this will be reported to operational managers to explore further accommodation opportunities for quiet	Clinical Director	12/09/25

	environment in which the reporter was working within. This was because the reporting room was shared with the duty radiologist, we were told this could be noisy when there were queries or many people waiting to speak to the duty radiologist. This could be a potential patient safety issue as ideally there should be a quiet space for reporting, with the potential distraction being an issue.			space reporting for reporting radiologists and reporting radiographers.		
13.	Outcomes from clinical audits were discussed at bi-monthly meeting (learning and errors	The employer must ensure that all audits are discussed at regular meetings, to ensure	IR(ME)R 2017, Regulation 7	13. All clinical audits to be recorded on a centrally held clinical audit programme. All clinical audits to be	Led by Clinical Director supported by Quality Lead / Governance	31/03/26

	meeting). However, it was not made clear which audit results were being presented and when.	actions are completed and learning shared.		presented at the Radiology clinical audit meeting. Actions and learning outcomes will be tracked and shared with all Radiology staff.	Radiographer (to be appointed)	
14.	The only procedure describing the audit process was the employer's procedure on clinical audit, as a result there may be confusion between the difference of a clinical audit and IR(ME)R audit.	The employer must ensure that the relevant employer's procedure includes: • Details on the formal process and responsibilities of identifying and conducting both clinical and IR(ME)R audits • Reference to the audit report templates that should be used	IR(ME)R 2017, Regulation 7	14. Employers Procedure 21 to be reviewed and amended to include: • Details on the formal process and responsibilities of identifying and conducting both clinical and IR(ME)R audits • Reference to the audit report templates that should be used and included as an appendix.	Deputy Head of Radiology	01/01/26

		• Specific terminology to ensure clarity between clinical and IR(ME)R audits.		• Specific terminology to ensure clarity between clinical and IR(ME)R audits.		
15.	We were provided with examples of three audits, one was an "observational audit of staff compliance with IR(ME)R-2017-Employer Procedures". It was not clear what was being checked for each task listed, for example for "pregnancy checks" we were told this was the retrospective audit of forms. It was	The employer must improve the audit process for nuclear medicine by: • Setting dates in advance to discuss clinical audits at clinical audit meetings • Discussing nuclear medicine audits (IR(ME)R and clinical) at the wider radiology department audit meetings	IR(ME)R 2017, Regulation 7	15. • The bi-monthly clinical audit meeting will include an agenda item "next clinical audits" to ensure clinical audit programme is adhered to. • The bi-monthly clinical audit meeting will be structured to include a range of clinical audits	Led by Clinical Director supported by Quality Lead / Governance Radiographer (to be appointed) Led by Clinical Director supported by Quality Lead / Governance Radiographer	31/03/26 31/03/26

	highlighted that the MEG provide an IR(ME)R audit schedule. The frequency was usually six monthly or annually, depending on the audit being carried out. The IR(ME)R audit schedule was due to be ratified at the next MEG meeting.	• Reviewing and formalising IR(ME)R audit schedule.		from differing modalities and specialities. • Reviewing and formalising the IR(ME)R audit schedule at MEG.	(to be appointed) Deputy Director of Health Science	28/10/25
16.	If determined there is a CSAUE the practitioner and referrer should always be informed. The relevant employer's procedure needed to be updated to make clear the practitioner, referrer and operator are informed.	The employer must ensure that the relevant employer's procedure is updated to include: • Clarity on the circumstances of informing or not informing patient • Making it clear that the relevant	IR(ME)R 2017 Regulation 8 and Schedule 2(1)(k)	16. Employers Procedure 19 to be reviewed and updated to include: • Clarity on the circumstances of informing or not informing patient • Making it clear that the relevant practitioner,	Deputy Head of Radiology	01/01/26

	The SAF described the process in place for recording and analysing accidental or unintended exposures including near misses. However, the employer's procedure only stated that incidents were presented to the Medical Exposure Group. The employer's procedure should be updated to reflect what happens in practice. We also noted that the employer's procedure referred to X-ray equipment only, the procedure should also include reference to nuclear medicine equipment.	practitioner, referrer and operator should always be informed of any CSAUEs • The process in place for recording and analysing accidental or unintended exposures including near misses • References to nuclear medicine equipment.		referrer and operator should always be informed of any CSAUEs • The process in place for recording and analysing accidental or unintended exposures including near misses References to nuclear medicine equipment.		

17.	The record associated with carers or comforters was linked to the patient record only. Staff confirmed that they asked the person if they have been a carer or comforter previously. We were told that there was an audit planned to investigate if carer or comforter dose constraint (2mSv) was exceeded. It was not clear from the DAG or the procedure if the radiographer was acting as the practitioner or operator. The DAG did not have a criterion for authorisation, this should be included.	The employer must ensure that the authorisation guidelines and the employer's procedure is updated to correctly reflect the process and ensure there is clarity on who is authorising the exposure to carers and comforters.	IR(ME)R 2017, Schedule 2(1)(n)	17. The carers and comforters DAG will be reviewed and reissued for CT and nuclear medicine In addition, the Employer's Procedure will be amended to offer specific guidance to staff and including recording of authorisation following advice from MPE.	Clinical Director for Radiology / Consultant Radiologist Superintendent Radiographer / Medical Physics (SBUHB) / Consultant Radiologist / Head of Radiology	28/10/25 28/10/25

18.	The MPE advice listed in the SLA did not include nuclear medicine and referred to X-ray only. Additionally, the equipment quality assurance programme only referred to X-ray, it did include CT as part of single-photon emission computed tomography (SPECT-CT) but there were no other references to nuclear medicine services. Nuclear medicine MPE services should be included in the SLA. The requirement for an SLA was raised at the last inspection in July 2021.	The employer must ensure there is a formal SLA in place for nuclear medicine medical physics support.	IR(ME)R 2017, Regulation 14	18. Develop and finalise formal SLA for Nuclear Medicine Medical Physics support.	Medical Physics (SBUHB)	01/03/26

19.	The gamma camera was identified as a single point of failure. We were also told that the CT component of the current gamma camera had failed regularly. A photomultiplier tube correction had been required on the gamma camera. The version of the computer software used, to process scans, was also no longer supported by the manufacturer.	The employer must ensure that the replacement of the gamma camera is completed, and contingency plans are put in place as a matter of priority to reduce the risk of this identified current single point of failure.	IR(ME)R 2017, Regulation 15	19. • Replacement of the gamma camera to be completed. • Contingency plans to be updated in the event of service or equipment failure. • Exploration of an SLA arrangement with a neighbouring healthboard	Deputy Head of Radiology Superintendent Radiographer Head of Radiology	01/04/27 01/11/25 01/06/26
20.	We saw evidence that during the review senior staff were made aware of the provision in regulation 240 of the Human	The employer must ensure that: • The adjuvant drugs used in nuclear	Human Medicines Regulations 2012, Regulation 240	20. • Nuclear Medicine drugs have been added to the Formulary.	Deputy Head of Radiology / Head of Radiology	Completed

	Medicines Regulations 2012 for IR(ME)R operators to administer prescription only medicines (POM) required as part of nuclear medicine procedures. This was confirmed by the MPE and also reflected in the Hywel Dda UHB Injectable and Infusion Therapy Policy. We were told that locally there is a requirement for medicines to be part of a formulary. The adjuvant drugs used as part of nuclear medicine need to be put on the formulary.	medicine are part of the formulary • The nuclear medicine protocols are ratified and approved to ensure compliance with regulation 240 of the Human Medicines Regulations 2012.		• Nuclear Medicine protocols to be reviewed, amended and ratified appropriately by Head of Radiology Services Manager, in consultation with the ARSAC licence holders and MPE to ensure compliance with regulation 240 of the Human Medicines Regulations 2012.	Head of Radiology/ ARSAC license holders / MPE	01/01/26
21.	HIW issued a questionnaire to staff	The health board is required to reflect on	H&CQS – Leadership	Finalisation of an action plan has been to explore	Deputy Director of Health	12/09/25

	to obtain their views about the department at the hospital. We received eight responses from staff at this setting. Written responses by staff could be considered critical of senior management. Additionally, some of the responses were not positive.	some of the less favourable responses from staff throughout this report and inform HIW of the actions they will take to address these issues.		in detail the responses from the staff survey	Sciences / Head of Radiology	
22.	We noted that the service level agreement (SLA) for the Provision of Radiopharmaceuticals with Swansea Bay University Health Board support, was reviewed in June 2023 for a period of 12 months, with a review date of March 2024.	The employer must ensure that the SLA for the Provision of Radiopharmaceuticals with Swansea Bay University Health Board is reviewed and updated.	IR(ME)R 2017, Schedule 3	22. SLA for the Provision of Radiopharmaceuticals with Swansea Bay University Health Board will be reviewed and updated.	Head of Radiology	01/06/26

	However, the SLA required review and updates.					
23.	The electronic staff record (ESR) was used to monitor and record training compliance. However, we were told that there was no mandatory oxygen cylinder training on ESR.	The health board must ensure that staff complete the relevant oxygen cylinder training.	H&CQS – Workforce	23. • All relevant Radiology staff will complete mandatory oxygen cylinder training. • Discussions with Learning and Development to add the mandatory training module to be added to all clinical staff ESR records.	Site Lead Superintendent Radiographers Deputy Head of Radiology	01/12/25 01/10/25
24.	There was not a standard theoretical training list relating to IR(ME)R, that staff should complete.	The employer must ensure that: • A document list of relevant IR(ME)R	IR(ME)R 2017, Regulation 6 (3) (b) and 17, and Schedule 3	24. • Preceptorship document to be developed for Nuclear Medicine	Superintendent Radiographer / Medical Physics (SBUHB)	01/10/25

	Operators had a detailed practical competency list they needed to complete. Practitioners were required to complete appropriate medical training to obtain a practitioner licence. The relevant employer's procedure did not refer to the review of training or training records. Senior staff we spoke with stated that the review was conducted as part of performance appraisals. A check of performance appraisal records showed this was not formally recorded.	theoretical training is introduced and completed by staff • The relevant employer's procedure states the process for the review of training records and how the review of training records is recorded.		staff to include theoretical IR(ME)R training prior to entitlement. Advice will be sought from the UHB preceptorship lead. • Process added to Employers Procedure around review of training records.	Deputy Head of Radiology	01/01/26

25.	There were four members of staff who said they faced discrimination at work in the last 12 months. A similar number said they did not have fair and equal access to workplace opportunities and that the workplace was not supportive of equality and diversity.	The health board must ensure that processes are in place to ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken.	H&CQS – Equality	25. To address this we will follow the process in point 21.	Deputy Director of Health Sciences / Head of Radiology	12/09/25

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): **Jonathan Arthur**

Job role: **Deputy Director of Health Science**

Date: **Updated 08 09 2025**