

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

Nuclear Medicine Department and
Mobile PET-CT Unit, Singleton
Hospital, Swansea Bay 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.



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1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department and the mobile PET-CT unit at Singleton Hospital, Swansea Bay University Health Board on 10 and 11 October 2023. During our inspection we looked at how the department and the mobile unit complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and two Scientific Advisors from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. The inspection was led by a HIW Senior Healthcare Inspector.

Before 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 27 questionnaires were completed by patients or their carers and 25 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.

This (full) report is designed for the setting, and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our [website](#).

2. Summary of inspection

Quality of Patient Experience

Overall summary:

Patients provided positive feedback about their experiences of attending the Nuclear Medicine Department or the mobile PET-CT unit.

We found staff treated patients with courtesy, respect and kindness. Feedback from patients also supported this. We also found staff provided care in a way that protected and promoted patients' rights.

Patients told us they had been provided with sufficient information and had been involved as much as they had wanted to be in their care.

This is what we recommend the service can improve

- The health board needs to make relevant health promotion material available to patients attending for a PET-CT scan
- The health board needs to encourage Welsh speaking staff to wear badges or lanyards to show they are happy to communicate in Welsh
- The health board needs to make staff aware they should always ask patients their preferred language they wish to use to communicate.

This is what the service did well:

- Patients provided positive feedback and comments about the attitude and approach of the staff looking after them
- Patients told us they didn't have to wait long for their examination or scan.

Delivery of Safe and Effective Care

Overall summary:

We found good compliance with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017, across the Nuclear Medicine Department and the mobile PET-CT unit.

We also found effective arrangements were in place to provide patients with safe and effective care.

This is what we recommend the service can improve

- The employer for the Nuclear Medicine Department and the employer for the mobile PET-CT unit need to review and update some of their written

procedures to make them clearer and to reflect the working arrangements described

- The employer for the Nuclear Medicine Department needs to make arrangements to clearly show the outcome of clinical audits, the actions to be taken, the person responsible and the date for completion
- The employer for the mobile PET-CT unit needs to make arrangements to carry out clinical audit as defined by IR(ME)R 2017
- The employer for the mobile PET-CT unit needs to ensure the equipment inventory contains all the information required by IR(ME)R 2017.

This is what the service did well:

- Senior staff working for the Nuclear Medicine Department provided good examples of clinical audit and we saw a good example of optimisation for parathyroid examinations as a result of audit activity
- Senior staff for the mobile PET-CT unit provided good examples of learning from incidents and ‘near-misses’.

Quality of Management and Leadership

Overall summary:

Swansea Bay University Health Board did not have its own facilities to provide a PET-CT service. This was provided on behalf of the health board by InHealth, an independent healthcare provider, using a mobile PET-CT unit that regularly visited the hospital site.

The Chief Executives of both organisations were the designated employers under IR(ME)R 2017. Clear lines of reporting and accountability were described and demonstrated during the inspection. However, the governance document setting out the working and governance arrangements would benefit from being reviewed to accurately reflect those described.

Feedback from staff was generally positive around the leadership and management of the organisations they worked for.

This is what we recommend the service can improve

- The employer for the Nuclear Medicine Department and the employer for the mobile PET-CT unit need to make arrangements to demonstrate staff remain competent to carry out their duty holder roles
- The health board needs to make arrangements to show how patient feedback has been used to make changes
- The health board needs to make available to patients details of the recourse available, such as the Public Services Ombudsman for Wales and LLAIS, to

patients who may raise concerns or complaints about the mobile PET-CT service delivered at the hospital.

This is what the service did well:

- Staff feedback was generally positive around the management and leadership of the organisations they worked for
- Suitable and effective arrangements were described for seeking patient feedback, for managing concerns and complaints, and for acting on these to make improvements where needed
- An effective working relationship between the health board and the independent provider was described and demonstrated.

Details of the concerns for patient's safety and the immediate improvements and remedial action required are provided in [Appendix B](#).

3. What we found

Quality of Patient Experience

Patient Feedback

Feedback received was positive across all areas considered, with all respondents who answered the question (26/26) rating the service they had received as ‘very good’.

Patient comments included the following:

“Staff were helpful and friendly and put me at my ease, making the experience easier”

“Friendly and attentive staff, clean and new facilities”

Person Centred

Health Promotion

We saw health promotion material was displayed in the waiting areas within the Nuclear Medicine Department. This included information on the benefits of not smoking.

There was less health promotion material displayed in the separate waiting area (located within the main hospital) used by patients waiting for their scan at the mobile PET-CT unit.

The health board is required to provide HIW with details of the action taken to make relevant health promotion material easily available to patients attending for a PET-CT scan.

Dignified and Respectful Care

We saw suitable arrangements were in place to promote the privacy and dignity of patients attending the Nuclear Medicine Department or the mobile PET-CT unit.

We found all staff treated patients with courtesy, respect, and kindness.

All respondents who completed a HIW patient questionnaire told us staff had treated them with dignity and respect. All those who answered the question (26/26) told us measures were taken to protect their privacy.

All staff who completed a HIW questionnaire also told us the privacy and dignity of patients is maintained.

Individualised Care

All respondents who completed a HIW questionnaire told us they were given information on how to care for themselves after their examination or scan. In addition, the majority of respondents who answered the question in the HIW patient questionnaire (22/25) also told us they had been given written information on who to contact for advice following their examination or scan.

All respondents who answered the question in the HIW patient questionnaire (26/26) told us they had been involved as much as they wanted to be in decisions about their examination or scan. Similarly, all respondents who completed a HIW patient questionnaire told us staff had explained what they were doing, had listened to them and answered their questions.

All staff who completed a HIW questionnaire also told us patients are informed and involved in decisions about their care.

All staff also told us they were satisfied with the standard of care and support they give to patients. In addition, all staff who completed a HIW questionnaire told us they would be happy with the standard of care provided by their organisation for themselves or their friends/families.

Timely

Timely Care

Staff told us patients did not usually have to wait long for their examination after arriving at the hospital. When there were unexpected delays, we were told staff would inform patients of these and would endeavour to keep them up to date.

The majority of respondents who completed a HIW patient questionnaire (26/27) told us they thought the wait time between their referral and their appointment was reasonable. The majority of respondents who answered the question (23/25) also told us they were told how long they would likely have to wait to be seen.

Equitable

Communication and Language

We saw bilingual signage, in both Welsh and English, displayed within the Nuclear Medicine Department.

We were told there were Welsh speaking staff working within the Nuclear Medicine Department. We saw some staff were wearing badges or had symbols embroidered onto their uniforms to show patients they were Welsh speakers.

The majority of staff who completed a HIW questionnaire (18/23) told us they were not a Welsh speaker. When asked whether they wear a badge or lanyard to tell patients they are happy to communicate in Welsh, the majority of staff who answered the question (5/7) told us they did not. The remainder told us they did (1/7) or they sometimes did (1/7).

The health board is required to provide HIW with details of the action taken to encourage those staff who are happy to do so to wear badges or lanyards to show patients they are happy to communicate in Welsh.

Staff we spoke with told us patients' language preference is confirmed prior to attending for their examination or scan. However, responses from staff who answered the question within the HIW questionnaire indicated this did not always happen, with most (4/7) telling us 'No' and few (3/7) telling us 'Sometimes'.

The health board is required to provide HIW with details of the action taken to make staff aware they should always ask patients their preferred language they wish to use to communicate.

All respondents who answered the question in the HIW patient questionnaire told us their preferred language is English. Where required, staff told us they could access a translation service to facilitate communication with those patients whose first language is not English.

Posters were clearly displayed advising patients who are or might be pregnant or breastfeeding to inform staff prior to them having their examination or scan. This information was displayed in both Welsh and English and suitable pictograms were also used.

We were told information booklets were given to patients before attending the Nuclear Medicine Department or the mobile PET-CT unit. These provided information for patients on what to expect when attending for their examination or scan. Staff we spoke with also confirmed they verbally explained to patients what to expect before patients had their examination or scan.

Posters were also clearly displayed within the waiting areas, advising patients of the benefits of having the examination or scan (exposure) and the risks associated with the radiation dose.

Rights and Equality

We found staff working in the Nuclear Medicine Department and the mobile PET-CT unit provided care in a way that protected and promoted patients' rights.

Staff we spoke with felt their organisations effectively promoted equality and diversity. Staff also told us training on equality and diversity matters formed part of their organisation's mandatory training programme.

The majority of respondents who answered the question in the HIW patient questionnaire (24/25) told us they had not faced discrimination when accessing the service provided by the Nuclear Medicine Department or the mobile PET-CT unit.

The majority who answered the question (23/26) also told us they felt they can 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 remainder either told us they could not (2/25) or preferred not to say (1/25).

Delivery of Safe and Effective Care

Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017

Employer's Duties: Establishment of General Procedures, Protocols and Quality Assurance Programmes

Procedures and Protocols

The employer for the Nuclear Medicine Department and the employer for the mobile PET-CT unit had established written procedures and protocols as required under IR(ME)R 2017.

We were told some of the employer's written procedures in place for the Nuclear Medicine Department were also used by the mobile PET-CT unit. The arrangements for providing the PET-CT service were described within a governance document (see 'Quality of Management and Leadership' section of this report) and this included a list of which employer's written procedures applied.

Suitable arrangements were described for the quality assurance of the written procedures and protocols used in the Nuclear Medicine Department and the mobile PET-CT unit. Both the employer for the Nuclear Medicine Department and the mobile PET-CT unit had written procedures in this regard.

The sample of written procedures and protocols we reviewed included suitable document control identification.

Referral Guidelines

We were told referrals for examinations at the Nuclear Medicine Department and for scans at the mobile PET-CT unit were organised and managed by the health board.

Therefore, the employer for the Nuclear Medicine Department had responsibility for the establishment of referral guidelines and for making these available to entitled referrers.

The employer had established referral guidelines for examinations performed at the Nuclear Medicine Department and for scans performed at the mobile PET-CT unit. Suitable arrangements were described for making these available to individuals entitled to act as referrers. However, we confirmed there were no referral guidelines in place for nuclear medicine therapy.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to establish referral guidelines for nuclear medicine therapy and to make these available to relevant referrers.

Diagnostic Reference Levels

There was a suitable employer's written procedure in place for the use and review of diagnostic reference levels (DRLs) for nuclear medicine examinations performed at the Nuclear Medicine Department. However, we identified the DRL table within the written procedure should include the maximum and minimum range of administered activity for each procedure, rather than percentages for greater clarity.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to include the maximum and minimum range of administered activity within the employer's written procedure for the use and review of diagnostic reference levels.

A separate, suitable employer's written procedure was also in place for scans performed at the mobile PET-CT unit.

We confirmed local DRLs had been established for both nuclear medicine examinations and for PET-CT scans. These were equal to or below national DRLs. We identified this as noteworthy practice.

We confirmed DRL audits were conducted taking into account all administrations at all the sites the mobile PET-CT unit attends. Senior staff may wish to consider conducting DRL audits on a local basis for the patient administrations that are performed at the Singleton Hospital site only.

Medical Research

We were told research involving medical exposures was conducted at the Nuclear Medicine Department and the mobile PET-CT unit.

Suitable governance arrangements were described for research trials, with appropriate involvement of Medical Physics Experts (MPEs). These included processes to ensure appropriate employer and practitioner licenses are in place. Suitable arrangements were also described for managing research trials, including the correct identification of referrals and the correct selection of the relevant protocol to be used.

There was a suitable employer's written procedure, describing these governance arrangements, in place for medical exposures performed for research at the Nuclear Medicine Department.

A separate employer's written procedure was in place for the mobile PET-CT unit. This described the above governance arrangements. However, the written procedure did not describe the process to ensure individual patients had not exceeded the dose constraint for all exposures which occur within a research trial.

The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to update the written procedure in relation to research so it clearly describes the process to ensure individual patients had not exceeded the dose constraint for all exposures which occur within a research trial.

Entitlement

There was a suitable employer's written procedure in place to identify individuals entitled to act as referrer, practitioner, or operator within a specified scope of practice at the Nuclear Medicine Department.

A separate, suitable employer's written procedure was also in place for the mobile PET-CT unit.

We confirmed the entitlement of referrers in relation to nuclear medicine examinations, PET-CT scans and nuclear medicine therapy was the responsibility of the employer for the Nuclear Medicine Department.

The responsibility for the entitlement of practitioners and operators working in the Nuclear Medicine Department and the mobile PET-CT unit was the responsibility of the employer for the Nuclear Medicine Departments and the mobile PET-CT unit, respectively.

The governance document was inconsistent regarding the above and should be reviewed to clearly reflect the entitlement arrangements described above.

Patient Identification

There was a suitable employer's written procedure in place to correctly identify the individual to be exposed to ionising radiation for examinations performed in the Nuclear Medicine Department.

A separate, suitable employer's written procedure was also in place for scans performed in the mobile PET-CT unit.

Both included details of the action to be taken by duty holders where patients are unable to identify themselves. In addition, both written procedures addressed those situations where more than one operator is involved in the examination or scan.

Staff we spoke with described the action they would take to correctly identify patients prior to examinations or scans being performed. This was consistent with the relevant employer's procedure.

Individuals of Childbearing Potential (Pregnancy Enquiries)

There was an employer's written procedure in place for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding for examinations performed in the Nuclear Medicine Department. We were told this was in the process of being updated to take account of guidance¹ issued by the Society of Radiographers (SoR) and notes for guidance² issued by the Administration of Radioactive Substances Association (ARSAC).

A separate, employer's written procedure was also in place for scans performed in mobile PET-CT unit. We were told this was also in the process of being reviewed to provide further clarification for duty holders on the correct procedure to follow.

We identified some improvement could be made to clarify both written procedures.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding:

- so the flowchart includes more details to guide duty holders on when to make the enquiry and the different enquiry options
- to clearly demonstrate to whom enquiries should be made and how this is managed in a sensitive manner.

The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to revise and update the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding:

¹ Inclusive pregnancy status guidelines for ionising radiation: Diagnostic and therapeutic exposures - https://www.sor.org/getmedia/1d256f96-40cb-4eeb-b120-90fe27daf7e9/Inclusive-Pregnancy-Status-Guidelines-for-Ionising-Radiation_LLv2

² ARSAC notes for guidance: good clinical practice in nuclear medicine - <https://www.gov.uk/government/publications/arsac-notes-for-guidance>

- so the procedure for staff is clear and to include reference to the circumstances when a pregnancy test should be considered.

While we identified the written procedures could be clarified, we were assured staff were making suitable enquiries in relation to pregnancy and breastfeeding.

Benefits and Risks

Suitable arrangements were described for providing patients with adequate information on the benefits of having the examination or scan (exposure) and the risks associated with the radiation dose.

We saw posters explaining the risk and benefits clearly displayed within the waiting areas for the Nuclear Medicine Department and mobile PET-CT unit for patients to see.

We were told patients were provided with a patient information leaflet prior to their examination or scan and saw information on benefits and risks was included within the leaflet. We were also told staff would reiterate this information to patients verbally when they attended for their examination.

All respondents who completed a HIW patient questionnaire told us they had been given enough information about the benefits and risks of their examination or scan.

Clinical Evaluation

We were told the clinical evaluation of examinations performed at the Nuclear Medicine Department and of scans performed at the mobile PET-CT unit were organised and managed by the health board. Therefore, the employer for the Nuclear Medicine Department had responsibility for the establishment of an employer's written procedure for clinical evaluation.

There was an employer's written procedure in place. This clearly indicated it applied to all nuclear medicine examinations, including PET-CT scans conducted at the hospital.

We identified some improvement could be made to clarify the written procedure, in relation to the arrangements for outsourcing clinical evaluation and the clinical evaluation of nuclear medicine therapies.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the employer's written procedure for the clinical evaluation of exposures:

- to accurately reflect the arrangements for outsourcing the clinical evaluation of some PET-CT scans as described by senior staff
- to include the arrangements for the clinical evaluation of nuclear medicine therapies.

References were made to named duty holders entitled to provide a clinical evaluation. In addition, reference was also made in the written procedure to other duty holders listed on 'entitlement registers'. The employer may wish to review this approach and direct staff to one point of reference where these duty holders are recorded.

Non-medical Imaging Exposures

We were told non-medical imaging exposures were not performed at the Nuclear Medicine Department nor the mobile PET-CT unit. Both the employer's written procedures in place for the Nuclear Medicine Department and the mobile PET-CT unit clearly indicated this was the case.

Employer's Duties - Clinical Audit

We were provided with examples of the clinical audits conducted for the Nuclear Medicine Department and the mobile PET-CT unit.

While good examples of clinical audit were provided for the Nuclear Medicine Department, such as the optimisation of exposures for parathyroid examinations, some key information was not always included. They did not always clearly show the outcome, how this is acted upon, the person responsible for completing the actions and a date for completion.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to clearly show the outcome of clinical audits, the actions to be taken, the person responsible for the actions and the date for completion.

The examples provided for the mobile PET-CT unit were considered by HIW to be audits of compliance with IR(ME)R rather than clinical audits.

The employer of the mobile PET-CT unit is required to provide HIW with details of the action taken to carry out clinical audit as defined by IRMER 2017, taking into account guidance issued by the RCR.

Employer's Duties - Accidental or Unintended exposures

There was an employer's written procedure in place for the reporting, recording, investigating and the analysis of significant accidental or unintended exposures involving radiation for the Nuclear Medicine Department.

A separate, employer's written procedure was also in place for accidental or unintended exposures for the mobile PET-CT unit.

We saw both the written procedures referred to guidance jointly agreed by the English, Welsh, Scottish and Northern Ireland enforcement authorities. Updated guidance was published in April 2023. Both the written procedures should, therefore, be reviewed taking into account the updated guidance³. Particular attention should be given to ensuring the written procedures consider the notification criteria applicable in Wales.

The arrangements for informing the referrer, practitioner and the patient were well described in the written procedures.

In relation to the mobile PET-CT unit, we were provided with good examples of learning from incidents and 'near-misses'.

We were told the employer's quality assurance programme for the Nuclear Medicine Department did not include a study of the risk of accidental or unintended exposures in relation to nuclear medicine therapy. This would help to identify known risks so that appropriate control measure can be put in place.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to include in the employer's quality assurance programme a study of risk for of accidental or unintended exposures in relation to nuclear medicine therapy.

All staff who completed a HIW questionnaire told us their organisation encourages them to report errors, near misses or incidents. We identified this as noteworthy practice to promote patient safety. The majority of staff told us their organisation treats staff involved in incidents fairly (22/25), takes action to ensure they do not happen again (23/25) and provides them with feedback about changes made in response (22/25). The remainder disagreed.

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 sample of referral forms we examined showed referrals to both the Nuclear Medicine Department and the mobile PET-CT unit had been made in accordance

³ Notifying significant accidental and unintended exposures under IR(ME)R - Guidance for employers and duty holders - https://www.hiw.org.uk/sites/default/files/2023-04/20230327SAUEGuidanceVersion3_.pdf

with the established referral guidelines. We saw the forms included sufficient clinical details and had been appropriately completed.

We were provided with examples of audits that showed suitable arrangements were in place to monitor staff compliance with the employer's written procedures used in the Nuclear Medicine Department and the mobile PET-CT unit.

Justification of Individual Exposures

We were told exposures performed at the Nuclear Medicine Department were justified and authorised by entitled practitioners working at the Nuclear Medicine Department. Operators could also authorise exposures in accordance with Delegated Authorisation Guidelines (DAG) issued by the practitioner.

All exposures performed at the mobile PET-CT unit were justified and authorised by entitled practitioners working at the Nuclear Medicine Department. Therefore, the employer for the Nuclear Medicine Department had responsibility for the establishment of an employer's written procedure in this regard.

There was a suitable employer's written procedure in place. This clearly indicated it applied to all nuclear medicine examinations, including PET-CT scans conducted at the hospital.

Given the arrangements described, there was no DAG in place, nor required, for operators working in the mobile PET-CT unit to authorise scans. However, the governance document made reference to a DAG for operators working in the mobile unit to use. This was inconsistent with the arrangements described as being in place.

The sample of referral documentation we examined had evidence of the above written procedure being followed.

For the Nuclear Medicine Department, we were told exposures to carers or comforters were justified and authorised by entitled practitioners working at the Nuclear Medicine Department. Operators could also authorise exposures in accordance with DAG issued by the practitioner.

There was an employer's written procedure in place for the justification and authorisation of exposures to carers and comforters at the Nuclear Medicine Department. We were told the authorisation would be recorded on a carer or comforter consent form, however the written procedure did not describe this.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the employer's written

procedure for the justification and authorisation of exposures so it clearly describes the procedure for recording the authorisation of exposures to carers or comforters.

We also reviewed the DAG for exposures to carers or comforters and felt it could include more detail regarding the criteria which operators follow and to be consistent with the employer's procedure.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the DAG for the authorisation of exposures to carers or comforters, by entitled operators, so it includes more detail regarding the criteria which operators follow and to be consistent with the employer's procedure.

We were told operators working in the mobile PET-CT unit had been entitled as practitioners to justify and authorise exposures to carers or comforters, in some locations. However, this was not yet in place at this site. The practitioner for the administration of the radioactive activity was the practitioner for the justification and authorisation of exposures to carers or comforters. A suitable employer's written procedure was in place in this regard and included details of how authorisation should be recorded.

We confirmed the employer and practitioners held valid licences to undertake the intended exposures involving the administration of radioactive substances.

Optimisation

Suitable arrangements were described in relation to how practitioners and operators ensure exposures performed at the Nuclear Medicine Department and the mobile PET-CT unit were as low as reasonably practicable (ALARP). These arrangements included how practitioners and operators pay particular attention in relation to individuals in whom pregnancy cannot be excluded, individuals who are breastfeeding and exposures involving high doses to the individual.

Paediatrics

We were told the Nuclear Medicine Department did not routinely perform nuclear medicine examinations on children. However, where this was the case, suitable arrangements were described for the optimisation of such exposures. These included reducing DRLs, scaling down adult administered activity according to a child's weight and operators adjusting clinical protocols accordingly.

We were told scans of children were not performed on the mobile PET-CT unit.
Carers or Comforters

There was a suitable employer's written procedure in place to establish dose constraints and guidance for the exposure to carers or comforters for the Nuclear Medicine Department. This clearly set out the dose constraints for all nuclear medicine examinations.

A separate, employer's written procedure was also in place for the exposure to carers and comforters for the mobile PET-CT unit. The dose constraint stated in the overarching employer's written procedures was '1mSv per annum whole body dose limit'. This differed to that of '0.5mSv' constraint described in the employer's written procedure specifically relating to carers and comforters. Therefore, arrangements should be made to ensure both documents are consistent.

Expert Advice

We confirmed the employer for the Nuclear Medicine Department and the employer for the mobile PET-CT unit had appointed and entitled MPEs to provide advice on radiation protection matters and compliance with IR(ME)R 2017.

Equipment: General Duties of the Employer

The employer for the Nuclear Medicine Department and the employer for the mobile PET-CT unit had quality assurance programmes in respect of the equipment used in the department or the unit.

Suitable arrangements were described for the acceptance testing of new equipment, performance testing at regular intervals and performance testing following equipment maintenance.

In addition, a suitable process was described for identifying, reporting and escalating equipment faults to senior staff so appropriate action can be taken. This included removing equipment from service.

Up-to-date equipment inventories for equipment at the Nuclear Medicine Department and the mobile PET-CT unit were available and provided to HIW.

We saw the inventory for the Nuclear Medicine Department contained the information required under IR(ME)R 2017. However, the inventory for the mobile PET-CT unit did not include the equipment serial number or other unique identifier, the year of manufacture nor the year of installation.

The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to ensure the equipment inventory contains all the information required by IR(ME)R 2017. This includes the name of the manufacturer, the serial number or other unique identifier, year of manufacture and year of installation.

Safe

Risk Management

The environment of the Nuclear Medicine Department and the mobile PET-CT mobile unit appeared well maintained and in a good state of repair.

We did not identify any obvious hazards to the health and safety of staff working in the department or the mobile unit or to patients and other individuals visiting these areas. Signage was clearly displayed to alert patients and visitors not to enter controlled areas where examinations or scans were performed.

During our tour of the department and the mobile unit, it was evident staff placed an emphasis on patient and visitor safety.

All staff who completed a HIW questionnaire told us they were content with the efforts made by their organisation to keep them and patients safe.

Generally, we found the reception areas for the Nuclear Medicine Department and the mobile PET-CT unit to be well signposted. The majority of respondents who completed a HIW questionnaire (25/27) also told us they were able to find the department or the unit easily.

Waiting areas were of a suitable size and sufficient seating was provided for the number of patients attending.

The mobile unit was located in a designated area within the hospital grounds and near the main hospital building. The reception area for the mobile unit was located within the main hospital building. We were told staff would greet patients in this area and accompany them to the mobile unit to promote patient safety.

There was level access to the department making it easily accessible for patients. Similarly, the mobile PET-CT unit could be accessed via stairs, or by a lift attached to the unit, making it accessible to patients.

Designated toilets for patients attending the Nuclear Medicine Department and the mobile PET-CT unit were available and clearly signposted to reduce the risk of unintentional exposure to radiation by visitors to the hospital.

Infection Prevention and Control (IPC) and Decontamination

All areas of the Nuclear Medicine Department and the mobile PET-CT unit accessible by patients were visibly clean and free of clutter. The equipment we saw was also visibly clean. Staff described equipment was cleaned and decontaminated between patient use.

Flooring and furnishings within the Nuclear Medicine Department and the mobile PET-CT unit facilitated effective cleaning.

We saw patients and staff had access to suitable handwashing and drying facilities. We also saw personal protective equipment (PPE) was readily available for staff to use.

All respondents who completed a HIW patient questionnaire told us, in their opinion, the environment was 'very clean'. In addition, the majority of the respondents (24/27) told us, in their opinion infection, prevention and control measures were being followed, with the remainder either telling us measures were partially being followed (1/27) or telling us they did not know (2/27).

All staff who completed a HIW questionnaire (25/25) told us their organisation implements an effective infection control policy and the environment allows for effective cleaning. The majority of staff (24/25) also told us appropriate PPE is supplied and used.

Safeguarding of Children and Safeguarding Adults

Staff we spoke with were aware of their organisation's safeguarding policies and procedures and where to find these. Staff were also able to describe the action they would take should they have a safeguarding concern.

In addition, staff confirmed they had completed mandatory safeguarding training.

The majority of staff who completed a questionnaire (24/25) told us if they were concerned about unsafe practice, they would know how to report it. When asked whether they felt secure raising concerns, the majority of staff (22/25) told us they were, with the remainder telling us they were not (1/25) or they didn't know (2/25). Most staff (15/25) told us they were confident their organisation would address their concerns, with the remainder either telling us they were not (2/25), or they didn't know (6/25). Given the responses, senior staff may wish to explore this further.

Effective

Record Keeping

We reviewed a sample of referral records for sixteen patients. These included patients having examinations at the Nuclear Medicine Department and scans at the mobile PET-CT unit.

The sample we reviewed had a clear layout and had generally been completed in full.

They showed evidence of the relevant employer's written procedures, such as patient identification checks and confirmation of pregnancy, being followed by duty holders. They also showed evidence of exposures having been authorised, and hence justified, and a clinical evaluation being completed.

Quality of Management and Leadership

Staff Feedback

Feedback received was generally positive across all areas considered.

Staff comments included the following:

“I feel we are able to deliver quality and effective care at an individual patient level. What we struggle with is the volume so people are waiting for longer than I would like to access said care.”

“Staff members (technologists & support staff) work very well together. There is a strong sense of working together as a team and helping colleagues wherever possible.”

“Best working environment I have worked in...”

“I feel we are constantly striving to improve for the benefit of our patients.”

Leadership

Governance and Leadership

Swansea Bay University Health Board did not have its own facilities to provide a PET-CT service. This was provided on behalf of the health board by InHealth, an independent healthcare provider, using a mobile PET-CT unit that regularly visited the hospital site.

The Chief Executive for the health board and the Chief Executive for the independent provider were the designated employers under IR(ME)R 2017. The joint working and governance arrangements for providing the PET-CT service were set out within an agreed governance document. Senior staff had identified this document was in need of review so that it more accurately reflected the current working and governance arrangements.

Management structures were in place for both the Nuclear Medicine Department and the mobile PET-CT unit. Clear lines of reporting and accountability were described and demonstrated during the inspection.

Senior staff representing both organisations described appropriate systems to monitor and report on the quality and safety of services provided at the Nuclear Medicine Department and the mobile PET-CT unit. They also demonstrated a

strong commitment to learn from the HIW inspection and take action to make improvements where needed.

All staff who completed a HIW questionnaire told us the care of patients was their organisation's top priority.

The majority of staff who completed a HIW questionnaire (21/25) told us they would recommend their organisation as a good place to work. In addition, the majority told us their organisation is supportive (23/25), supports staff to identify and solve problems (23/25), and takes swift action to improve when necessary (22/25). The remainder disagreed.

When asked about their immediate managers, the majority of staff who completed a HIW questionnaire (20/23) told their manager can be counted upon to help them with a difficult task at work. The majority (21/25) told us their manager gives them clear feedback about their work. In addition, the majority (21/25) told us their immediate manager asks for their opinion before making decisions that affect their work. The remainder disagreed.

When asked about their senior managers, the majority of staff who completed a HIW questionnaire (22/25) told us senior managers are visible and most (18/25) told us communication between senior managers and staff is effective. The remainder disagreed. Given this response, senior staff may wish to explore this further.

All staff who completed a HIW questionnaire felt senior managers were committed to patient care.

The majority of staff who completed a HIW questionnaire (24/25) told us their organisation was supportive of equality and diversity. In addition, the majority (24/25) told us all staff have fair and equal access to workplace opportunities. The remainder preferred not to say.

When asked whether they had faced discrimination at work (within the last 12 months), the majority of staff (23/25) told us they had not. The remainder (2/25) either told us they had or preferred not to say.

Workforce

Skilled and Enabled Workforce

We were provided with details of the numbers and skill mix of staff working at or on behalf of the Nuclear Medicine Department and the mobile PET-CT unit. Staffing consisted of Consultant Radiologists, Consultant Cardiologists, a Cardiology

Associate Specialist, Radiographers, Clinical Technologists, Medical Physics Experts, Clinical Scientists, a Radiopharmacist and Radiopharmacy Technicians.

Representatives for the Nuclear Medicine Department described some challenges in relation to having a sufficient number of Consultant Radiologists and MPEs. Arrangements were described to mitigate against this to ensure services were provided.

No concerns were raised around the staffing capacity of the mobile PET-CT unit.

It was evident the staff teams were committed to providing a good service to patients attending for their examination or scan.

Most staff who completed a HIW questionnaire (17/25) felt there were enough staff for them to do their job properly. The majority of staff (20/25) told us they were able to meet the conflicting demands on their time at work. The remainder disagreed.

When asked about their health and wellbeing at work, most staff (18/25) told us their job was not detrimental to their health. The majority (21/25) told us their working pattern allowed them to achieve a good work-life balance. The majority (20/25) also told us their organisation takes positive action on health and wellbeing. The remainder disagreed. The majority of staff (23/25) were aware of the Occupational Health support available to them.

The majority of staff who completed a HIW questionnaire (24/25) told us they have adequate materials, supplies and equipment to do their job. Similarly, the majority (24/25) told us they are able to access the ICT systems they need to provide good care and support for patients.

Staff we spoke with were knowledgeable about their duty holder roles and responsibilities.

We reviewed a sample of training and entitlement records for five staff working in the Nuclear Medicine Department or the mobile PET-CT unit. Generally, these showed staff had completed training relevant to their role and as required by IR(ME)R 2017, staff had been entitled to carry out their duty holder roles, and details of their scope of practice. However, we identified some improvements could be made to the records.

The records for staff working in the Nuclear Medicine Department and the mobile PET-CT unit did not show when reviews had taken place to ensure staff remained competent to carry out their roles. The records for staff working in the mobile

PET-CT unit did not show all the pieces of equipment they would be using, and their scope of practice could be made clearer.

The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to show practitioners and operators remain competent to carry out their roles.

The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to show practitioners and operators have completed training on the use of all relevant equipment they use, to clearly show their individual scope of practice and to show they remain competent to carry out their roles.

The majority of staff who completed a HIW questionnaire (24/25) told us they felt they had the appropriate training to perform their role. The remainder (1/25) answered the question with ‘partially’.

When asked what other training they would find useful, staff comments included:

“Cannulation training”

“Project management training”

The majority of staff who completed a HIW questionnaire (23/25) told us they had received an appraisal of the work within the last 12 months. The remainder told us they had not.

Culture

People Engagement, Feedback and Learning

We saw information was clearly displayed for patients on how they could provide feedback or make a complaint on their experiences of visiting the Nuclear Medicine Department or the mobile PET-CT unit. Patients could provide feedback using electronic tablets located in the waiting areas or by using a suitable mobile device to scan a QR code to access an electronic feedback form.

While most respondents who completed a questionnaire (17/27) told us they would know how to make a complaint, the remainder (10/27) told us they would not. The health board and the independent service provider may wish to consider how they can further make patients aware of how they can make a complaint.

Information on how patient feedback had been used by the Nuclear Medicine Department and the mobile PET-CT unit, to make changes to the service was not

displayed in the waiting areas. This would help communicate to patients the changes made in response their feedback.

The health board is required to provide HIW with details of the action taken to communicate to patients how patient feedback has been used to make changes.

When asked about patient feedback, the majority of staff (24/25) who completed a HIW questionnaire told us this was collected within their area and the remainder (1/25) said they didn't know. The majority of staff (19/25) told us they receive regular updates on patient feedback, with the remainder telling us they didn't (5/25) or they didn't know (1/25). When asked whether feedback is used to inform decisions made in their area, most staff (14/25) told us it was, with the remainder either telling us it was not (3/25), or they didn't know (8/25). Given the responses, senior staff may wish to explore this further.

Representatives described suitable arrangements for the recording, investigating and responding to complaints or concerns from patients about the Nuclear Medicine Department or the mobile PET-CT unit. They also described a suitable system to manage and share information on complaints depending on which aspect of the service received the complaint or concern.

Both organisations confirmed written complaints procedures were in place and these were made available to HIW. We were told complaints about services delivered (on behalf of the health board) by the mobile PET-CT unit would be managed under the independent organisation's procedure. While this complaints procedure included reference to other agencies in England to who patients could refer their complaint, reference to those in Wales, such as the Public Services Ombudsman of Wales (PSOW) and LLAIS, was not included where the service is delivered in Wales.

Representatives for the health board were aware of the Duty of Candour which is applicable in Wales. They confirmed a senior member of staff within the Nuclear Medicine Department was responsible for ensuring the Duty of Candour procedure was correctly followed. The complaints procedure relating to the mobile PET-CT unit did not include reference to the notification arrangements under the Duty of Candour and to the health board having responsibility for complying with the Duty where the service is delivered in Wales.

The health board is required to provide HIW with details of the action taken to ensure relevant policies include:

- details of the recourse available to patients who raise concerns or complaints about the mobile PET-CT unit for services delivered in Wales on behalf of the health board

- details of the notification procedure, specifically in relation to the Duty of Candour, where incidents occur at the mobile PET-CT unit.

All staff who completed a HIW questionnaire told us they knew and understood the Duty of Candour, understood their roles in meeting the Duty of Candour standards and their organisation encourages them to raise concerns and to tell patients when something has gone wrong.

4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

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

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A - Summary of concerns resolved during the inspection

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

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns identified that required escalation.	-	-	-
-	-	-	-

Appendix B - Immediate improvement plan

Service: Nuclear Medicine Department and Mobile PET-CT Unit, Singleton Hospital

Date of inspection: 10 and 11 October 2023

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
-	No immediate improvement plan required.	-	-	-	-

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 and Mobile PET-CT Unit, Singleton Hospital

Date of inspection: 10 and 11 October 2023

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
We found the provision of health promotion could be improved within the waiting area for the mobile PET-CT unit.	The health board is required to provide HIW with details of the action taken to make relevant health promotion material easily available to patients attending for a PET-CT scan.	Patient Centred			
We found Welsh speaking staff could not always be identified.	The health board is required to provide HIW with details of the action taken to encourage those staff who are happy to do so to wear badges or lanyards to show patients they are happy to communicate in Welsh.	Patient Centred			

We found patients' language preferences were not always being confirmed.	The health board is required to provide HIW with details of the action taken to make staff aware they should always ask patients their preferred language they wish to use to communicate.	Person Centred			
We found referral guidelines had not been established for nuclear medicine therapy.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to establish referral guidelines for nuclear medicine therapy and to make these available to relevant referrers.	IR(ME)R 2017 Regulation 6 (5)(a)			
We found the employer's written procedure for the use and review of diagnostic reference levels would benefit from including in the DRL table the maximum and minimum range of administered activity.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to include the maximum and minimum range of administered activity within the employer's written procedure for the use and	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(f)			

	review of diagnostic reference levels.				
We found the employer's written procedure did not describe the process to ensure individual patients had not exceeded the dose constraint for all exposures which occur within a research trial.	The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to update the written procedure in relation to research so it clearly describes the process to ensure individual patients had not exceeded the dose constraint for all exposures which occur within a research trial.	IR(ME)R 2017 Regulation 12(4)(c)			
We found the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding would benefit from being clearer.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding:	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(c)			

	<ul style="list-style-type: none"> so the flowchart includes more details to guide duty holders on when to make the enquiry and the different enquiry options to clearly describe to whom enquiries should be made and how this is managed in a sensitive manner. 				
We found the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding would benefit from being clearer.	<p>The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to revise and update the employer's written procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding:</p> <ul style="list-style-type: none"> so the procedure for staff is clear and to include reference to the circumstances when a 	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(c)			

	pregnancy test should be considered				
We found the employer's written procedure for the clinical evaluation of exposures did not clearly reflect the arrangements described.	<p>The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the employer's written procedure for the clinical evaluation of exposures:</p> <ul style="list-style-type: none"> • to accurately reflect the arrangements for outsourcing the clinical evaluation of some PET-CT scans as described by senior staff • to include the arrangements for the clinical evaluation of nuclear medicine therapies. 	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(j)			
We found further details needed to be recorded around the process of clinical audit.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to clearly	IR(ME)R 2017 Regulation 7			

	show the outcome of clinical audits, the actions to be taken, the person responsible for the actions and the date for completion.				
We found the clinical audit programme related to audit of IR(ME)R compliance.	The employer of the mobile PET-CT unit is required to provide HIW with details of the action taken to carry out clinical audit as defined by IRMER (2017) and taking into account guidance issued by the RCR.	IR(ME)R 2017 Regulation 7			
We found the employer did not have a written study of risk for of accidental or unintended exposures in relation to nuclear medicine therapy.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to include in the employer's quality assurance programme a study of risk for of accidental or unintended exposures in relation to nuclear medicine therapy.	IR(ME)R 2017 Regulation 8(2)			
We found the employer's written procedure for the justification and	The employer for the Nuclear Medicine Department is required to	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(n)			

authorisation of exposures would benefit from being clearer in relation to recording the authorisation of exposures to carers and comforters.	provide HIW with details of the action taken to revise and update the employer's written procedure for the justification and authorisation of exposures so it clearly describes the procedure for recording the authorisation of exposures to carers and comforters.				
We found the DAG for the authorisation of exposures to carers and comforters would benefit from being more detailed.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to revise and update the DAG for the authorisation of exposures to carers or comforters, by entitled operators, so it includes more detail regarding the criteria which operators follow and to be consistent with the employer's procedure.	IR(ME)R 2017 Regulation 6(1)(a) Schedule 2(1)(n)			
We found the equipment inventory did not include	The employer for the mobile PET-CT unit is required to provide HIW with details of	IR(ME)R 2017 Regulations 15(1)(b) and 15(2)			

all the information required by IR(ME)R 2017.	the action taken to ensure the equipment inventory contains all the information required by IR(ME)R 2017. This includes the name of the manufacturer, the serial number or other unique identifier, year of manufacture and year of installation.				
We found the training records would benefit from being more detailed to demonstrate ongoing competence.	The employer for the Nuclear Medicine Department is required to provide HIW with details of the action taken to show practitioners and operators remain competent to carry out their roles.	IR(ME)R 2017 Regulation 17(1)			
We found the training records would benefit from being more detailed to demonstrate ongoing competence.	The employer for the mobile PET-CT unit is required to provide HIW with details of the action taken to show practitioners and operators have completed training on the use of all relevant equipment, to clearly show their individual scope of	IR(ME)R 2017 Regulation 17(1)			

	practice and to show they remain competent to carry out their roles.				
We found information available on site on how the Nuclear Medicine Department and the mobile PET-CT unit had acted on patient feedback could be improved.	The health board is required to provide HIW with details of the action taken to communicate to patients how patient feedback has been used to make changes.	Health and Care Quality Standards Culture			
We found documentation did not clearly show the recourse available to patients who raise concerns or complaints about the mobile PET-CT unit nor the notification procedure in relation to the Duty of Candour for services delivered in Wales on behalf of the health board.	<p>The health board is required to provide HIW with details of the action taken to ensure relevant policies include:</p> <ul style="list-style-type: none"> • details of the recourse available to patients who raise concerns or complaints about the mobile PET-CT unit for services delivered in Wales on behalf of the health board • details of the notification procedure, specifically in relation to the Duty of Candour, where incidents 	Health and Care Quality Standards Culture			

	occur at the mobile PET-CT unit.				
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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: