Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

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

The Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC), Cardiff University

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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 Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC), Cardiff University on 12 and 13 July 2022.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and a Senior Clinical Officer 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.

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:

There was very positive feedback provided by patients about their experiences when attending the department.

We saw that arrangements were in place to promote privacy and dignity of patients and found that staff treated patients in a kind, respectful and professional manner.

Information provided indicated that there were adequate arrangements in place to meet the communication needs of patients attending the department. The setting could improve these arrangements further by providing patients with the 'active offer'.

This is what we recommend the service can improve

- Need to provide patients with the 'active offer to encourage patients to ask to speak to someone in Welsh
- Displaying a board with the results, comments and actions from feedback.

This is what the service did well:

- Comments received from patients confirmed they were highly satisfied with their experience of visiting the department
- Staff placed an emphasis on promoting the privacy and dignity of patients
- Well maintained environment with good signage.

Safe and Effective Care

Overall summary:

There was good compliance overall with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R. We found arrangements were in place to provide patients visiting the department with safe and effective care.

Information provided indicated that appropriate arrangements had been implemented by the service to allow for effective infection prevention and control within the department.

This is what we recommend the service can improve

- Provide full information on the entitlement process for referrers and operators
- Include dose information in referral guidelines
- Ensure that audits completed by clinicians, particularly those outside the PETIC are fed into the audit programme and the results to enhance the service provided.

This is what the service did well:

- Effective use of Q-Pulse, the quality management software, to manage employer's procedures and work instructions
- Good levels of consultant and medical physics expert (MPE) support
- Training provided for operators and practitioners
- Ensuring doses for diagnostic procedures are as low as reasonably practicable
- Practitioners and MPE involved in setting diagnostic reference levels, below the national levels.

Quality of Management and Leadership

Overall summary:

There was a management structure with clear lines of reporting in place. There were effective governance arrangements in place to support ongoing regulatory compliance. We found visible and supportive leadership being provided within the department.

Staff demonstrated they had the correct knowledge and skills to undertake their respective roles within the department.

Staff were also positive in the questionnaire with their comments about the quality of care they gave to patients and recommending their organisation as a place to work.

This is what we recommend the service can improve

- Ensure all required procedures are in place and then review this information to ensure everything is included from the SAF.

This is what the service did well:

- HIW self-assessment questionnaire completed in a timely manner
- Good compliance with staff mandatory training and appraisals
- Good management evidenced.

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

During the inspection we used paper and online questionnaires to obtain views and feedback from patients and carers on services carried out by the Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC), Cardiff University School of Medicine. In total, we received 65 paper responses during the HIW inspection in July 2022. The majority of responses indicate a positive patient experience by users of this service. Most comments were complimentary about staff and the overall service. The main suggestions for improvement were for environmental changes, such as signage and comfortable seating.

Patients were asked in the questionnaire to rate their overall experience of the service. A total of 97% as 'very good' the remainder rated it as 'good'. The following comments were made regarding patients' overall experience:

> ***"The setting today was outstanding; staff were courteous and efficient."***
>
> ***"Staff very friendly and professional."***
>
> ***"The service I have received has been excellent."***
>
> ***"Excellent service. Staff amazing."***

We asked how this setting could improve the service it provides. The following comments were made:

> ***"Better chairs."***
>
> ***"Comfortable chairs and room temp too cold."***
>
> ***"I felt there was no improvement needed as I received first class service."***
>
> ***"I can't think of anything more that could be done to improve the experience."***

Staff Feedback

HIW issued an online questionnaire to obtain staff views on services carried out by PETIC. In total, we received 18 responses from staff at the setting. Responses from staff were generally positive, with all respondents being satisfied with the quality of care they give to patients and recommending their organisation as a place to work.

The areas attracting the most positive responses were in dignified care, infection prevention and control, incident reporting, raising concerns and senior managers. There were a few negative comments from staff. The main issue raised was inadequate staffing and new equipment required.

Staying Healthy

Health Protection and Improvement

We found health promotion material was displayed within the department. This included information on a range of medical conditions such as cancer, dementia and memory problems, together with details of other organisations that could be contacted for help and advice. Written information for patients on what to expect during their procedure was clearly displayed within the waiting room. Relevant information was also displayed on posters in the department, including information on research that had been carried out in the department.

Dignified care

All patients who answered agreed staff treated them with dignity and respect and all agreed measures were taken to protect their privacy. We were told:

> ***"Friendly staff. Reassuring."***
>
> ***"… made to feel welcomed and cared for."***

All bar one member of staff agreed that patients' privacy and dignity was maintained, that patients are informed and involved in decisions about their care and they are satisfied with the quality of care they give to patients, one disagreed.

Communicating effectively

Staff we spoke with confirmed that there was a hearing loop system available. They told us that additional arrangements would be made, where required, if patients had any other communication requirements. This included access to

translation services, should a patient attend the unit and be unable to communicate in English. There was also a British Sign Language advocate that would be used.

We saw good provision of bilingual information posters. However, there was no information displayed to inform patients that they could speak to staff in Welsh, also known as the 'active offer'. Three patients indicated that Welsh is their preferred language, none of the three were actively offered the opportunity to speak Welsh throughout their patient journey. One said they did not feel comfortable using Welsh within the hospital environment and two felt this was not applicable to them. One said healthcare information was available in Welsh, one said it was not and one felt this was not applicable to them.

We were told, there were some Welsh speaking staff at the department and there were other Welsh speaking staff working in the wider radiology department. Two of the 18 staff respondents indicated that they were Welsh speakers. One of the two wore the 'Iaith Gwaith' badge or lanyard and one did not. One of the two said that patients were asked to state their preferred language and one said they sometimes were.

The two respondents who answered indicated that they used Welsh in everyday conversations. The one respondent who answered indicated that they are sometimes given the opportunity to complete their training in Welsh.

All patients agreed they were able to speak to staff about their procedure or treatment without being overheard by other patients and they said that staff listened to them and answered their questions.

Patient information

Staff confirmed that written information about what to expect when attending for their procedure was enclosed with the booking letter sent to patients ahead of their appointments. We were told that patients were also screened for COVID-19 before they attended the department and were instructed not to attend if they had any symptoms. Staff also confirmed that post-procedure advice was provided to patients verbally when they attended the department. Written information was available bilingually.

There was sufficient signage to direct patients to the department. Within the department, there were coloured doors and corresponding coloured arrows were displayed on the floor to unable patients to identify the relevant room being used. There was also clear signage to ensure no one entered the scanner or uptake rooms when they were in use.

All bar one patient agreed they were given enough information to understand the risks and benefits of the procedure or treatment and all patients agreed staff explained what they were doing. Patients told us:

> ***"I was kept fully informed throughout the procedure and made to feel at ease throughout…"***
>
> ***"Procedure explained. Very pleasant, helpful staff."***
>
> ***"Very friendly staff who explained each step. A pleasant experience."***

All agreed they had been given information on how to care for themselves following their procedure or treatment. All bar one patient agreed they had been given written information on who to contact for advice about any 'after-effects' from their procedure or treatment.

Timely care

Timely Access

Patients appeared to be seen in a timely manner and arrangements were described to inform patients of delays in providing their procedures.

All patients bar two who completed the questionnaire agreed it was easy to get an appointment and two disagreed and all bar one agreed they were able to find the department easily at the hospital clinic and one disagreed. Again, all bar two agreed they were told at the department how long they would likely have to wait.

Individual care

People's rights

We observed staff to be kind and helpful when speaking to patients. Suitable arrangements were seen to be in place to promote the privacy and dignity of patients attending the department for their procedures. Arrangements were also described when children attended for procedures. Within the waiting area all the chairs were seen to be of the same height and design. The service provider may wish to consider introducing chairs of different heights for patients with mobility difficulties to allow patients to sit down and be able to stand easier from a seated position. Consideration could also be given to introducing a portable screen in the area where patients' height and weight are measured.

We were told that the university were good in promoting gender diversity and there was an ethnically diverse team. Managers also made sure that staff had religious breaks and orientations within the team.

We were told that there was an equality and diversity policy within the organisation as well as mandatory training on this area. All 18 staff who responded to the questionnaire indicated that they had not faced discrimination at work within the last 12 months. One staff member said:

"No discrimination at work, PETIC has an inclusive policy."

All staff who expressed an opinion agreed that staff have fair and equal access to workplace opportunities (regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation) and two preferred not to say. Similarly, all staff who expressed an opinion agreed that their workplace was supportive of equality and diversity.

The doors to the various rooms were wide enough to allow access for wheelchair users. Whilst the department was on the ground floor of the hospital access did require travel through the hospital and the use of lifts to access the department from the main concourse.

All patients who answered agreed they were involved as much as they wanted to be in any decisions about their procedure or treatment.

Of the patients who answered, 56 of the 58 patients who answered said they felt 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) but two said they felt they could not.

Listening and learning from feedback

Information was clearly displayed for patients and their representatives on how to raise a concern or a complaint. Staff we spoke with were also confident in being able to address a concern should one arise.

Staff described a system for obtaining feedback from patients about their experience of using the department. At the time of our inspection, we were told that the results of the previous satisfaction survey were being analysed. However, we did not see any information on learning from feedback being displayed for patients to see.

A total of 12 staff respondents to the questionnaire agreed that patient experience feedback was collected within their department, six did not know. Whilst 11 respondents agreed that they receive updates on patient experience feedback in their department, two disagreed, and five did not know. Again 11 agreed that feedback from patients was used to make informed decisions within their department, one disagreed and six did not know.

Delivery of Safe and Effective Care

Compliance with Ionising Radiation (Medical Exposure) Regulations

Prior to our inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire (SAF). This was to provide HIW with detailed information about the department and the employer's key policies and procedures in respect of IR(ME)R 2017. This document was used to inform the inspection approach.

The SAF was returned to HIW within the agreed timescale and was comprehensive. Where we required additional information or clarification in respect of the responses within the self-assessment, senior staff provided this promptly.

Duties of employer

Patient identification

Staff we spoke with were able to describe the procedure to be used to correctly identify individuals, using the three-point check. They also described how they would correctly identify those patients who may not be able to identify themselves. The department carried out an annual patient identification audit to measure compliance of staff in this area. The audit was programmed in the quality management software (Q-Pulse).

All 60 patients who answered agreed they were asked to confirm their personal details.

The referral records checked confirmed that the three-point check had been completed appropriately.

Individuals of childbearing potential (pregnancy enquiries)

There was a written employer's procedure to cover this area and to cover the need to ensure how exposures to individuals in whom pregnancy could not be excluded were optimised. There was reference to ensuring the administration of the radiopharmaceutical only occurred after explicit consent had been obtained from the practitioner. This was to ensure that consideration had been given that the clinical benefits from the scan outweighed any risk to the unborn foetus and expectant mother. Dose reduction strategies would then be used.

We noted that the explanation given in the SAF relating to the procedure to addresses situations where more than one operator was directly involved in the exposure was not included in the employer's procedure. The SAF stated that if an operator performing the administration was different to the one that completed the proforma the patient identity and pregnancy check was re-performed, checked against the proforma and countersigned. Additionally, the explanation in the SAF where a person may not be able to respond to the inquiry, for example an unconscious patient, was not in the employer's procedure.

Staff we spoke with were aware of the procedure for making enquiries of individuals of childbearing potential to establish whether they were pregnant or breastfeeding.

The department also carried out a pregnancy check audit to measure compliance of staff in this area. The audit was also programmed in Q-Pulse.

Non-medical imaging exposures

Non-medical imaging did not take place at the department and this was explained in the relevant employer's procedure.

Referral guidelines

The system used to ensure referral guidelines were established and made available to all referrers was explained. The SAF explained the process for establishing referral guidelines, based on the commissioning policy from the Welsh Health Specialised Services Committee (WHSSC). This was confirmed by staff we spoke with. However, the policy did not include dose information as required by the regulations.

The local health board radiology information system (RADIS) was used to identify referrers.

Duties of practitioner, operator and referrer

The department use the referrers on the system, managed by the local health board. During our discussion of the SAF with senior staff at the department, it was noted that they had identified that all referrers in the RADIS system used had been entitled by the local health board. This has been raised as a non-conformance by the department on Q-Pulse as they may not have been entitled by the university. To correct this, the department were proposing to draft a memorandum of understanding (MOU) that would be added to the service level agreement (SLA). This would state that any referrer entitled by the local health board would be

automatically entitled by the university. The department also need to ensure that there are no gaps in this process so that referrals from English Trusts and research referrals were all entitled through the local health board.

We were told that as the university did not input this list of referrers, the practitioners within the department would review all referrals and reject any inappropriate referrals.

Justification of Individual Medical Exposures

The processes of how justification was performed and where this was recorded were described in the SAF. All referrals were justified by a practitioner, operators did not authorise. The practitioner would sign on the paper referral as a record of justification and authorisation. The process was also described in the employer's procedure relating to the justification of individual exposures.

We discussed justification of exposures to carers and comforters with senior staff, including consideration of pregnancy status and levels of patient care required as part of the justification decision. There was a specific employer's procedure in place in relation to dose constraints and guidance for nuclear medicine exposures of carers and comforters. Justification of carers and comforters exposures would be carried out by a practitioner or may be authorised by an operator following authorisation guidelines.

The operator matrix in the employer's procedure did not include the need for justification and authorisation of carers and comforters exposures, operators were not authorised to complete this operation and were not entitled.

Staff we spoke with were aware of where the authorisation of patient exposures was recorded on the relevant form, along with the relevant protocol. They were also able to describe the process and guidance relating to carers and comforters. The carers and comforters would be asked to sign an information leaflet supplied.

Optimisation

The process described in the SAF relating to how practitioners and operators ensure doses for diagnostic procedures are as low as reasonably practicable, to include any methods for dose reduction, was an example of good practice. The administered PET dose had to be within 10% of the optimised diagnostic reference level (DRL). The automated dispenser would not allow administrations above 10% of DRL unless specifically overridden by senior staff using a password. Patients were asked to hydrate and micturate to minimise their dose. Patient uptake rooms were shielded to avoid irradiation from the adjacent patient room.

We noted that the reference in the SAF to the increase in bed-time for patients over 150kg was not documented in protocols. This should be documented to ensure the consistency of operation, by all scanning staff. Staff described the process of optimisation including using weight-based scaling for patients. Older teenagers usually followed the adult patient protocol, whereas younger or lighter patients, use the European Association of Nuclear Medicine (EANM) guidelines.

We were told that information leaflets were sent to the patient before the appointment. Staff provided written instructions and information to patients (or their representatives) undergoing diagnosis with radioactive substances. The process for providing the individual to be exposed (or their representative) with adequate information on benefits of having the exposure and the risks associated with the radiation dose was described in the SAF.

Diagnostic reference levels (DRLs)

We noted the good practice that practitioners and MPEs involved in establishing local DRLs with optimisation where possible. The established local DRLs were displayed in the clinical pharmaceutical preparation area. In addition, it was positive to note that local DRLs were lower than national DRLs for all adult scans. Audits were undertaken of administered activity with 100% of administrations within 10% of the local DRL. We were told that local DRLs were not changed that often.

Senior staff we spoke with said that these local DRLs would be further reviewed when a new scanner is installed. CT DRLs were set in conjunction with Velindre MPE support.

Staff were aware of the local DRLs that would be used as well as where the reminders were of these DRLs. They stated they would record and report the information on RADIS. Staff further stated whilst these DRLs were rarely exceed, they knew the actions to take if they were regularly exceeded.

Paediatrics

The system described to ensure how children's exposures were optimised, was also considered to be of good practice. The SAF stated that the administered activity was weighted dependent upon the EANM paediatric dosage card. Paediatric DRLs were optimised following best practice guidelines. For smaller adult patients and paediatric patients, the operator could select protocols with a reduced CT dose.

Clinical evaluation

Staff described how clinical evaluation was undertaken and evidenced for each type of exposure. These were reported by entitled practitioners. We checked a sample of 3 records and found that all exposures were clinically evaluated on the same day. We were also told by the clinical director that reports were available on RADIS and the picture archiving communications system (PACS) once validated. The information would be included on the Welsh clinical portal along with all clinical information including imaging reports and other laboratory data. The procedure was explained in the relevant employer's procedure.

Equipment: general duties of the employer

The employer had an inventory (list) of the equipment used within the department. The inventory contained the information required under IR(ME)R 2017. We reviewed the employer's procedure in place in relation to the quality assurance (QA) programme. We also viewed the quality assurance programme in place, as well as employer's procedures and written protocols, these were in date.

We noted the good practice that was described where dose calibrators received annual accuracy measurements to a secondary standard, the posijet was also calibrated annually. Both were also checked daily. Acceptance testing of all equipment upon installation was performed by the MPEs as stated in the employer's procedure and regular interval checks were performed.

Acceptable performance for each test was describe in the individual procedure and was usually based on manufacturers recommendations. Historic results and reference to baselines were stored in Q-Pulse when the test was performed. We were told that Q-Pulse workflow was also used to raise any non-conformances with equipment problems and this would also be communicated to the relevant staff working with the equipment.

Safe Care

Managing risk and promoting health and safety

The department was well maintained and seen to be fully accessible to patients and visitors. Systems were seen to be in place to prevent unauthorised access and signage was clearly displayed to alert individuals of areas where ionising radiation was used.

Staff we spoke with were confident in being able to ensure that adequate information was provided to individuals or their representatives relating to the benefits and risks associated with the radiation dose from exposures.

A total of 15 respondents to the questionnaire agreed they could meet the conflicting demands on their time at work, three disagreed. All respondents agreed they had adequate materials, supplies and equipment to do their work. Whilst 10 respondents agreed that there are enough staff to enable them to do their job properly, eight disagreed. The following suggestions were made in response to how this setting could improve the service it provides:

> ***"A new scanner is required to increase scanning capacity. The existing scanner has a limited capacity and the facility is operating at full capacity. Funding has been secured and being procured."***
>
> ***"Replace the PET/CT scanner with a modern digital system (tender in process)."***
>
> ***"Streamline excessive documentation, increase staffing levels."***

Most staff agreed they could access ICT systems they need to provide good care and support for patients. The following suggestion was made in response to how this setting could improve the service it provides:

> ***"As I am a new member of staff I am still getting used to the systems and it is quite difficult for me to comment. Improved IT services (particularly at CTM) are desperately needed, for example fully electronic requesting, vetting and scheduling."***

All bar two staff agreed they were involved in deciding on changes introduced that affect their work area and two disagreed.

We asked staff how the setting could improve the service it provides. Staff suggested:

> ***"streamline excessive documentation, increase staffing levels."***

Infection prevention and control (IPC) and Decontamination

All areas seen appeared to be clean and well maintained. Handwashing and drying facilities were seen around the department. Personal protective equipment (PPE) was available for staff to use and all staff were observed to be wearing masks. Chairs within the waiting area were seen to be socially distanced and information was displayed for patients and staff regarding COVID-19 precautions.

Staff we spoke with confirmed that all equipment was cleaned after each patient and that staff wore PPE such as masks, aprons, gloves and visors.

A total of 57 of the 60 patients who answered this question said the setting was 'very clean' and three said it was 'fairly clean'. For 58 of the 60 patients who answered this question they considered that COVID-19 infection control measures were being followed.

Training records inspected by HIW showed that staff had completed IPC training at a suitable level.

All staff who responded to the survey agreed that:

- Their organisation has implemented the necessary environmental changes and had implemented the necessary practice changes.
- There had been a sufficient supply of PPE and that there are decontamination arrangements for equipment and relevant areas.

Almost all staff agreed there are appropriate infection prevention and control procedures in place.

Safeguarding children and safeguarding adults at risk

Staff and senior staff we spoke with stated that safeguarding training was completed up to level two. Staff were aware of the procedures in place and the actions that needed to be taken in the event of there being a safeguarding concern.

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

Effective care

Quality improvement, research and innovation

Clinical audit

There was an employer's procedure that covered clinical audit. Audits would be programmed into Q-Pulse and carried out when required. The reports and non-conformance would also be recorded on Q-Pulse linked to the audit.

The cognition dementia pilot review audit was seen as a good example of clinical audit as the consultant concerned wanted to work with PETIC to start the clinical service for fluorodeoxyglucose (FDG) dementia imaging and PET amyloid. Whilst the initial submission to WHSSC was rejected, the cognition audit was used as evidence to support the commissioning case. This service is now available to

patients. The process of how outcomes of clinical audit fed into the commissioners' approval process was also described and how this fed into the annual funding.

It was acknowledged that many requests were received for information by the department, relating to clinical audits by clinical staff outside the university. The results of these audits would not always be made known to the department.

The department were also aware of the importance of feeding back good compliance to the staff and a system was now in place to record compliments. Letters from patients were all shared with staff

Expert advice

We were provided with a clear and comprehensive response within the SAF of how MPEs were involved within the department. Good examples were also provided on how MPEs contributed to areas including radiation protection of patients and others, installation design and technical specification of equipment, and analysis of accidental or unintended exposures.

Staff we spoke with said that they could access this expert advice, they were aware of who the MPEs were and were able to access them in a timely manner.

There was also clear evidence of the consultant support to the department.

Medical Research

There was an explanation in the SAF of how research procedures would only be undertaken with the prior agreement of the clinical director and department director. All research procedures involving patients had to comply with the relevant employer's procedure. The governance arrangements in place for research trials involving ionising radiation exposures were well described in the employer's procedure. All research exposures would have a written record of the clinical evaluation of the research scan. The relevant employer's procedure described the general procedure and that research referrals would be identified through the trial name being listed on the clinical information.

Record keeping

We checked a sample of three current patient referral documents and three retrospective documents. The layout of the paper referral documentation was clear. The referrals checked were appropriately completed in accordance with referral guidelines with sufficient clinical details included. There was clear

evidence that staff had completed suitable training on radiation production, radiation protection and statutory obligations relating to ionising radiations.

For the current forms, there were good records of compliance in completing referrals and scanning paper records onto RADIS. One patient pregnancy form was not scanned into RADIS but the paper record was available in the department and subsequently scanned onto RADIS during inspection.

For the retrospective referrals we noted that all records were complete.

Quality of Management and Leadership

Governance, Leadership and Accountability

A management structure with clear lines of accountability and reporting was noted. The clinical technologists and radiographers worked on a rotational basis from the Nuclear Medicine Department within the University Hospital of Wales (UHW), where the PETIC department was also located. The superintendent radiographer worked permanently within the department and was also employed by UHW. There were several SLAs in place with local health boards to cover the governance of the processes within the department.

The department were reliant on the SLA with Cardiff and Vale University Health Board for technologists and radiographers as described above and also for other areas such as the infrastructure including RADIS. The SLA arrangements in place with other health boards included consultant radiologist support to the department. As practitioner appointments had dedicated PET time within their job plan, this made the posts more attractive and ensured support across the department.

The director of PETIC would feed into the annual appraisal report for the superintendent radiographer and the superintendent would feed into the annual appraisal reporting for the technologists and radiographers. An annual review or appraisal had been carried within the last 12 months for 14 staff, four indicated that they had not had an appraisal. Of the 14 who had an annual review or appraisal in the last 12 months, nine stated that training, learning or development needs were identified but five stated they were not. Staff said that their manager supported them to receive training, learning or development, for 10 of the 13 who answered, three said they did not. It should be noted that most of these responses related to appraisals outside of PETIC.

Staff we spoke with confirmed that they felt supported by their line manager. Staff also told us that they felt that the managers were very visible and approachable should they have any issues or queries they wish to discuss.

Duties of the employer

Entitlement

Staff we spoke with were aware of their duties and scope of entitlement under IR(ME)R and knew where to find the written procedures relevant to their practice.

The ionisation radiation (IR) policy stated that the PETIC Director, under a delegation from the vice chancellor and head of school, was responsible for entitlement of duty holders under the IR(ME)R 2017 regulations. The SAF explained how practitioners, operators and referrers were entitled to carry out their duties which was included in the relevant procedure. Relevant staff received entitlement letters and these letters are also available through Q-Pulse. The information contained within the letter was generic. The operator matrix in the employer's procedure had more detail but there were not dates included as to when entitlement was given.

Procedures and protocols

We reviewed the employer's procedures provided as evidence to support the SAF and considered there to be effective use of Q-Pulse to manage the procedures and any change of procedures and subsequent workflow. There is a need to review the list of procedures in schedule one to make sure they are all in place including 1k – probability and magnitude and 1l relating to clinically significant accidental or unintended exposures (CSAUE).

Senior staff we spoke with described how procedures were made available to staff, through Q-Pulse. Paper copies of procedures were also available in the scanning room for scanning staff. Currently scanning staff on rotation from the local health board can only see these procedures when in the PETIC department. We were told this would change in the future within the new version of Q-Pulse, which would be cloud based so procedures would be accessible anywhere.

Staff we spoke with knew where to find the written procedures relevant to their practice and said that they were clear and easy to understand.

We saw evidence that the ionisation radiation policy stated that most of the responsibilities were held by the PETIC Director. A Radiation Protection Committee was also in place that met twice a year. Reports from this meeting were provided to the university Radiation Working Group and the local health board Radiation Protection Group. This information was also reported to the University Vice Chancellor, who is the IR(ME)R employer, to ensure they were aware of their responsibilities.

Significant accidental or unintended exposures

There was a relevant written employers' procedure relating to unintended radiation exposure procedure and risk. We spoke with senior staff about the process for the immediate management of accidental or unintended exposures involving ionising radiation. The SAF mainly described the actions that would be

carried out by the operator. Senior staff stated that the decision as to what further action needed to be carried out would be determined depending on the nature and risk from the exposure.

We noted that the employer's procedure did not define what a clinically significant accidental or unintended exposures was. Additionally, there needs to be a system in place to record near misses as well as significant events. The regulations require that the employer must establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice.

Unintended radiation exposure to the patient along with radiation risks and dose comparisons would be made known to the relevant consultant radiologist, PETIC Director and MPE. The timetable of events leading up to and after the exposure occurred would be completed on DATIX and as a non-conformance on Q-Pulse. The process used to perform dose calculations and this information would be available in sufficient time was also described. The MPE would lead the detailed investigations of the incidents, with Q-Pulse used to manage the process

Staff we spoke with were aware of the correct procedure for reporting accidental or unintended exposures and other incidents. Learning from incidents would also be shared through Q-Pulse, as well as using whatsapp, email and informal meetings.

All staff respondents said that, in the last month, they had not seen any accidental or unintended exposure incidents of staff. All staff who answered said that in the last month, they had not seen any accidental or unintended exposure incidents of patients. Two of the 17 who answered said that, in the last month, they had seen errors, near misses or incidents. Fifteen said they had not.

Nine of the sixteen who answered said that the last time they saw an unintended exposure, error, near miss or incident, they or a colleague reported it and seven did not know. Staff said:

> ***"Open and positive culture regarding incidents and learning from near misses."***

> ***"I have never seen any unintended exposure, error, near miss or incident so have not needed to report this, however I am confident that if this happened it would be reported by myself and any other staff member who was aware of the event."***

All 18 respondents agreed their organisation encouraged them to report errors, near misses or incidents. The vast majority agreed their organisation treats staff who are involved in errors, near misses or incidents fairly and one disagreed. All who expressed an opinion agreed that, when errors, near misses or incidents are reported, their organisation takes action to ensure that they do not happen again. Similarly, all respondents agreed that they are given feedback about changes made in response to reported errors, near misses and incidents.

Whilst 17 respondents agreed that, if they were concerned about unsafe practice, they would know how to report it, one disagreed. A lower number of 15 said they would feel secure raising concerns about unsafe clinical practice, one said they would not and two did not know. A total of 13 said they were confident that their concerns would be addressed, one said they are not and four did not know.

Workforce

Staff we spoke with said that the staff numbers and skill mix were appropriate with appointments booked based on the number of staff on duty.

Training records

We examined the training records of a random sample of five staff. These showed good compliance with mandatory training. We identified that two members of staff required update training on IPC and one member of staff required update training on moving and handling. Arrangements should be made to explore the reasons for this and to support staff to complete this training as a matter of priority.

The two training and competency records checked were good for operators with a good level of detail. The department need to consider how they can use this information to improve the content of the entitlement letters referred to above. Induction and training programmes in place for all newly appointed duty holders under IR(ME)R was also considered to be good practice. Training records were clear and there was an appropriate system to identify when training was due. All bar one member of staff said that they have had appropriate training to undertake their role and one felt they have not, giving the following explanation:

> ***"Still undergoing training."***

We asked if there was any other training staff would find useful. Staff told us:

> ***"Good level of training is provided within this facility and external training opportunities are actively encouraged by the director of the facility."***

“I am getting required training in PETIC to do my job.”

“Not at the moment except for general stuff around my role which is scheduled.”

A total of 15 staff agreed that their training, learning and development helped them do their job more effectively but three strongly disagreed. Additionally, 14 respondents who expressed an opinion agreed that their training, learning and development helped them to stay up to date with professional requirements, again three strongly disagreed. Again 14 respondents agreed that their training, learning and development helped them deliver a better patient experience there was one who disagreed and three strongly disagreed.

All 18 respondents agreed that their organisation encourages teamwork, is supportive and supports staff to identify and solve problems. We were told:

“PETIC is staffed by excellent, caring staff who are a pleasure to work with.”

“I cannot think of any way which improvements could improve the service which are not already in progress or in place.”

All bar two respondents agreed that the organisation takes swift action to improve when necessary. All bar one agreed that care of patients is their organisation's top priority and one disagreed. A member of staff told us:

“As somebody new to PETIC, I am impressed by the focus on continual improvement and commitment to providing a good quality service for the benefit of the patient.”

All staff agreed that their organisation acted on concerns raised by patients and were content with the efforts of their organisation to keep them and patients safe. All staff agreed they would recommend their organisation as a place to work and that they would be happy with the standard of care provided by this organisation for themselves, friends or relatives.

Most staff agreed that their immediate manager could be counted on to help with a difficult task at work, but two disagreed. Again, most staff agreed that their immediate manager gave them clear feedback on their work, again two disagreed.

All bar one member of staff agreed that their immediate manager asked for their opinion before making decisions that affected their work.

Regarding the senior management all staff knew who the senior managers were and all bar one agreed that senior managers were visible and one disagreed. All 18 respondents agreed that communication between senior management and staff is effective. All bar one respondents agreed that senior managers were committed to patient care.

Wellbeing

Senior staff we spoke with described a range of mental health and counselling services to support staff over the period of the pandemic. Staff said that occupational health support was accessible and staff were able to talk to management at any time, should they wish.

Whilst 13 respondents agreed that their job was not detrimental to their health, five disagreed. All bar two respondents agreed their organisation took positive action on health and wellbeing. Over 85% agreed that their current working pattern/off-duty allowed for a good work-life balance. Almost every respondent agreed that they were aware of the occupational health support available to them and one disagreed. A total of 15 staff respondents agreed that they are offered full support in the event of challenging situations and three disagreed.

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 were identified on this inspection.			

Appendix B - Immediate improvement plan

Service: The Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC), Cardiff University

Date of inspection: 12 and 13 July 2022

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.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues.				

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: The Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC), Cardiff University

Date of inspection: 12 and 13 July 2022

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.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The university is required to ensure that action is taken to promote the availability of Welsh speaking staff or support within the department to help deliver the 'Active Offer'.	Standard 3.2 Communicating effectively	PETIC will publicise the Active Offer within the department and patient correspondence.	Chris Marshall	30th September 2022
		PETIC will also audit its service against Cardiff University's Setting the Standards with regards to the Welsh Language to identify further improvements.	Chris Marshall	30th November 2022
		PETIC will provide a copy of the audit against the Setting the Standards document		

The university must ensure that the results of any feedback or satisfaction questionnaires are made know to patients.	Standard 6.3 Listening and Learning from feedback	PETIC will publicise and display the results of its internal satisfaction questionnaires in the main patient waiting area. Monthly Key Performance indicators will also be summarised and displayed	Kristin Philips Kristin Philips	30th September 2022 30th September 2022
The employer must ensure that the employer's procedures are updated to include the information to address situations where more than one operator is directly involved in the exposure.	IR(ME)R Reg 11 (3) (d)	PETIC has created SOP PT 3050 to address this non-conformance. PT 3050 is currently undergoing approval. PETIC will update its employer's procedures to refer to this document. A copy of the updated PT 3050 will be provided as evidence.	Lee Bartley	30th September 2022
The employer must ensure that the employer's procedures are updated to include the additional actions carried to establish whether a patient, who cannot respond, is pregnant or breastfeeding.	IR(ME)R Reg 11 (3) (d)	PETIC has created SOP PT 3050 to address this non-conformance. PT 3050 is currently undergoing approval. PETIC will update its employer's procedures to refer to this document.	Lee Bartley	30th September 2022

		A copy of the updated PT 3050 will be provided as evidence.		
The employer must ensure that the commissioning policy, which established referral guidelines includes the dose information as required by the regulations (6 (5) (a).	IR(ME)R Reg 6 (5) (a)	PETIC will discuss adding this information to the WHSSC PET Commissioning Policy. PETIC will provide a copy of the updated commissioning policy or will update an appropriate document if WHSSC advise that this should not be added to the commissioning policy.	Chris Marshall	30th November 2022
The employer must ensure that the entitlement letters clearly define the duty holder roles and tasks that individuals are allowed to undertake.	IR(ME)R Reg 6 Schedule 2.1 (b)	PETIC will update its entitlement letters to clearly define the duty holder roles based upon the training logs in use in PETIC. The training logs will also be updated to include an entitlement section. A copy of the training log template will be provided as evidence.	Chris Marshall Lee Bartley	30th September 2022 30th September 2022

The employer must ensure that the entitlement process is reviewed in full.	IR(ME)R Reg 6 Schedule 2.1 (b)	PETIC will audit its internal entitlement process to ensure it is compliant with the regulations. PETIC will also audit C&V UHB entitlement of referrers in collaboration with Dr Matthew Talboys to ensure it also meets PETIC's requirements. A copy of the audit reports will be provided as evidence.	Chris Marshall/Luiza Haberska Rhodri Smith/Luiza Haberska	30th September 2022 30th November 2022
The employer must ensure that the relevant employer's procedure is updated to include the need for justification and authorisation of carers and comforters exposures.	IR(ME)R Reg 6 (5) (d) (ii) and Reg 11 (1) (c)	PETIC will update its employer's procedures to include the need for justification and authorisation of carers and comforters exposures A copy of the updated Employers procedures will be provided as evidence. PETIC will update its Carer and Comforter induction form (QM 4044) to accurately capture justification and authorisation	Rhodri Smith/Luiza Haberska Lee Bartley	30th September 2022 30th September 2022

		A copy of QM 4044 will be provided as evidence		
The employer must ensure that the reference in the SAF to the increase in bed-time for patients over 150kg is documented in protocols, to ensure the consistency of operation, by all scanning staff.	IR(ME)R Reg 12 (3)	PETIC has updated it's scanning protocol (PT 3150) to state the process for scanning patients >150 kg. This confirms that 1 minute per bed position is added to the acquisition protocol. A copy of PT 3150 will be provided as evidence.	Lee Bartley	COMPLETED
The employer must ensure that the department are informed of the results of all audits, particularly those performed outside the department, to include as part of the clinical audit evidence.	IR(ME)R Reg 7	PETIC has already updated QM 2019 Management of Clinical Governance to enhance the process of Clinical Audit. All requests for information to assist clinical audit will require form QM 4028 to be completed. This will be logged in the audit module of Q Pulse and used to track and capture all external clinical audit. Clinical audit is now a standing agenda item at the clinical management meeting.	Chris Marshall	COMPLETED

		A copy of QM 2019 and QM 4028 will be provided as evidence.		
The employer must ensure that the list of procedures in schedule two to IR(ME)R are all in place including 1k – probability and magnitude and 1l relating to CSAUE.	IR(ME)R Schedule 2 1 (k) and 1 (l)	PETIC will review its employer's procedures against the list of procedures in schedule two and update its employer's procedures accordingly. This will include adding a section to address 1k and 1l. A copy of the updated Employers procedures will be provided as evidence.	Rhodri Smith/Luiza Haberska	30th September 2022
The employer must ensure that the relevant employer's procedure clearly defines what is a CSAUE.	IR(ME)R Reg 8 (1)	PETIC will update its employer's procedures to clearly define what is a CSAUE. A copy of the updated Employers procedures will be provided as evidence.	Rhodri Smith/Luiza Haberska	30th September 2022
The employer must ensure that there is a system in place to record	IR(ME)R Reg 8 (3)	PETIC already records Near Misses on the C&V Datix system which is then reviewed by C&V UHB Clinical Governance. PETIC	Lee Bartley	30th September 2022

near misses as well as significant events.		will update its SOPs to clearly define what is a near miss. A copy of the updated Employers procedures will be provided as evidence.		
The university must ensure that all staff are up to date with their mandatory training.	Standard 7.1 Workforce	PETIC will ensure all University staff are up to date with their mandatory training. C&V UHB staff will be audited on an annual basis as part of the Staff State Registration audit to determine compliance with the C&V UHB Mandatory training policy. PETIC will provide a report on mandatory training compliance by University staff and request a report from C&V UHB.	Chris Marshall Chris Marshall Chris Marshall/Lee Bartley	30th November 2022 30th November 2022 30th November 2022

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): Christopher Marshall

Job role: Director of PETIC

Date: 8th September 2022