Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

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

Nuclear Medicine Department, Simbec-Orion Clinical Pharmacology Unit (CPU), Merthyr Tydfil

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

Our purpose

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

Our values

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

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

Our goal

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

Our priorities

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

Contents

1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department at Simbec-Orion Clinical Pharmacology Unit (CPU), on 15 and 16 January 2026. During our inspection we looked at how the department complied with the Regulations and met the National Minimum Standards for Independent Health Care Services in Wales. No procedures were being conducted at the time of the inspection. This report is based on the self-assessment form and supporting paperwork completed in advance of the inspection, together with conversations with staff about the theory of the processes.

Our team for the inspection comprised of two HIW healthcare inspectors and a Specialist Clinical Officer from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity.

During the inspection we invited participants 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 two questionnaires were completed by participants or their carers and four were completed by staff. Feedback and some of the comments we received appear throughout the report.

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

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

2. Summary of inspection

Quality of Patient Experience

Overall summary:
The service was accessible, with level access, lift provision and translation services. Equality, diversity and inclusion were actively promoted, supported by staff training and ongoing organisational monitoring.

The inspection found health promotion materials available to participants on the screen in enrolment services. The environment supported dignity and privacy, with appropriate use of privacy screens, individual transfers to the gamma camera room and private areas for sensitive discussions.

Study approvals outlined participant numbers and dose constraints, with details included in study protocols and manufacturing batch records. Participant appointments were scheduled in advance, with study officers responsible for communication and managing delays.

Participants received written information sheets and consent forms containing radiation risk explanations. Staff supported individuals with sensory or language needs and pre-screening identified language preferences. Welsh speakers were available, though not clearly identified and some bilingual information was displayed. The employer must ensure Welsh-speaking staff are clearly signposted.

This is what we recommend the service can improve:

- Ensure Welsh-speaking staff are clearly signposted.

This is what the service did well:

- Accessible setting with a lift to upper floors
- Written information supplied to participants
- The environment supported dignity and privacy.

Delivery of Safe and Effective Care

Overall summary:
Staff understood where to locate written procedures, which were accessible via the Quality Management System (QMS). Governance arrangements existed for validating employer and practitioner licences but checks against Administration of Radioactive Substances Advisory Committee (ARSAC) research approval were not embedded in trial approval documentation and must be incorporated. Significant procedural updates had been made on written employer's procedures.

The QMS supported distribution, acknowledgement and version control of procedures, though improvements were required to the scan protocol detail and gamma-camera optimisation. Delegated authorisation guidelines were absent, meaning individual justification of exposures was not evidenced; this must be addressed before further studies proceed.

Entitlement records were outdated and inconsistent with staff interviews. These records required full review, alongside clearer practitioner appointment letters. Training records for externally employed practitioners were insufficient and radiation protection training relied too heavily on reading policies.

Processes for identity checks, pregnancy and breastfeeding enquiries and communication of benefits and risks were described, though breastfeeding processes were not reflected in employer procedures. Dose constraints were inconsistently documented and needed definition in protocols, audited and adhered to. Clinical evaluation processes were in place and the Medical Physics Expert (MPE) was available and involved in quality assurance, though audits were overdue and must be re-established.

Equipment was appropriate, with gaps in annual physics testing. Sharps bins lacked full compliance, though infection, prevention and control (IPC) arrangements, personal protective equipment (PPE) availability and cleaning processes were good. Safeguarding training was up to date. The environment was accessible, safe and well maintained, with risk assessments and alerts effectively managed.

This is what we recommend the service can improve:

- Delegated authorisation guidelines needed to be drafted to ensure individual justification of exposures can be evidenced
- Entitlement records were needed to be consistent
- Training records for externally employed practitioners needed to be evidenced
- Dose constraints needed to be defined in protocols, audited and adhered to.

This is what the service did well:

- The QMS supported distribution, acknowledgement and version control of procedures
- Clinical evaluation processes were in place and the MPE was available and involved in quality assurance
- Significant procedural updates had been made.

Quality of Management and Leadership

Overall summary:
The inspection found strong governance and accountability arrangements within the setting. Staff reported senior managers were accessible, operated an open-door policy and communicated regularly through meetings and emails. Clear leadership structures were in place and the self-assessment form was well-completed and timely. The management team showed commitment to learning from HIW findings and demonstrated robust quality assurance processes, supported by a comprehensive QMS that staff used to access policies, procedures and updates. Procedures had been updated to align with IR(ME)R requirements ahead of the inspection.

Workforce planning and development were effective, with staff confirming adequate skill mix, staffing levels and annual appraisals, with 100% compliance. Mandatory training was monitored through the QMS and management oversight, with overall compliance at 99%. Whilst staff had completed required modules such as safeguarding, IPC and resuscitation training, some areas relied too heavily on reading policies rather than practical, interactive training. The employer must ensure mandatory training includes practical components.

Citizen engagement processes were well established, with visible information on how to provide feedback and how the service acted on it. Complaints procedures were accessible in English and Welsh and learning from complaints and compliments was shared with staff. Staff could also raise concerns through an employee voice mechanism.

This is what we recommend the service can improve:

- Ensure practical input at mandatory training

This is what the service did well:

- Appraisal compliance at 100% and mandatory training at 99%
- Governance and leadership was positive with clear leadership evident
- Complaints and compliments processes in place.

3. What we found

Quality of Patient Experience

Patient feedback
HIW issued online questionnaires to obtain participant views on the services carried out at the Nuclear Medicine Department at Simbec-Orion Clinical Pharmacology Unit (CPU) to complement the HIW inspection. We received two responses from participants which were both positive. However, due to the low number of responses we were unable to draw any conclusions or themes from this reply.

Health promotion, protection and improvement
We were told information was provided during pre-screening and screening, advising what foods and drink to avoid. Additionally, the large screen in the enrolment services reception contained information that was available for all persons attending the site. This included health and safety information (including fire / first aid), health and wellbeing links and quick response (QR) codes, Health Information Resources NHS Wales, NHS Stop Smoking Service and physical activity guidelines

Dignity and respect
There were no participants at the setting at time of the inspection.

From our observations we noted there were not any issues with the environment which would impact participant dignity. Privacy screens were available and treatment room doors were kept close when in use. Participants would be taken to the gamma camera room individually. There were separate rooms and areas available for any sensitive discussions.

Care planning and provision
The self-assessment form (SAF) completed by the setting in advance of the inspection described the approval process for the research. Each study specific approval specifies the number of participants to be dosed. Dose constraints (a prospective value of dose that is expected to be delivered to trial participants) would be determined on a study specific basis and documented in the study protocol and in the study specific manufacturing batch records (MBR) used to produce the radiolabelled dosage forms.

We were told the time for each participant would be arranged in advance for a fixed period. Each study had a study officer appointed and their job would be to

communicate with the participant and the supervisory team. Any delay would be communicated to participants by the study officer.

Patient information and consent
We noted the staff team images and names were displayed on a notice board in the ward corridor.

The SAF explained the process that participants were provided with a written participant information sheet and consent form. This contained relevant radiation risk language outlining the exposures compared with annual background radiation and relevant comparative examples.

Communicating effectively
We were told staff would help people with difficulties in hearing, sight and reading English, this would usually be picked up as part of the pre-screening process.

The informed consent process was described as lengthy, the setting contact centre would send information to participants for them to familiarise themselves with the study and they would then complete a pre-screening questionnaire. In addition, there were comprehensive onsite checks, medicals and inductions carried out.

Whilst the participants for the research would come from a wide area, including abroad, the criteria on acceptance would be that they had to be able to communicate with the study team in English to enable consent. As part of pre-screening, participant language preference was obtained and If participants indicated Welsh, translated documents would be prepared ready for their attendance at the setting.

We were told that several members of staff spoke Welsh. However, they did not wear a “iaith gwaith” badge to identify them as Welsh speakers. There was some bilingual information displayed, although the consent policy required consent to be given in English.

Senior staff we spoke with said they would include information of the staff who could speak Welsh on the ‘who’s who’ board in the reception area.

The employer must ensure the setting clearly identifies to participants, the staff that can speak Welsh.

People’s rights
Arrangements were in place to make the service accessible to participants. There was good access around the setting, with level floors and a lift available for those with mobility issues. Translation services were also accessible

We were told equality and diversity was promoted within the organisation through an equality, diversity and inclusion (EDI) policy. This included the corporate objective which was embedded into the culture of the setting. All staff had completed EDI training. Additional work had been carried out by the Human Resources Department on neurodiversity metrics, which was reported to the board monthly, as well as EDI information on demographics and general Initiatives.

Delivery of Safe and Effective Care

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

There were no procedures being undertaken at the setting at the time of the inspection. The site only performed planar and dynamic nuclear medicine imaging. Within the context of clinical studies conducted at Simbec-Orion CPU, the following radionuclides had been administered previously - Technetium-99m, Krypton-81m.

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

Procedures and protocols
Staff we spoke with were aware of where to find the written procedures relevant to their practice and they said these were easy to follow. Any reviews or amendments to the procedures and protocols in place would be informed to staff through an automated email on the quality management system as well as through staff meetings. However, staff who did not work at the setting, including the MPE, practitioner and the provider of gamma scintigraphy services, had to monitor these changes manually.

The SAF stated the governance arrangements for ensuring employer and practitioner licences were valid and appropriate for the scope of service. We were told there was a check of licences against ARSAC research approvals to ensure the appropriate procedure codes were included. However, the trial management approval process did not currently refer to the check of employer and practitioner licences against ARSAC research approval.

The employer must ensure the check of the employer and practitioner licences are included in the documentation provided to agree the proposed study.

Evidence provided showed the employer was aware of their responsibilities under IR(ME)R and how the employer delegated the task of carrying out IR(ME)R duties to others. This included an organogram from the employer through the organisation to relevant committees.

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

During the time that elapsed between the submission of the SAF and the inspection, the setting had made significant changes to the POL00012, Compliance with the Ionizing Radiation (Medical Exposure) Regulations 2017 and Subsequent Amendments. The overall legal responsibility for compliance with IR(ME)R was now defined in SOP583, Management of Ionizing Radiation (Medical Exposure) Regulations. We were told SOP583 was used by staff and POL00012 directly referred to SOP583.

We were told the setting ensured the written employer's procedures were complied with by all duty holders through the quality management system (QMS). The QMS allowed all staff to access documents, for each role the head of department would decide who needed to read which documents. The QMS then forwarded relevant procedures and policies to each member of staff and this showed who had read which procedures. There was also some assessment of training prior to reading the procedures, which was built into training records.

There was a written employer's procedure for quality assurance programmes in respect of written procedures, written protocols and equipment, were followed. The purpose of the procedure was to ensure regular reviews of all policies, procedures and protocols were followed.

We reviewed an individual scan protocol, analysis protocol and evaluation protocol during the inspection. The scan protocol could be improved by including a summary of detail and parameters used for imaging.

The employer must ensure the scan protocol includes a summary of detail and parameters used for imaging.

Scan parameters of the gamma camera had been set and not changed from historical values. The setting need to consider if the camera performance is still suitable and imaging parameters could be optimised.

The employer must ensure images are optimised by completing prospective phantom work or retrospective work after the next trial.

Referral guidelines
The SAF described how the employer ensured referral guidelines were established and made available to all referrers and the process for making, amending, cancelling any referrals. However, this did not address how referrals were made.

We noted the document, Clinical Pharmacology IR(ME)R Document Referral Form, stated "Exposure authorised by signature of referring clinician (under delegation from Practitioner)". However, there was not a delegated authorisation guideline

(DAG) in place. This is discussed further in the section on justification of individual exposures.

Referrals were also discussed with senior staff as part of the initial tour of the setting. We were told the referral was not available in the gamma camera room at the time of administration. The identity checks were completed as the participant was checked in and on the ward. We were also told that some paperwork was sent with the participant to the gamma camera room and the referral could be sent down with this paperwork.

The employer must ensure the referral form:

- **Is updated to allow for the relevant signatures to be completed, including the signatures of the referrer, the authorising operator and who has carried out identification and the pregnancy and breastfeeding checks**

- **Accompanies the participant when the procedure takes place in the gamma camera room.**

Diagnostic reference levels (DRLs)
DRLs were not required by IR(ME)R for exposures in research

The SAF stated the only exposures conducted at the setting were part of research studies to assess the performance of pharmaceutical dosage forms and devices, thus DRLs were not established for routine exposures.

Medical research
The setting only performed research studies, no diagnostic or therapeutic procedures were performed.

Entitlement
Evidence was provided on how named individuals or groups of individuals were entitled to act as referrers. We spoke with staff about how they were made aware of their duties and scope of entitlement under IR(ME)R. However, recently signed entitlement records did not match the information provide by staff in interviews. Entitlement records should be reviewed to ensure the tasks listed were practical aspects supporting the exposure. This must be corrected before any further studies are carried out.

The employer must ensure they review all tasks in entitlement records to ensure they are relevant, completed and to ensure staff are aware of their requirements, including identity checks, pregnancy and breastfeeding checks.

There was a process by which licensed practitioners were entitled. However, the entitlement letter also included some duties that were not practitioner duties. We were told the setting were aware of the issues. We also noted a different format for referrer and operator entitlement records used compared to practitioner letter. The practitioner appointment letter should be reviewed to ensure it is specific to the practitioner role.

The employer must amend the appointment letter to ensure it is specific to the duties of the practitioner role.

The supplied entitlement records were originally signed in 2019, some of these had been subsequently updated prior to inspection in January 2026. These records had lapsed during the time when no trials had been in place.

The employer must ensure the entitlement records are reviewed and updated on a regular basis.

The training programmes in place for all duty holders under IR(ME)R and how training records for practitioners and operators were managed were described. However, this relied on the fact that the practitioner contracted, worked in the NHS and training was managed by their NHS employer.

We were told training was defined within the electronic QMS, learner roles and curricula were assigned to each member of staff as appropriate for their role within the organisation. An examination of how practitioner training could be evidenced by the setting showed there was not sufficient evidence of training maintained. Radiation protection training had been issued to all relevant staff through training assignments from the QMS. However, this training only involved the reading of a policy. External contractors also had access to procedures via the QMS, training records were reviewed by the setting during audits.

The employer must ensure they have access to the training records relevant to scope of practice for all staff and others employed working outside the setting such as the MPE and practitioners managed by the NHS -

Participant identification
Senior staff described the process involving checking the participant wrist band, dosage number and evidenced this on the clinical research form (CRF).

The employer's procedure for patient identification provided a link to the standard operating procedure (SOP) on study medication administration which provided full details on how the patient identity was checked.

Individuals of childbearing potential (pregnancy enquiries)
Staff we spoke with said the enquiries of individuals of childbearing potential to establish pregnancy or breastfeeding were carried out by medical staff.

The SAF described the process for making enquiries of individuals of childbearing age to establish whether the individual was, or may be, pregnant or breastfeeding and how it was recorded, this had been completed correctly. However, there was not a reference in the employer's procedure to what breastfeeding checks were completed. We were told this information was in the research study protocol, but it was not clear whether the research study protocol was part of the employer's procedures. This must be completed before any further studies are carried out.

The employer must ensure the employer's procedure for pregnancy and breastfeeding enquiries are updated to reflect what is done in practice.

Benefits and risks
Staff we spoke with said the participants would be verbally told about the risks associated with the research radiation dose. The SAF stated a written participant information sheet and consent form would be provided to participants with adequate information on the risks associated with the radiation dose.

All information presented to participants was aligned to the requirements for radiation risk set out by the Health Research Authority (HRA) and the Administration of Radioactive Substances Advisory Committee (ARSAC). The documentation was subject to review prior to regulatory submission by the appointed MPE, Clinical Radiation Expert (CRE) and the pharmaceutical imaging company employed.

Clinical evaluation
The evidence provided described how clinical evaluation was undertaken and evidenced for each type of exposure. This included all participants that were dosed would be evaluated and the data included in the Clinical Study Report (CSR).

Non-medical imaging exposures
Non-medical imaging examinations were not undertaken in the department.

Employer's duties - clinical audit
The process for clinical audit and how any follow-on actions were identified and completed as part of the audit was detailed in four documents provided.

The document POL00012 stated procedures relating to IR(ME)R were to be reviewed at least every two years as part of the radiation protection advisor (RPA)

audit. We found that procedures had not been reviewed every two years. This reference should also refer to an MPE audit rather than RPA audit.

The MPE we spoke with stated an MPE review of some of the procedures had been carried out as part of the update of procedures. They were involved in the review prior to inspection and stated they would review them again after the inspection and in future would work to implement two yearly checks. Additionally the annual quality assurance of the gamma camera and calibrator had not been completed as part of an MPE audit.

The employer must ensure MPE audits are established and completed as required.

The description provided in the SAF of the process for IR(ME)R audits and how any follow-on actions were identified and completed did not answer the question as it referred to clinical audits not what IR(ME)R audit would look at, such as compliance with identity procedures. We were told the setting had not completed an IR(ME)R audit but they agreed this would be completed and some elements were covered in other Medicines and Healthcare products Regulatory Agency (MHRA) process.

The employer must ensure IR(ME)R audits are established and completed as required.

Employer's duties - accidental or unintended exposures (AUE)
Senior staff we spoke with described the procedure for reporting accidental or unintended exposures or other incidents. Depending on the issue, the setting liaised with the radiation protection supervisor (RPS) and the MPE to determine the extent of the exposure. This would determine whether this would be reported to HIW.

There would be an analysis of the process to prevent this from reoccurring together with the corrective and preventative actions (CAPA) process and tracking. Senior staff also described how learning from incidents, as well as IR(ME)R incidents, was shared. The results would be reported to staff and what was put in place to prevent it happening again.

There had not been any accidental and unintended exposures that needed to be notified to HIW.

The relevant employer's procedure, referred to the United Kingdom (UK) Department of Health guidance and the link redirected the reader to the general UK Department of Health and Social Care guidance, instead of the Welsh

references. Whilst HIW was referred to as the relevant enforcing authority for Wales there was a need to review links to Care Quality Commission (CQC) guidance. HIW published guidance must be used.

The employer must ensure the IR(ME)R documentation refers to Welsh guidance and requirements.

The process in place for recording and analysing accidental or unintended exposures including near misses was included in SOP 583 but was limited in detail. The line in the SOP only stated, "Any actual and potential accidental or unintended exposures would be analysed and reviewed and appropriate actions taken".

The employer must ensure the SOP includes detail on how AUE would be analysed and reviewed as well as the recording and analysing AUE, including near misses.

Duties of practitioner, operator and referrer
The duties of the practitioner operator and referrer were described in the SAF and the employer's procedures. The SAF explained how practitioners, operators and referrers were entitled to carry out their duties which was included in an employer's procedure.

The employer entitled an NHS consultant radiologist through a practitioner entitlement letter, who signed and returned the letter to formally acknowledge acceptance to act in the role of practitioner.

Justification of individual exposures
The processes of how justification and authorisation of individual exposures was performed and where this was recorded, was described in the SAF. This stated the practitioner signed the ARSAC PRA form thereby justifying and authorising the planned exposures. However, the practitioner signing the PRA form did not justify and authorise individual referrals. There was therefore no evidence of individual justification. The fact the practitioner signed the initial Preliminary Research Assessment (PRA) did not justify all exposures in the trial. Senior staff told us they were planning to introduce study specific Delegated Authorisation Guidelines (DAG) to delegate the act of authorisation. This must be completed before any further studies are carried out.

The setting agreed a DAG would be introduced, together with a process around this as well as training and entitling operators who could authorise the referrals.

The employer must draft delegated authorisation guidelines for each trial.

Optimisation
Written information was provided to participants about the radioactive substances involved in the research.

The SAF stated the setting did not perform diagnostic procedures. All administrations related to research projects designed to evaluate the performance of pharmaceutical dosage forms and devices. The doses planned for administration in each research study were reviewed by ARSAC and needed to be judged as acceptable before the study could begin.

The setting should consider an image optimisation review to ensure scan parameters were appropriate as discussed above.

Paediatrics
Individuals under the age of 18 were not involved in research studies.

The SAF described how dose constraints and targets were established and what measures were in place to ensure they were adhered to on a study specific basis. These were documented in the study protocol and in the study specific manufacturing batch records (MBR) used to produce the radiolabelled dosage forms. We were told dose constraints were set in the Integrated Research Application System (IRAS) PRA form and listed in the research study protocol, but the research study protocol shared as part of this inspection did not have a dose constraint. The batch record was reviewed as part of the quality assurance process. The process for establishing dose constraints must be completed before any further studies are carried out.

The employer must ensure:

- **They update the research study protocol template to ensure dose constraints are specified for each trial**

- **Measures to ensure dose constraints are adhered to must be included in local processes**

- **They complete a dose constraint audit in future research studies.**

Carers or comforters
There was an employer's written procedure for the establishment of appropriate dose constraints and guidance for the exposure of carers and comforters.

Expert advice

Staff we spoke with said the MPE was readily available to provide advice in a timely manner and there was more interaction when studies were ongoing.

The current MPE had been involved with the setting since the commissioning of the gamma camera. The MPE would routinely visit the setting twice a year to quality check the calibrator and gamma camera.

We were told the MPE provided advice to the employer on compliance with the regulations including being involved in changes to procedures. The MPE had pointed out DAG requirements and justification regulatory compliance prior to the inspection. The MPE stated RPA and radioactive waste advisor RWA reports had been completed.

The SAF described how the MPE was involved in all nuclear medicine services.

Equipment: general duties of the employer
The equipment used was appropriate for the scope of the service.

There was a quality assurance programme in place for all relevant equipment including testing of any equipment before first use, performance testing at regular intervals and testing following maintenance.

The SAF described the measures in place to improve inadequate or defective equipment, any corrective actions may be taken and how equipment issues were communicated to the employer. There should be annual testing of the gamma camera. However, there was a two-year gap noted in the required medical physics testing. Gamma camera preventative maintenance was carried out every quarter by an external organisation.

We spoke with senior staff about plans for replacement of the gamma camera. We were told there was not any immediate plan to replace the camera.

There were procedures for ensuring the accurate verification of the administered activity.

Safe

Managing risk and health and safety
The setting and department was easy to find, with disabled access and was accessible throughout, including a lift to the upper floors. The environment was clean, well maintained and the furniture, fixtures and fittings were in a good condition. The environment was suitable for the way it was used with enough chairs and facilities. The premises were safe and secure with key card access

limiting access to only those areas the participants required to visit. There were no hazards seen.

Staff we spoke with were able to describe the departmental and study risk assessments in place and where these could be accessed. These included risk management processes for the radiation equipment and radiolabelling.

The setting received safety notices, alerts and other communications which were shared and acted upon, including MHRA alerts regarding devise or drug issues, which were shared, evaluated and investigated.

Infection prevention and control (IPC) and decontamination
The environment and equipment were clean and in a good state of repair. There were sharps disposal bins used, but these were not all secured or in a secure location on the ward. The labels on the sharps disposal bins did not all have the required information recorded.

The employer must ensure the sharps disposal bins at the location:

- **Are secured when in use**

- **Have the relevant information correctly recorded on the bin.**

Suitable hand washing and drying facilities were available and there was sufficient accessible, appropriately stored and in-stock personal protective equipment (PPE) seen.

Staff we spoke with were aware of the IPC arrangements in place. We were told of the annual IPC audit completed by an external company who audited IPC at the setting. The senior nurse and other nurses reported on the results of the audit to the health and safety committee. They also presented on IPC to staff.

Staff described the process for decontaminating medical devices, equipment and relevant areas of the unit. Infectious participants would not normally be allowed to initially take part in any study. If a participant did become infectious during the study staff were able to describe the process for isolating the participant and the cleaning arrangements.

There was an in-date IPC policy in place.

Safeguarding children and safeguarding vulnerable Adults
There was evidence from the training records checked that staff had received appropriate training in safeguarding. Staff we spoke with were aware of where to

find the organisations safeguarding policies, which were in date. They confirmed if there were any safeguarding issues they would escalate these to their immediate supervisor, who would escalate the concern appropriately, if necessary to the safeguarding lead.

Effective

We were provided with examples of the arrangements to promote an efficient service. The setting had recently invested in a new online system providing electronic recording, linked from the equipment to the central system, providing system information in real time. We were also told the new volunteer website had made operation of the system easier and the setting were looking into introducing an electronic informed consent system.

Record management

There were not any current or retrospective records to check at the setting.

Quality of Management and Leadership

Staff Feedback
HIW issued a questionnaire to staff to obtain their views about the department at the hospital. We received four responses from staff at this setting, responses by staff were generally positive. However, due to the low number of responses we were unable to draw any conclusions or themes from this reply.

Governance and accountability framework
Staff we spoke with confirmed senior managers were accessible and engaged with staff on a regular basis. Managers we spoke with said there was an open-door policy and staff had regular access to line management, heads of department and senior managers.

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

There was evidence of QA throughout the operation, including a QA overview SOP giving an overview of the activities conducted under the control of QA.

Staff we spoke with knew where to find general policies and procedures relevant to their practice on the QMS.

All staff described how information was shared between management and staff. This included regular meetings and emails, these meetings included fortnightly heads of management, with information cascaded to staff. There were regular senior leadership team (SLT) meetings, again with reports sent to staff regularly. Staff were able to meet with HR and the SLT whenever needed.

Senior staff described the process for the review and amendment of general policies relevant to the department. All procedures and policies had a three yearly review lifecycle, although they could be updated earlier. The QMS system in place maintained and controlled policies and procedures with staff access and reminders and updates.

Work had been carried out on the procedures between the announcement and the inspection to ensure the procedures complied with the requirements of IR(ME)R including the recent amendments.

Workforce planning, training and organisational development
Staff we spoke with agreed the number and skill mix of staff was appropriate for the setting. They said staff were able to undertake a number of the varying functions at the setting. Staff agreed they had enough time to perform their duties and they received regular appraisals on an annual basis. Senior staff confirmed these arrangements and stated appraisal compliance was 100%. They also stated nursing and medical staff had appraisals linked to their registration requirements.

Staff said they were able to report concerns to management.

Senior staff described the arrangements in place to monitor compliance with mandatory training. We checked a random sample of five staff mandatory training records. There was clear evidence staff had completed safeguarding training at the relevant level. Whilst there was evidence staff had completed health and safety training this only required staff to read the global health and safety policy. IPC training had been completed, this was a mixture of reading the procedure and a skills workshop. The staff checked had completed either ALS or ILS resuscitation training. Four of the five staff checked had completed face to face training in the use of portable oxygen.

Staff had completed additional training which was evidenced on the QMS and by departmental managers. The training compliance was reported at the monthly QA meetings. Additionally, the learning and development department monitored and notified management of training gaps.

We were told overall training compliance was positive at 99%. The mandatory training staff were required to complete was dependent on their job role. Some of the training we evidenced only involved reading a policy (such as manual handling) whereas these areas needed more interactive training including classroom-based training.

The employer must ensure staff mandatory training is relevant and includes practical training in addition to reading policies.

Citizen engagement and feedback
We noted there was information displayed at the setting about how participants were able to provide feedback about their time at the setting, including at the enrolment stage and on the ward.

There was also information displayed on how the setting acted on feedback received. The setting may benefit from including this information on the setting website. The results of the feedback were also reported to monthly meetings of the management team. There was also an internal employee recognition process.

Information was displayed about the complaint's procedure on the television screen in the reception area. Bilingual written copies in English and Welsh of the complaints process were available at the reception. Whilst there was no named complaints handler listed in the complaints process, we were told the Head of Enrolment Services generally handled complaints.

Staff we spoke with were aware of what actions to take should there be a complaint. Senior staff described the process in place to analyse the feedback and concerns received to highlight themes and determine relevant action. We were also told staff could raise any concern through the employee voice process, a way people communicate their views to their employer and influence matters that affect them at work.

We were told learning from complaints was shared with staff across the department and organisation. Compliments for employees were also shared with staff.

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

The improvement plans should:

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

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

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

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

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B - Immediate improvement plan

Service: Simbec-Orion Clinical Pharmacology Unit

Date of inspection: 15 and 16 January 2026

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

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	There were no immediate non-compliance 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: Simbec-Orion Clinical Pharmacology Unit

Date of inspection: 15 and 16 January 2026

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

	Risk/finding/issue	Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	We were told that several members of staff spoke Welsh. However, they did not wear a “iaith gwaith” badge to identify them as Welsh speakers.	The employer must ensure the setting clearly identifies to participants, the staff that can speak Welsh.	NMS - Communicating effectively	Welsh speaking staff have been identified and the ‘Who’s Who’ notice board on the Clinic floor has been updated to clearly disseminate this information. Within the Clinic a new notice board will be added to the participant lounge area and will contain relevant lifestyle information.	Deborah Evans Clinic Manager Deborah Evans Clinic Manager	Completed 26-Jan-2026 30-Apr-2026

2.	The trial management approval process did not currently refer to the check of employer and practitioner licences against ARSAC research approval.	The employer must ensure the check of the employer and practitioner licences are included in the documentation provided to agree the proposed study.	Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) regulation 11, 1 (a)	The Clinical Pharmacology Management Approval Form (TEMP-00553) has been updated to include a documented check that the confirmation ARSAC approval letter contains the correct employer and practitioner licence numbers.	Laura Llewellyn Director of Project Management	Completed 10-Mar-2026
3.	We reviewed an individual scan protocol, analysis protocol and evaluation protocol during the inspection. The scan protocol could be improved by including a summary of detail and parameters used for imaging.	The employer must ensure the scan protocol includes a summary of detail and parameters used for imaging.	IR(ME)R regulation 6 (5)(b), regulation 6(4) schedule.2, 1(d))	The study specific In Vivo Image Acquisition Plan (TEMP-01189) template has been modified to prompt the Operator to generate a Scan Protocol and include it as an appendix to the document. This has further been updated to include an example of scan protocol which will be created per study.	Simon Warren CSL Research Director Simon Warren CSL Research Director	Completed 16-Mar-2026 Completed 20-Mar-2026

4.	Scan parameters of the gamma camera had been set and not changed from historical values. The setting need to consider if the camera performance is still suitable and imaging parameters could be optimised.	The employer must ensure images are optimised by completing prospective phantom work or retrospective work after the next trial.	IR(ME)R regulation 12(3))	Images acquired during the next research study will be reviewed to ensure consistency with those from previous studies. Current study timelines not yet known but expected to be completed in 2026.	Simon Warren CSL Research Director	31-Dec-2026
5.	Referrals were also discussed with senior staff as part of the initial tour of the setting. We were told the referral was not available in the gamma camera room at the time of administration. The identity checks were completed as the participant was checked in and on the ward. We were also	The employer must ensure the referral form: • Is updated to allow for the relevant signatures to be completed, including the signatures of the referrer, the authorising operator and who has carried out identification and	IR(ME)R Schedule 2, 1(p)	The Clinical Pharmacology IR(ME)R Referral Form (TEMP-00588) has been updated as follows: - 'Yes' options removed for pregnancy and breast-feeding status, dates added for screening and admission - Statement added above signature box that referring clinician has reviewed documented	Laura Llewellyn Director of Project Management	Completed 10-Mar-2026

	told that some paperwork was sent with the participant to the gamma camera room and the referral could be sent down with this paperwork.	the pregnancy and breastfeeding checks • Accompanies the participant when the procedure takes place in the gamma camera room.		pregnancy and breastfeeding status - Additional signature box for operator to confirm receipt and review of referral form An additional ID check performed by the Operator now added to V6.0 SOP-00360 - Clinical Pharmacology Principal Investigator Oversight, Delegation of Responsibilities and Handover has been updated to include the process for completing, signing and filing the Referral forms. - An additional confirmation of ID by the operator will be included in section 4.3.3.	Laura Llewellyn Director of Project Management Laura Llewellyn Director of Project Management	Completed 25-MAR-2026 30-Apr-2026

6.	Recently signed entitlement records did not match the information provide by staff in interviews. Entitlement records should be reviewed to ensure the tasks listed were practical aspects supporting the exposure. This must be corrected before any further studies are carried out.	The employer must ensure they review all tasks in entitlement records to ensure they are relevant, completed and to ensure staff are aware of their requirements, including identity checks, pregnancy and breastfeeding checks.	IR(ME)R regulation 6 and 10 (3), Schedule 2 1(b)	The Clinical Pharmacology IR(ME)R Entitlement Form (TEMP-00586) has been updated to remove Monitoring of volunteer health and safety before, during and after dosing – as this responsibility does not fall under the regulations and is covered by the Delegation of Responsibilities Log. In addition, a documented check has been added regarding requirement for IR(ME)R Entitlement Forms to be reviewed and updated (if required) for each ionizing radiation studies.	Laura Llewellyn Director of Project Management	Completed 10-Mar-2026
7.	There was a process by which licensed practitioners were entitled. However, the entitlement letter also included some duties that were not	The employer must amend the appointment letter to ensure it is specific to the duties of the practitioner role.	IR(ME)R regulation 6 and Schedule 2 1(b)	Practitioner appointment letter has been updated to reflect current guidelines and the specific duties of the practitioner role.	Anne Hall QA Manager Anne Hall	Completed 26-Feb-2026 Completed

	practitioner duties. We were told the setting were aware of the issues. We also noted a different format for referrer and operator entitlement records used compared to practitioner letter. The practitioner appointment letter should be reviewed to ensure it is specific to the practitioner role.			Documents now uploaded to Veeva Vault Quality on an annual review cycle to ensure it is reviewed regularly and remains current.	QA Manager	18-Mar-2026
8.	The supplied entitlement records were originally signed in 2019, some of these had been subsequently updated prior to inspection in January 2026. These records had lapsed during the time when no trials had been in place.	The employer must ensure the entitlement records are reviewed and updated on a regular basis.	IR(ME)R regulation 6 and 10(4), Schedule 2 1(b)	SOP-00583 Management of Ionizing Radiation (Medical Exposure) Regulations has been amended to state that signed Entitlement forms are stored electronically in a central location and should be reviewed periodically, typically annually* and always before the initiation of a new study, with new Entitlement	Jonathan Womack Head of Laboratory Services	Completed 05 Mar 2026

				forms issued on a three-year cycle or before the initiation of a new study. Entitlement form status will be captured on the Clinical Pharmacology Risk Register (TEMP-00585). * Documents now uploaded to Vault Quality on an annual review cycle to ensure they are reviewed annually and remains current.	Anne Hall QA Manager	Completed 23-Mar-26
9.	Radiation protection training had been issued to all relevant staff through training assignments from the QMS. However, this training only involved the reading of a policy. External contractors also had access to procedures via the QMS, training records	The employer must ensure they have access to the training records relevant to scope of practice for all staff and others employed working outside the setting such as the MPE and practitioners managed by the NHS -	IR(ME)R regulation 6 (3) (b), 6A and 17, Schedule 3	The process for appointing MPE/Practitioner is detailed within SOP-00447 Service Provider Process and SOP-00541 Temporary Worker Process. Practitioner: A copy of Dr Rees's GMC registration details and ARSAC Practitioner license are on file and are reviewed at the time appointment letters are	Anne Hall QA Manager	Completed 18-Mar-2026

	were reviewed by the setting during audits.			reviewed (annual periodic review). MPE: Evidence of Continuous Professional Development training covering the scope of activity undertaken for Simbec-Orion will be obtained and saved alongside the Service Provider qualification documentation to ensure it is reviewed during each periodic requalification as detailed in SOP-00447 Service Provider Process.	Anne Hall QA Manager	31-May-2026
10.	There was not a reference in the employer's procedure to what breastfeeding checks were completed. We were told this information was in the research study protocol, but it was not clear whether the research study	The employer must ensure the employer's procedure for pregnancy and breastfeeding enquiries are updated to reflect what is done in practice.	IR(ME)R regulation 6 and Schedule 2 1(c)	POL-00012 Policy Statement on Ionizing Radiation Safety: Updated to include study participants including those who are pregnant or breast feeding. SOP-00583 Management of Ionizing Radiation (Medical Exposure) Regulations updated Section 3.1 Employer	Jonathan Womack Head of Laboratory Services Jonathan Womack Head of Laboratory Services	Completed 12-Feb-2026 Completed 19-Feb-2026

	protocol was part of the employer's procedures.			responsibilities to include measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding. SOP-00583 states that in the case of female participants of childbearing potential, the study specific protocol, approved by the relevant regulatory authorities, will detail pregnancy test procedures that must be performed during screening and on the planned day of dosing. Simbec-Orion follows Clinical Trial Facilitation Group (CTFG) guidelines; Recommendations related to contraception and pregnancy testing in clinical trials (March 2024). No exposures are conducted until all regulatory approvals are in place in accordance with SOP-00563 Project Management of Clinical Trials Conducted		

				in the Clinical Pharmacology Unit – Conduct.		
				SOP-00360 Clinical Pharmacology Principal Investigator Oversight, Delegation of Responsibilities and Handover updated to include responsibility of the medical team to complete the Clinical Pharmacology IR(ME)R Referral form (TEMP-00588) for each participant (as appropriate) at screening and again on admission to confirm pregnancy test results and breast-feeding status. Prior to dosing the operator responsible for administering radioisotopes will review and sign the referral form; to confirm they have reviewed the medical assessment that participants are not pregnant or breast feeding.	Laura Llewellyn Director of Project Management	Completed 24-Feb-2026
				GUID-00104 Nuclear Medicine Study Poster (English) and	Jonathan Womack	Completed

				GUID-00105 Nuclear Medicine Study Poster (Welsh) have been created for display in the Scintigraphy area and details well-being information for participants including awareness to pregnant or breastfeeding individuals.	Head of Laboratory Services	19-Feb-2026
11.	The annual quality assurance of the gamma camera and calibrator had not been completed as part of an MPE audit.	The employer must ensure MPE audits are established and completed as required.	IR(ME)R regulation 6 and 14, Schedule 2 1(d)	Annual quality assurance of the gamma camera and dose calibrator are regularly performed and reported by the MPE, aside from a period when no clinical imaging was scheduled, although routine QC was performed throughout this time. However, it is acknowledged that the annual test reports were not included as part of a formal MPE audit, therefore SOP-00583 Management of Ionizing Radiation (Medical Exposure) Regulations has been updated to confirm that	Anne Hall QA Manager	Completed 25-Mar-2026

				IR(ME)R specific audit will be conducted every 2 years by the MPE and scheduled as part of the QA Audit Schedule. The requirement for annual quality assurance tests on the gamma camera is already captured in SOP-00527 Use and Maintenance of the Axis Dual Head Gamma Camera section 4.2.2 (V1.0 dated 06-Feb-2024).		
12.	We were told the setting had not completed an IR(ME)R audit but they agreed this would be completed and some elements were covered in other Medicines and Healthcare products Regulatory Agency (MHRA) process.	The employer must ensure IR(ME)R audits are established and completed as required.	IR(ME)R regulation 6 (5)(b) and Schedule 2 1(d)	SOP-00583 Section 6.15 Procedure for The Carrying Out of Clinical Audit, And for Any Appropriate Action to Be Taken, has been updated to confirm that IR(ME)R specific audits will be conducted every 2 years by the MPE as part of the QA Audit Schedule.	Anne Hall QA Manager	Completed 25-Mar-2026

13.	Whilst HIW was referred to as the relevant enforcing authority for Wales there was a need to review links to Care Quality Commission (CQC) guidance. HIW published guidance must be used.	The employer must ensure the IR(ME)R documentation refers to Welsh guidance and requirements.	IR(ME)R regulation 2 (1)	SOP-00583 Management of Ionizing Radiation (Medical Exposure) Regulations has been updated to include instruction to follow HIW process instead of CQC for unintended exposure. Further updated to remove all reference to CQC.	Jonathan Womack Head of Laboratory Services Anne Hall QA Manager	Completed 19-Feb-2026 25-Mar-2026
14.	The process in place for recording and analysing accidental or unintended exposures including near misses was included in SOP 583 but was limited in detail. The line in the SOP only stated, "Any actual and potential accidental or unintended exposures would be analysed and reviewed and	The employer must ensure the SOP includes detail on how AUE would be analysed and reviewed as well as the recording and analysing AUE, including near misses.	IR(ME)R regulation 8 (3)	SOP-00116 Study Medication Administration describes procedures to be followed in instances of accidental or unintended exposure. Further guidance is provided in SOP-00583 Management of Ionizing Radiation (Medical Exposure) Regulations. In the unlikely event of an actual and potential accidental or unintended exposure, SOP-00316 Significant Non-Compliance Reporting and	Annelize Koch Senior Medical Director Jonathan Womack Head of Laboratory Services	Completed 24-Feb-2026 Completed 19-Feb-2026

	appropriate actions taken".			Tracking process will be followed ensuring that the event will be fully analysed and reviewed, and appropriate actions are taken, including notifying the referrer, practitioner and the individual exposed. The "Notifying IR(ME)R Incidents" process, defined by Healthcare Inspectorate Wales (HIW), will be followed when exposures are judged to be 'significant' or 'clinically significant' accidental or unintended exposures.		
15.	The practitioner signing the PRA form did not justify and authorise individual referrals. There was therefore no evidence of individual justification. The fact the practitioner signed the initial Preliminary	The employer must draft delegated authorisation guidelines for each trial.	IR(ME)R regulation 11 (1)(b), (c) and 11 (5)	Delegated Authorisation Guideline for Radioisotope Exposures and Administrations at Simbec-Orion Clinical Pharmacology Unit (TEMP-01497) has been introduced to the QMS. SOP-00360 - Clinical Pharmacology Principal Investigator Oversight, Delegation of Responsibilities	Laura Llewellyn Director of Project Management	Completed 10-Mar-2026

	Research Assessment (PRA) did not justify all exposures in the trial. Senior staff told us they were planning to introduce study specific Delegated Authorisation Guidelines (DAG) to delegate the act of authorisation. This must be completed before any further studies are carried out.			and Handover has been updated as follows: For studies involving ionizing radiation, a Delegated Authorisation Guideline for Radioisotope Exposures and Administrations at Simbec-Orion Clinical Pharmacology Unit (TEMP-01497) must be completed before the initial version of the Clinical Pharmacology General Delegation of Responsibilities Log (TEMP-00560) is completed. Further revision conducted within SOP-00583 and TEMP-01497 to denote the responsibility of the practitioner under the DAG.	Anne Hall QA Manager	Completed 25-Mar-2026
16.	We were told dose constraints were set in the Integrated Research Application System (IRAS) PRA form	The employer must ensure:	IR(ME)R regulation 6 (5) (d) and 12 (4) (c), Schedule 2 1 (g)	The Clinical Pharmacology Clinical Study Protocol General (TEMP-00571) has been updated to include an additional section (9.7.5) to	Laura Llewellyn Director of Project Management	Completed 10 Mar 2026

	and listed in the research study protocol, but the research study protocol shared as part of this inspection did not have a dose constraint. The batch record was reviewed as part of the quality assurance process. The process for establishing dose constraints must be completed before any further studies are carried out.	• They update the research study protocol template to ensure dose constraints are specified for each trial • Measures to ensure dose constraints are adhered to must be included in local processes • They complete a dose constraint audit in future research studies.		include dose constraints for scintigraphy studies. Study specific batch records for manufacturing radiolabelled test products specify the permissible upper limit of radioisotope (MBq) within the dosage form to ensure compliance with the dose constraint (mSv). This information is documented in the Protocol and /or IMPD. Batch records are reviewed as appropriate by Simbec's Production Manager, QP and / or QA to assure compliance with the Protocol / IMPD (SOP-00227 Master Batch Records). SOP-00371 Quality Control of Data has been amended to state that after each research study a review of administered radioactivity and associated dosimetry (mSv) will be performed and recorded on the Dose	Simon Warren CSL Research Director	Completed 24-Feb-2026

				Constraint Audit Record (TEMP-10501).		
17.	The environment and equipment were clean and in a good state of repair. There were sharps disposal bins used, but these were not all secured or in a secure location on the ward. The labels on the sharps disposal bins did not all have the required information recorded.	The employer must ensure the sharps disposal bins at the location: • Are secured when in use • Have the relevant information correctly recorded on the bin.	NMS - Infection prevention and control (IPC) and decontamination	Email sent by Senior Nurse to operational staff on 22 January 2026 with 'read and understood' voting buttons as evidence of receipt. Staff were reminded about correct assembly, completion of labels and correct storage during use and when not in use. Refresher sharps bin audit training is arranged for April 2026 which will include a PowerPoint presentation and practical training (staff will be required to conduct their own audit in a ward setting).	Richard Phillips Senior Nurse	30-April-2026
18.	The mandatory training staff were required to complete was dependent on their job	The employer must ensure staff mandatory training is relevant and includes	NMS - Workforce planning, training and	Interactive training has been undertaken however not everything was found in Veeva during the inspection.	Richard Phillips Senior Nurse	23-Mar-2026

	role. Some of the training we evidenced only involved reading a policy (such as manual handling) whereas these areas needed more interactive training including classroom-based training.	practical training in addition to reading policies.	organisational development	Examples of classroom training already undertaken: • Emergency Record and NEWS Assessment • CPR, Airway Management and EpiPen Administration • Hand Hygiene, CPR, Choking, and Albacmat Evacuation Training (including manual lifting) • Emergency Skills Workshop Classroom Session • National Early Warning Score and Emergency Record Updates • Equity, Diversity & Inclusion Learning Burst • Neurodiversity - ADHD Awareness - Learning Burst September 2022 • Setting Up and Administering a Nebuliser		

				• Setting Up and Administering Oxygen • Drawing Up IV Drugs • Record Keeping During a Medical Emergency February 2023 • National Early Warning Score and Emergency Record Updates April 2023 • Choking July 2023 • ECG electrode Placement • Nebuliser • Oxygen • IV drugs • CPR September 2023 • Emergency Record • NEWS Assessment • Signs and Symptoms of Hypoglycaemia • Capillary Blood Glucose • Administering Glucogel • Preparation of Glucagon for Injection		

				January 2024 • CPR, Airway Management and EpiPen Administration • October 2024 • ABCDE Assessment and Use of Adjuncts During Airway Management February 2025 • ABCDE assessment and NEWS Cymru • Introduction to ECG Interpretation • Airway Management & CPR • CPR teamwork • ABCDE assessment and NEWS Cymru April 2025 • Introduction to ECG Interpretation • Airway Management & CPR • CPR teamwork • Scenario training December 2025		

				• Oxygen, Nebuliser and IV Drugs Workshop		

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): **Anne Hall**

Job role: **Quality Assurance Manager**

Date: **26 March 2026**