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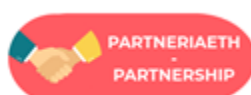
Pwyllgor Gwasanaethau Iechyd  
Arbenigol Cymru (PGIAC)  
Welsh Health Specialised  
Services Committee (WHSSC)

# **Specialised Services Service Specification: CP50b**

## **Positron Emission Tomography (PET) (Fixed and Mobile Site)**

*September 2020*

*Version 0.20*



Document information	
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<b>Description</b>	NHS Wales propose to routinely commission this specialised service in accordance with the criteria described in this document
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## **Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission the service of positron emission tomography – computed tomography (PET-CT) for all ages in accordance with the criteria outlined in this specification.

In creating this document WHSSC has reviewed the requirements and standards of care that are expected to deliver this service.

## **Disclaimer**

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this document.

## 1. Introduction

This document has been developed as the Service Specification for the planning and delivery of positron emission tomography – computed tomography for people of all ages resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

### 1.1 Background

Positron emission tomography (PET) has become a central diagnostic tool in the management of patients with cancer and many other non-cancer conditions, and its role continues to evolve. PET influences clinical decision making, and there is an increasing body of high quality evidence to demonstrate the contribution of PET to improved patient outcomes in a number of disease areas<sup>1,2</sup>. All indications included in the WHSSC Commissioning policy for Positron Emission Tomography (CP50a) are supported by the best available evidence and updated annually when possible.

In Wales in 2019-20, PETIC performed 2,939 PET-CT scans and North Wales service performed 819. This equates to a total of 3,758 scans per annum for the whole of Wales and is equivalent to 1,198 scans per million population<sup>3</sup>. Demand for PET continues to grow and it has been estimated that the total number of scans performed in Wales in 2020-21 could be 4,671 (1,489 per million population)<sup>4</sup>.

According to the NCRI<sup>5</sup> there are 1.05 PET-CT scanners per million population in England. The 2005 RCR recommendations suggest an allowance of approximately 1 scanner per million population. In Wales, there are currently 0.39 PET Scanners per million population, which is significantly lower than the rest of the UK. However, from June 2020 a new mobile PET service will operate for two days each week. at Singleton Hospital, Swansea.

### Plain language summary

A PET-CT scan is a nuclear medicine imaging technique that produces a three dimensional image or picture of functional processes in the body. The purpose of a PET-CT scan is to improve diagnosis and treatment planning for both cancer and non-cancer indications.

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<sup>1</sup> Relationship between Cancer Type and Impact of PET and PET/CT on Intended Management: Findings of the National Oncologic PET Registry Hillner, B. Et al., [Journal of Nuclear Medicine](#) 49(12):1928-35 December 2008.

<sup>2</sup> Evidence-based indications for the use of PET-CT in the UK 2013/16 The Royal College of Radiologists, Royal Colleges of physicians, British Nuclear Medicine Society, Administration of Radioactive substances Advisory Committee <https://www.rcr.ac.uk/publication/evidence-based-indications-use-pet-ct-united-kingdom-2016>

<sup>3</sup> PETIC annual report 2019-20, Cardiff University

<sup>4</sup> All Wales PET Advisory Group and WHSSC

<sup>5</sup> UK PET Core Lab - Home Page <http://www.ncri-pet.org.uk/>

PET-CT is a non-invasive imaging technique that combines information from two different modalities. PET provides information about functional and metabolic cellular activity, while a CT scanner gives precise anatomical localisation.

The procedure usually involves injecting a radio-labelled tracer into the body. The radio-labelled tracer can be a sugar (glucose), an amino acid, or a vitamin. The tracer is taken up and accumulates in metabolically active cells (such as malignant cells), and emits gamma rays detected by the PET and CT scanner to produce colour-coded images of the body demonstrating the cellular activity of both normal and malignant tissue.

Images acquired from both PET and CT devices can be combined into a single superimposed image (PET-CT). This image provides important diagnostic information as well as assessing the effectiveness of treatment in cancer. The radio-labelled tracers are then passed out of the body in the urine or bowel movement.

## **1.2 Aims and Objectives**

The aim of this service specification is to define the requirements and standard of care essential for delivering PET-CT for people of all ages resident in Wales.

The objectives of this service specification are to:

- detail the specifications required to deliver PET-CT for people who are residents in Wales
- ensure minimum standards of care are met for the use of PET-CT
- ensure equitable access to PET-CT
- Deliver a high quality PET service for people resident in Wales
- Identify centres that are able to provide PET-CT for people resident in Wales
- improve outcomes for people accessing PET-CT services

## **1.3 Relationship with other documents**

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).
- **WHSSC policies and service specifications**
  - [CP50a, Positron Emission Tomography](#), Commissioning Policy May 2020.
  - CP50a, Positron Emission Tomography, Evidence Review Appendix 1, May 2020

- WHSCC commissioning of the Epilepsy Surgery Programme. (Some brain FDG PET scans are performed as part of the pre-surgical evaluation of epilepsy and within the costs of the Epilepsy Surgery Programme)
- **National Institute of Health and Care Excellence (NICE) guidance**
  - [Epilepsies: diagnosis and management](#), NICE Clinical Guideline (CG137) February 2020
  - [Colorectal Cancer: diagnosis and management](#), NICE Guideline (NG151). NICE, January 2020.
  - [Prostate Cancer: diagnosis and management](#), NICE Guideline (NG131), May 2019
  - [Early and locally advanced breast cancer: diagnosis and management](#), NICE Guideline (NH101), July 2018.
  - [Myeloma: diagnosis and management](#), NICE Guideline (NG35), October 2018.
  - [Pancreatic cancer in adults: diagnosis and management](#), NICE Guideline (NG85), February 2018.
  - [Oesophago-gastric cancer: assessment and management in adults](#), NICE Guideline (NG83), January 2018.
  - [Advanced Breast Cancer: diagnosis and management](#), Clinical Guideline (CG81) NICE, August 2017.
  - [Non-Hodgkin's lymphoma: diagnosis and management](#), Clinical Guideline (NG52). NICE, July 2016.
  - [Bladder cancer: diagnosis and management](#), NICE guideline (NG2), February 2015.
  - [Lung Cancer: diagnosis and management](#), NICE Guideline (NG122). NICE, March 2019.
  - [Ovarian Cancer: recognition and initial management](#), NICE Clinical Guideline (CG122), April 2011
  - [Metastatic malignant disease of unknown primary origin in adults: diagnosis and management](#), Clinical Guideline (CG104) NICE, July 2010.
  - [Improving Outcomes for people with Sarcoma](#), Cancer Service Guideline (CSG9) NICE, March 2006.
  - [Improving Outcomes in head and neck cancers](#), Cancer Service Guideline (CSG6) NICE, November 2004.
- **Relevant Scottish Medicine Consortium (SMC) policies**
  - [PET-CT Guidelines](#), Scottish Clinical Imaging Network (SCIN), NHS Scotland.
  - [PET-CT Review of Indications report V2.0](#), Scottish Clinical Imaging Network (SCIN), NHS Scotland, July 2017.



- **Relevant NHS England policies**
  - [18F-fluorodeoxyglucose \(FDG\) positron emission tomography-computer tomography \(PET-CT\) as part of radical radiotherapy treatment planning for oesophageal cancer \(all ages\)](#), Clinical Commissioning Policy, NHS England. Reference 170115P, March 2019.
  - [Positron Emission Tomography – Computed Tomography \(PET-CT\) Scanning \(All Ages\)](#), 2013/14 NHS Standard Contract, NHS England, Service Specification, 2013.
- **Other published documents**
  - [Evidence-based indications for the use of PET-CT in the United Kingdom, 2016](#). The Royal College of Radiologists. BFCR (16)3. 2016
  - [PET-CT in the UK. A strategy for development and integration of a leading edge technology within routine clinical practice.](#) The Royal College of Radiologists. (August 2005).

## 2. Service Delivery

The Welsh Health Specialised Services Committee will commission the service of positron emission tomography – computer tomography (PET-CT) for all ages, in-line with the criteria identified in this specification.

### 2.1 Access Criteria

This specification covers both children and adults who meet the criteria for treatment as defined in WHSSC [Commissioning policy for Positron Emission Tomography \(PET\), CP50a](#).

### 2.2 Service description

The service will be viewed as part of an All Wales PET-CT provision (and not a local regional service). All mobile sites will actively co-operate with fixed site PET services to ensure that patients receive the same turnaround and quality of service throughout Wales. For example in the case of service interruption and scanner failure the service provider will actively cross cover to image patients in order of clinical need not geographical location.

Although the imaging may be performed in a variety of centres, this should be viewed as one service with equal access for all patients and as far as possible the same acquisition protocols and reporting criteria.

All PET service providers should work together to ensure that they are interpreting and implementing the WHSSC commissioning policy for Positron Emission Tomography (CP50a)<sup>6</sup> consistently.

In addition to the standards required within the Contract, specific quality standards and measures will be expected. The provider must also meet the standards as set out below:

### Licensing

IR(ME)R requires employers<sup>7</sup> and practitioners to hold a licence<sup>8,9</sup> for the administration of radioactive substances for a specified purpose:

- Each employer is required to hold a licence at each medical radiological installation where radioactive substances are to be administered

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<sup>6</sup> <http://www.whssc.wales.nhs.uk/specialised-services-commissioning-polic-4>

<sup>7</sup> The Employer is an accountable representative of the organisation, such as the Chief Executive Officer, The Medical Director or other equivalent individual. The practitioner should hold a substantive consultant post, and is clinically responsible for the justification of administrations of radioactive substances. [A guide to understanding the implications of Ionising Radiation \(Medical Exposure\) Regulations in diagnostic and interventional radiology](#).

<sup>8</sup> IR(ME)R Licences are issued by the [Administration of Radioactive Substances Advisory Committee](#) (ARSAC)

<sup>9</sup> Any valid ARSAC certificates after 6th February 2018 (when IR(ME)R came into force) are considered to be legally equivalent to a licence until its expiry date.

- Every practitioner is required to hold a licence in order to justify the administration of radioactive substances<sup>10</sup>

## Facilities

The service provider needs to:

- meet the technical standards in accordance with the equipment specification and equipment supplier's service delivery model
- have formal, detailed contingency plans and contracts in place to ensure that patient treatment can continue in the event of technical interruptions and/or breakdown, in order to minimise treatment delays and interruptions. This includes detailed contingency plans in the event of both gantry and cyclotron failure
- have adequate facilities for the administration of radio-labelled tracer
- have appropriate waiting facilities, toilets and waste disposal arrangements
- ensure that any Mobile PET-CT facilities are fully integrated with the main health board imaging services
- provide facilities that are accessible by wheel-chair users
- ensure that any radioactive material left on site will be done with mutual agreement, in consultation with local managers, Radiation Protection Advisors and/or the Radioactive Waste Advisor
- ensure that appropriate environmental permitting arrangements (i.e. under EPR2016) are agreed to ensure that accumulation and disposal of radioactive substances is adequately covered.

## Equipment

The service provider needs to:

- ensure all equipment complies with radiation protection, medical device, health and safety and other relevant legal requirements and standards
- ensure that all equipment will be optimised for paediatric use and use specific paediatric software
- ensure that the technical specification of the scanner will include as a minimum standard at all times:
  - CT component with minimum 16 slice capability
  - 3D Reconstruction capability
  - Time of Flight imaging capability
  - Facility to manipulate image data / view and report image data

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<sup>10</sup> Practitioners who wish to justify exposures as part of a PET-CT service will require training and experience additional to that required for conventional nuclear medicine procedures.  
[Administration of Radioactive Substances Advisory Committee - GOV.UK](#)

- ensure they are capable of imaging a minimum of 12 patients per day when using 3D/4D scanning from cranium to mid-thigh and 3D/4D reconstruction
- make available on the scanner site emergency resuscitation equipment and drugs, and all other safety related equipment needed for fire and medical emergencies.

### **Specialist teams**

In order to provide a PET service, the service provider needs to ensure they have a specialist team of staff appropriately trained in the use of PET-CT.

The specialist team should include:

- Consultants specialising in PET-CT imaging
- Consultant Radiologist
- Nuclear Medicine Technologists or Radiographers
- Radiopharmaceutical Scientist
- Medical Physics Expert
- Radiation Protection Adviser (RPA)
- Radiation Waste Adviser (RWA)
- Administrative support

### **Staffing**

The service provider needs to:

- use qualified PET reporters, these can be local or outsourced PET reporters or a combination of both
- have access to additional members as and when appropriate. This includes:
  - anaesthetists
  - qualified nurses
  - medical engineers
  - any other specialist deemed appropriate for service implementation
- meet the national standards for training and practice of the relevant professional bodies (equivalent to, for example, Royal College of Radiologists (RCR)<sup>11</sup>, Society and College of Radiographers (SCoR), Institute of Physics and Engineering in Medicine (IPEM) and Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER)
- have demonstrated processes for the management of risk to staff.

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<sup>11</sup> <https://www.rcr.ac.uk/>  
<https://www.sor.org/>  
<https://www.ipem.ac.uk/>  
<http://www.legislation.gov.uk/uksi/2000/1059/contents/made>

## **Acceptance of referrals and pre-scan assessment**

The referrer will:

- check all relevant clinical information has been received from the referring clinician
- check the indication is clinically appropriate and is covered by the current WHSSC Commissioning Policy for Positron Emissions Tomography (CP50a)
- liaise with the referring clinician if the request for PET-CT falls outside of the current list of PET indications.
- ensure patients are matched to the WHSSC commissioning Policy and referred to the most appropriate facility based on access and clinical need.

The IR(ME)R Practitioner Licence holder will:

- ensure referrals are clinically indicated and justified
- ensure the indication is covered by the current WHSSC Commissioning Policy for Positron Emissions Tomography (CP50a)
- liaise with the referrer if clinical information on the referral is insufficient or not clinically appropriate

The service provider:

- should have a secure means by which it can accept appropriate referrals
- will ensure that the medical exposure to any patient to ionising radiation is justified and authorised in accordance with Regulation 11 of the The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)
- will assess the patient to identify contra-indications to the administration of the relevant tracer and/or the scan.

## **Prior Imaging**

The accurate interpretation of PET-CT scans relies on assessment of clinical information and prior images.

The service provider should:

- obtain all relevant prior imaging and reports before any new scans are undertaken
- take responsibility for accessing all of the relevant prior imaging before the patient is scanned (to allow the reporting radiologist access to all of the relevant imaging in order to provide an accurate and comprehensive report).

The referring clinician should ensure that all previous imaging and reports are made available in a timely manner.

## **Provision of pre and post scan information**

- Before the PET-CT scan the service provider should ensure that patients and/or carers are given information in a format appropriate to their needs on:
  - the relative risks and benefits of the scan
  - the scan and the time, place and location.

## **Diagnostic Reports**

The service provider will:

- ensure that all staff producing diagnostic reports are adequately trained and are able to demonstrate continued competency in line with the appropriate bodies' guidelines<sup>12</sup>.

## **Information Management & Technology (IM&T)**

The service provider will ensure that

- referral information, images and reports can be received and delivered in electronic format that is compatible with patient information systems
- they comply with the information governance requirements of the referring organisation for personal identifiable data.
- clinical practice and the handling of associated patient datasets should be covered by explicit information governance arrangements and must comply with data protection legislation.

## **Time Standards**

The service provider will ensure that:

- diagnostic reports and images are completed and returned to the referring clinician within a maximum of ten business days

## **Anaesthetic and/or Sedation**

The service provider will:

- ensure when a PET-CT patient requires local anaesthetics and/or sedation it will be given in accordance with the National Minimum Standards, which includes statutory requirements.<sup>13</sup>

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<sup>12</sup> <https://www.rcr.ac.uk/>  
<https://www.sor.org/>

<sup>13</sup> [Chapter 10: Guidelines for the Provision of Paediatric Anaesthesia Services 2020 | The Royal College of Anaesthetists](#)

## **Paediatric specific Anaesthesia**

Where a paediatric patient requires anaesthesia to undergo a PET-CT the service provider must ensure that the patient is cared for in suitable facilities and by appropriately trained and experienced members of staff.<sup>14</sup>

## **Clinical Safety and Medical Emergency Measures**

The service provider will:

- ensure they operate within a clinically safe environment, with safe practices
- have adequate levels of equipment to deal effectively with medical emergencies
- ensure that all staff are appropriately trained and accredited, and hold a Life Support certificate which meets the standards set out by the Resuscitation Council ([www.resus.org.uk](http://www.resus.org.uk))
- have at least one member of staff qualified to Intermediate Life Support (ILS) level
- ensure all medicines and tracers are managed safely and securely, in accordance with local radiological rules, the NHS Litigation Authority (NHS LA) and relevant consents and law
- be responsible for arranging and rehearsing medical emergency procedures on site
- ensure they have access to a medical emergency response 'crash team'.

## **Clinical Standards**

The service provider needs to:

- ensure that all equipment is provided and maintained to an adequate minimum level to fulfil the standards outlined within this Specification (including the ability to perform scans using intravenous and oral contrast medium)
- carry out daily quality assurance and quality control checks on equipment to ensure minimum standards of operations are maintained in line with legal, professional, industry and manufacturers specifications and under the supervision of a Medical Physics Expert
- be accredited and inspected by the appropriate regulatory bodies.
- participate in national quality assurance programmes.
- ensure the protection of children and adults at risk is in-line with the requirements of the Welsh legislative frameworks including "in Safe Hands (Adult protection process in wales – 2000) and "Review of Safe

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<sup>14</sup> [Chapter 10: Guidelines for the Provision of Paediatric Anaesthesia Services 2020 | The Royal College of Anaesthetists](#)

Hands – 2010” and safeguarding in Wales (Children and Young People) 2018

- demonstrate processes are in place for the management of risk to patients

### **Paediatric specific clinical standards**

The service provider needs to:

- ensure that specialist paediatric anaesthesia is available if required, including induction and recovery rooms
- ensure that all clinical staff who have any contact with children, young people have up-to-date level 2 training in child protection<sup>15</sup>.
- Services should therefore be organised and delivered through “integrated pathways of care” ([National Service Framework for children, young people and maternity services](#) (Department of Health & Department for Education and Skills, London 2004).
- All services will comply with Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies, Department of Health, 2008.

### **Training and Education**

The service provider needs to ensure that:

- training and continued professional development should be undertaken by all staff involved in the delivery of PET-CT teaching and research are integral parts of the PET service provision and will make active efforts to co-operate with teaching and research.
- they actively participate in the teaching and training of staff from all disciplines and all levels. This includes undergraduate medical and radiography students, trainee clinical scientists, radiologists at core and higher level, where appropriate production staff and engineers.

### **Research**

Service Providers should:

- actively engage in and seek to actively support research
- seek to actively foster their own research programmes.

### **2.3 Interdependencies with other services or providers**

- NHS Trusts, Referring Clinicians, Reporting Clinicians, Multidisciplinary Teams, Royal Colleges, Cancer Registries, Cancer Networks, Cardiac Networks, Old Age Psychiatry Networks, Commissioning Organisations, Radiotherapy Services, Clinical

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<sup>15</sup> [Safeguarding Children and Young People: Roles and competencies for healthcare staff | RCPCH](#)



Networks, Research Institutions, Specialist out-patient anaesthetic services.

## **2.4 Exclusion Criteria**

Any indication not defined in WHSSC [Commissioning policy for Positron Emission Tomography \(PET\), CP50a](#)

## **2.5 Acceptance Criteria**

The proposed service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

## **2.6 Service provider/Designated Centre**

Clinicians in South East Wales, and parts of Mid Wales should refer their patients to:

- Wales Research and Diagnostic PET Imaging Centre (PETIC)  
University Hospital of Wales  
Heath Park  
Cardiff  
CF14 4XN

All children (aged 0-17 years) requiring a PET scan should be referred to PETIC.

Referral forms, contact details and further information on PETIC can be found on the PETIC website at [Wales Research and Diagnostic PET Imaging Centre - Cardiff University](#)

Clinicians in South West Wales, and parts of Mid Wales should refer their patients to:

- Nuclear Medicine  
Singleton Hospital  
Sketty Lane  
Swansea  
SA2 8QA

[Referral forms, contact details and further information can be found on the PETCT Swansea Website at: [Home Page - PETCT-Swansea.org.uk](#)

Clinicians in North Wales and parts of Mid Wales should refer their patients to:

- Nuclear Medicine  
Wrexham Maelor Hospital

Croesnewydd Road  
Wrexham  
LL13 7TD

The patient flow for mid Wales should generally follow the pattern for cancer referral to the north and south Wales specialist centres. Patients from mid Wales who would otherwise be referred to the Royal Shrewsbury Hospital for specialist treatment should be referred to north Wales for PET scans.

## **2.7 Exceptions**

If the patient does not meet the criteria for treatment as outlined in the commissioning policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

### **3. Quality and Patient Safety**

The service provider must work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems must be externally audited and accredited.

The centre must enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

#### **3.1 Quality Indicators (Standards)**

The service provider should follow the standards for Quality Assurance on PET-CT equipment as shown in the Institute of Physics and Engineering in Medicine (IPEM) report "Quality Assurance of PET and PET/CT Systems"<sup>16</sup>.

#### **3.2 Provider outcomes**

The service provider will ensure that all mandatory datasets and surveys are collected and reported in a format that is compatible with recipients systems.

The service provider should have:

- a structured clinical outcomes collection and analysis programme
- a Performance Management Monitoring dataset for collection of activity
- a audit practice to inform change
- a process to collect patient satisfaction data
- described links to clinical trials, national registries and academic studies

#### **3.3 Cancer waiting times**

The service provider should have regard to the fact that PET-CT Scanning waiting times impact on the Wales single cancer pathway<sup>17</sup> waiting times.

#### **3.4 Applicable National Standards**

The service provider will deliver PET-CT scans to the adult and paediatric population of Wales in accordance with the requirements as set out in this Service Specification and current industry guidelines and legislation. Some patients may require scanning at PETIC dependent on the clinical condition or procedure required.

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<sup>16</sup> [IPEM > Home](#)

<sup>17</sup> <http://www.walescanet.wales.nhs.uk/single-cancer-pathway>

The service provider should also:

- Be accredited by relevant national regulatory authorities, including HSE.
- Be fully compliant with the Ionising Radiation Medical Exposure Regulations(2017)<sup>18</sup> and Ionising Radiations Regulations 2017<sup>19</sup>.
- Provide treatment to patients in accordance with the nationally agreed (NCRI, CCL, CSG and NHRC) clinical trial protocols within the UKCRN Study Portfolio and guidelines<sup>20</sup> (CCLG) where these exist.
- Ensure protection of children and other vulnerable people in line with national standards:
  - The Wales Safeguarding Procedures (2019)
  - The Royal College of Radiologists: [Good Practice Guide for Paediatric Radiotherapy, 2018](#).
  - Royal College of Anaesthetists: [Guidance on the provision of paediatric anaesthesia services, 2019](#).
- Meet the national standards of the relevant professional bodies (equivalent to, for example, [Royal College of Radiologists](#) (RCR), [Society and College of Radiographers](#) (SCoR) and [Institute of Physics and Engineering in Medicine](#) (IPEM).
- Comply with the appropriate data protection and information governance requirements (see: [NHS Wales Informatics Service | Information Governance](#)).

### 3.5 Clinical Audit

Each centre should be able to demonstrate that they have appropriate mechanisms in place to ensure the quality of their reports. This may take the form of a formal programme of double reading of reports, intermittent audits of double reading, or regular discrepancy meetings.

The service provider needs to ensure that an appropriate method of clinical audit takes place which includes the following:

- ensure that an independent external clinician, at least weekly, double reports a minimum of 10% of the total number of Activity Outputs of each Reporting Clinician which, as far as the Provider is aware, were not presented at a Multidisciplinary Team Meeting at which the independent clinician was present.
- report promptly any clinically significant diagnostic reporting errors to the NHS Representative and Institute and ensure all necessary corrective plans and rectification plans are implemented immediately thereafter
- implement a monthly report of clinical performance including audit results by each clinician, showing volume of Activity Outputs

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<sup>18</sup> [The Ionising Radiation \(Medical Exposure\) Regulations 2017](#)

<sup>19</sup> [The Ionising Radiations Regulations 2017](#)

<sup>20</sup> [Home – UK Clinical Trials Gateway](#)

undertaken in the period

- take appropriate remedial action where audit rates of category 1 and 2 discrepancies are above 5% in any (6) month period. As defined below:

CATEGORY 5	Perfect report – complete agreement – Could not be improved upon.
CATEGORY 4	Trivial difference in opinion - report need not be amended.
CATEGORY 3	Minor disagreement - unlikely to be of any clinical significance - but report should be amended for the sake of completeness of the patient's record (eg, a lesion which one reader thinks is benign but may be malignant and the other thinks is malignant but may be benign).
CATEGORY 2	Moderate disagreement - could well be of clinical significance - report needs to be amended on an urgent basis in order to prevent inappropriate treatment.
CATEGORY 1	Major error in interpretation - likely to lead to adverse outcome - The referring clinician must be informed about the amended report.

- for each facility, collect data on the Referral, ICD10 code and PET-CT acquisition for national surveys and in response to any reasonable requests from time to time
- for each facility, provide clinical audit and activity data to the Regional Cancer Registry that is responsible for the region in which the relevant facility is located, and any relevant national registries on a routine basis (at least monthly), and in response to any reasonable requests from time to time
- for each facility provide Diagnostic Imaging Dataset data (DID) on NHS patients extracted and submitted monthly as defined by the Information Standards Board for Health and Social Care.

The Service Provider should have in place a quality assurance programme sufficient to provide assurance of the quality of the service and images, this needs to include routine quality assurance of the 3D scanning process.

### 3.6 Law and Consents

The Consents and Law required are as follows:

- Environmental Permitting Regulations (EPR) 2016<sup>21</sup> and as amended
- Medicines Act 1968 (as amended)<sup>22</sup>

<sup>21</sup> <http://www.legislation.gov.uk/uksi/2016/1154/contents/made>

<sup>22</sup> <http://www.legislation.gov.uk/ukpga/1968/67>

- Ionising Radiations Regulations 2017<sup>23</sup>
- Ionising Radiation (Medical Exposure) Regulations 2017 and as amended.<sup>24</sup>
- The Carriage of Dangerous Goods & Use of Transportable Pressure<sup>25</sup>
- Equipment Regulations 2009<sup>26</sup>

The following consents under the EPR 2016 are:

- Permit for the use of radioactive materials and any mobile radioactive apparatus and/or
- Permits for the disposal and accumulation of radioactive waste and the following Consents under the Ionising Radiation (Medical Exposure) Regulations 2017 (as amended).

The service provider shall ensure that:

- a reliable and adequate supply of Tracer is available for the performance of Scans
- the quality of Tracer is:
  - Appropriate for the Scans
  - Demonstrable by audit
- any supplier of the Tracer has in place a quality control programme sufficient to provide assurance of the integrity of the product, and methods for validation
- the Tracer is transported to the Facilities within such timescales as will facilitate the safe and efficient administration of the Tracer
- that all Tracers are prepared under Good Manufacturing Practice as defined by the Medicines and Healthcare products Regulatory Agency (MHRA) that all transport of radioactive material is compliant with the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) regulations.

### **3.7 Quality Requirements of the Diagnostic Report**

Any patient undergoing a PET-CT scan in Wales should expect the scan to be reported to the same high standard, regardless of the location at which they had their scan performed.

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<sup>23</sup> <https://www.hse.gov.uk/radiation/ionising/legalbase.htm>

<sup>24</sup> <http://www.legislation.gov.uk/ukxi//121/contents/made>

<sup>25</sup> <http://www.legislation.gov.uk/ukxi/2009/1348/contents/made>

<sup>26</sup> <http://www.legislation.gov.uk/ukxi/2009/1348/contents/made>

Accurate, relevant, concise and succinct Diagnostic Report will be sent to the referring clinician, in accordance with professional guidelines under the Society of Nuclear Medicine and European Association of Nuclear Medicine guidance ([www.snm.org](http://www.snm.org) and [www.eanm.org](http://www.eanm.org)) and "Reporting and Interpretation of Imaging Investigations" as published by the Royal College of Radiologists ([www.rcr.ac.uk](http://www.rcr.ac.uk))

### **3.8 Quality Requirements of Activity Outputs**

The service provider will ensure the referring clinician receives the Activity Output to agreed or mandated timescales or in line with clinical appropriateness.

The service provider will communicate any unusual, unexpected, urgent, or clinically significant findings that may require immediate or urgent clinical decisions in accordance with local guidance for red flag findings.

### **3.9 Quality Assurance**

The service provider shall:

- be clinically and managerially responsible and accountable for any scan carried out on the Patient
- operate an effective, comprehensive, clinical governance system with clear channels of accountability and supervision that reduces the risk of clinical system failure
- Continuously monitor clinical performance and evaluate unexpected clinical complications/adverse events arising from any scan. This shall also include, where relevant an evaluation of the accuracy of investigation interpretations and the contribution of the report to answering the clinical
- question posed, the clinical appropriateness of examinations undertaken and any further investigations suggested
- audit clinical care against standards, and use appropriate formal methods such as root cause analysis for untoward incidents.

### **3.10 Good Clinical Industry Practice**

The service provider will comply with good clinical industry practice which will include but is not limited to: standards for better health, relevant NICE guidance, Imaging Services Accreditation Scheme (ISAS), latest Medicines and Healthcare products Regulatory Agency (MHRA) guidance/technical notices.

### **3.11 Other quality requirements**

- the service provider will have a recognised system to demonstrate service quality and standards
- the service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site
- the quality system and its treatment protocols will be subject to regular clinical and management audit
- the service provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.



## **4. Performance monitoring and Information**

### **4.1 Performance Monitoring**

WHSSC will be responsible for commissioning services in line with this service specification. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this service specification the following approach will be adopted:

- **Service providers to evidence quality and performance controls**
- **Service providers to evidence compliance with standards of care**

WHSSC will conduct performance and quality reviews on an annual basis

### **4.2 Key Performance Indicators**

The service provider will be expected to monitor against the full list of Quality Indicators derived from the service description components described in Section 2.2.

The service provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

### **4.3 Date of Review**

This service specification is scheduled for review in 2023. Periodic reviews will also be undertaken to clarify if any evidence based processes are updated and will be incorporated into the next iteration of this service specification.

If an update is carried out the policy will remain extant until the revised policy is published.

## **5. Equality Impact and Assessment**

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services.

It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This service specification has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

## **6. Putting Things Right: Raising a Concern**

### **6.1 Raising a Concern**

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

### **6.2 Individual Patient Funding Request (IPFR)**

In cases where the scan is clinically indicated but cannot be authorised by the centre, the referring team should be informed of the availability of the IPFR route. The centre should keep records of all scans referrals in which they were not able to authorise the imaging. In these cases, records of telephone conversations and emails are important.

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## Annex i Codes

<b>Code Category</b>	<b>Code</b>	<b>Description</b>
OPCS	U10.4	Myocardial positron emission tomography
OPCS	U21.3	Positron tomography NEC
OPCS	U36.2	Positron emission tomography with computed tomography NEC

## **Annex ii Abbreviations and Glossary**

### **Abbreviations**

<b>AWMSG</b>	All Wales Medicines Strategy Group
<b>FDG</b>	Fluorodeoxyglucose
<b>IR(ME)R</b>	Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)
<b>IPFR</b>	Individual Patient Funding Request
<b>MHRA</b>	Medicines and Healthcare products Regulatory Agency
<b>PET</b>	Positron Emission Tomography
<b>PET-CT</b>	Positron Emission Tomography – Computed Tomography
<b>PETIC</b>	Positron Emission Tomography Imaging Centre
<b>SMC</b>	Scottish Medicines Consortium
<b>WHSSC</b>	Welsh Health Specialised Services
<b>ARSAC</b>	Administration of Radioactive Substances Advisory Committee
<b>AWPET</b>	All Wales Positron Emission Tomography Advisory Group

### **Glossary**

#### **Administration of Radioactive Substances Advisory Committee – ARSAC**

The Administration of Radioactive Substances Advisory Committee (ARSAC) is an advisory non-departmental public body of the government of the United Kingdom. It is sponsored by the Department of Health. The committee advises government on the certification of doctors and dentists who want to use radioactive medicinal products on people. Doctors and dentists who use radioactive medicinal products (radiopharmaceuticals) on people must get a certificate from health ministers. This certificate allows them to use radioactive medicinal products in diagnosis, therapy and research.

#### **All Wales Positron Emission Tomography Advisory Group (AWPET)**

AWPET is a subgroup of the Clinical Oncology Sub-Committee (COSC) of the Welsh Scientific Advisory Committee (WSAC). The group is tasked with reviewing the evidence base for PET-CT and advising WHSSC on the introduction of new indications, ensuring that all decisions are made following a systematic review of the available evidence.

#### **Fluorodeoxyglucose (FDG)**

A PET scan uses a small amount of a radioactive drug, or tracer, to show differences between healthy tissue and diseased tissue. The most commonly used tracer is called FDG (fluorodeoxyglucose), so the test is sometimes called an FDG-PET scan.

### **Individual Patient Funding Request (IPFR)**

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

### **Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)**

Medical ionising radiation is used widely in hospitals, dental care, clinics and in medical research to help diagnose and treat conditions. Examples are x-rays and nuclear medicine scans, and treatments such as radiotherapy. The regulations aim to make sure that it is used safely to protect patients from the risk of harm when being exposed to ionising radiation. They set out the responsibilities of duty holders (the employer, referrer, IR(ME)R practitioner and operator) for radiation protection and the basic safety standards that duty holders must meet.

### **Medicines and Healthcare products Regulatory Agency (MHRA)**

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.

### **Positron Emission Tomography – Computed Tomography (PET-CT)**

A PET-CT scan is a nuclear medicine imaging technique that produces a three dimensional image or picture of functional processes in the body. The purpose of a PET-CT scan is to improve diagnosis and treatment planning for certain indications in cancer. PET-CT is a non-invasive imaging technique that combines information from two different modalities. PET provides information about functional and metabolic cellular activity, while a CT scanner gives precise anatomical localisation.

### **Positron Emission Tomography Imaging Centre (PETIC)**

The Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC) provides researchers and routine clinical positron emission tomography scanning services from the heath Hospital in Cardiff.

### **Welsh Health Specialised Services Committee (WHSSC)**

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.