

Point of Care Testing Policy

Surrey Pathology Services (SPS)

(Ashford & St Peter's, Frimley Health and The Royal Surrey County NHS Foundation Trusts)

Author(s): Dr Kerry Whiting

Executive Lead: Dr Ian Fry

Status: Approval date: 11th June 2015
Ratified by: Trust Executive Committee
Review date: April 2018

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 1 of 36
-----------------	------------------------------	------------------------	---------	--------------

History

Policy and Version	Date issued	Brief summary of change	Author
PPS POCT Policy V1	March 2002	New document	Stephen Halloran
PPS POCT Policy V2	March 2003	Minor amendments	Kerry Whiting
PPS POCT Policy V3	July 2004	Minor amendments	Kerry Whiting
PPS POCT Policy V4	July 2005	Minor amendments	Kerry Whiting
PPS POCT Policy V5	July 2006	Minor amendments	Kerry Whiting
PPS POCT Policy V6	January 2008	Minor amendments	Kerry Whiting
ASPH POCT Policy V1	January 2009	New document produced in conjunction with PPS, adopting the same standards as the PPS POCT Policy.	PPS/David Cartwright
PPS POCT Policy V7	January 2011	Minor amendments	Kerry Whiting
Formation of SPS in April 2012			
Acquisition of Heatherwood & Wexham Park (HWP) by FPH in October 2014			
SPS POCT Policy V1	April 2015	Revision and merger of the existing ASPH and PPS POCT Policy documents to reflect the formation of SPS in April 2012 and acquisition of HWP in October 2014, update references, reflect state of the art in POCT and clarify responsibilities.	Kerry Whiting

PPS: Partnership Pathology Services – Joint venture between Frimley Park Hospital and The Royal Surrey County Hospital NHS Foundation Trusts.

For more information on the status of this document, please contact:	
Policy Author	Kerry Whiting
Department	Point of Care Testing, Surrey Pathology Services
Date of Issue	April 2015
Review due	April 2018
Ratified by	ASPH Trust Executive Committee
Audience	All Clinical Staff, Laboratory Scientific and Technical Staff

Executive Summary

Point of Care Testing (POCT) is now high profile in all healthcare sectors within the UK and is increasingly adopted by users self-testing at home.

The necessity for reform within the NHS is raising awareness of the opportunities available by using such technology, and it is important that we continue to promote POCT as a safe and effective alternative to central laboratory testing. This can only be done by ensuring that the professional standards demanded of medical laboratories are embedded into the management of POCT.

This policy has been developed to ensure that National Guidelines on POCT from the Medicines and Healthcare products Regulatory Agency and NHS England are adhered to by the Trusts, taking into consideration local processes and procedures and the requirement for all pathology diagnostic testing to be compliant with ISO 15189:2012 (Medical laboratories – Requirements for quality and competence) and ISO 22870:2006 (POCT-Requirements for quality and competence).

Contents

SECTION	Page
Executive Summary.....	3
1. Introduction.....	5
2. Scope.....	5
3. Purpose.....	5
4. Explanation of Terms.....	5
5. Duties and Responsibilities.....	6
6. Policy.....	8
7. Training.....	16
8. Stakeholder Engagement and Communication.....	16
9. Approval and Ratification.....	17
10. Dissemination and Implementation.....	17
11. Review and Revision Arrangements.....	17
12. Document Control and Archiving.....	17
13. Monitoring Compliance with this Policy.....	17
14. Supporting References/Evidence Base.....	18
 Appendices	 22-36
Appendix 1	Summary of Actions and Responsibilities
Appendix 2	POCT Business Case Proforma
Appendix 3	POCT Device Funding Authorisation Form
Appendix 4	Protocol for Pilot Trial of POCT Device
Appendix 5	POCT Location Specification
Appendix 6	POCT Accountability Chart
Appendix 7	Process Chart for POCT requests from secondary care
Appendix 8	Equality Impact Assessment
Appendix 9	Checklist for the review and approval of policies
See also:	Policy for Clinical Staff Medical Devices Training
	Policy for management of Medical Devices
	Policy for the Management and Reporting of Incidents
	Performance Review and Development Needs Assessment (Appraisal)

1.Introduction

1.1 With advances in technology and a focus on patient centred care pathways, the use of diagnostic pathology devices at the point of patient care has become highly desirable and commonplace in a variety of settings. Key issues are the speed of testing and the ability to make clinically effective decisions in a short time frame.

Although the concept of POCT is clear, the obstacles to effective implementation are many and without adequate management the full benefits of POCT cannot be realised.

2.Scope

2.1 This policy extends to the appraisal, introduction and use of Point of Care Testing (POCT) devices in wards, clinics and departments within all secondary care Trusts served by Surrey Pathology Services and the Community based services served by each of these Trusts.

The policy is applicable to all clinical and laboratory staff employed by the Trusts and purchasers of POCT services from the Trusts, as provided by Surrey Pathology Services.

2.2 The central involvement of the pathology department in such activities is recognised by the Trusts as it has been recognised by the Medicines & Healthcare products Regulatory Agency, the Joint Working Group on Quality Assurance, NHS England (Pathology Quality Assurance Review 2014) and the United Kingdom Accreditation Service (UKAS).

2.3 This policy only covers tests and analytical processes that would traditionally be performed by Pathology Departments.

Specific diagnostic medical devices that do *not* fall within the scope of this policy include pulse oximeters, breath carbon monoxide monitors and portable oesophageal pH monitors (refer to Trust's Medical Devices Policy).

3.Purpose

3.1 The purpose of this document is to detail Trust policy and procedures for the appraisal of requests to use Point of Care Testing devices, for their introduction and for their safe use.

4. Explanation of Terms Used

4.1 Point of Care Testing is any pathology analytical process performed for patient care outside the central laboratory.

4.2 An analytical process covers tests and investigations using fixed or portable devices (eg: blood gas analysers, urine stick analysers, glucose meters, coagulometers, blood count analysers, pregnancy testing) as well as eye readable technologies (eg: Respiratory Syncytial Virus, Human Immunodeficiency Virus testing).

4.3 The Clinical Unit Manager is the person in charge of a specific clinical area, eg: MAU, ED.

4.4 The Specialist Nurse is the person with particular responsibilities for clinical areas, eg: Diabetes.

4.5 The Technical Lead is a designated lead Healthcare Scientist in a Pathology specialty.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 5 of 36
-----------------	------------------------------	------------------------	---------	--------------

4.6 The Nurse Educator is a representative of the supplier who provides training in the use of the device.

4.7 The Designated Trainer is an individual who has been approved by the POCT manager or POCT Training Officer to perform training on specific POCT devices, in accordance with the SPS POCT device training policy. The designated trainer may be the Nurse Educator, identified Link Person or Cascade trainer from the clinical unit or a member of the POCT Team.

4.8 The Certificated Operator is a person who has been formally trained and assessed as competent in the use of a specific POCT device, has acknowledged this training and has a full understanding of their responsibilities.

4.9 The Link Person is an individual who has been trained and designated to carry responsibility for liaison with the POCT Team and for maintaining a register of POCT users in their clinical area. This responsibility should be identified within their job description.

4.10 The POCT Manager is a senior member of the pathology department who co-ordinates all POCT activities and manages the POCT Team to ensure compliance with this policy.

4.11 The POCT Team is a group of pathology staff specifically trained in the use of POCT devices. Members of the POCT Team are competent to formally train end users of POCT equipment, to carry out necessary maintenance, troubleshooting, document and stock control.

4.12 The POCT Specialty Lead is a senior member of the pathology department who is accountable for the provision of a safe, effective and comprehensive pathology POCT service.

5. Duties and Responsibilities

5.1 The Hospital Trusts are responsible for appointment of a POCT Committee (multidisciplinary POCT management group).

5.2 The POCT Committee consists of a chairperson drawn from the pathology senior staff, representatives of each pathology discipline and multidisciplinary members (clinical and non-clinical, including patient safety/risk representation) from primary and secondary care, who have specific responsibility for POCT. Due to the broad remit of Surrey Pathology Services, more than one POCT Committee may be required to cover all geographical sites, unified by the chairperson.

5.3 The POCT Committee chairperson is accountable to the SPS Executive Group through the Pathology Clinical Governance Committee and to the Clinical Risk Committees at the three trusts, for the activities of the POCT Committee(s).

In the absence of other committee members, the chairperson has the right to act in a discretionary capacity if immediate action is ever required, with the committee subsequently appraised of this action.

5.4 Pathology members of the POCT Committee are required to disseminate the business of the committee throughout their departments where appropriate, ensuring their Specialty Lead is aware of pertinent issues. Pathology members should report back to the Chairperson of the POCT Committee with a consensus view on all new business cases pertinent to their pathology discipline.

5.5 The POCT Committee is responsible for reviewing and monitoring the POCT Policy, for reviewing proposals to introduce new POCT devices and for reviewing the procedures and practices for the safe

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 6 of 36
-----------------	------------------------------	------------------------	---------	--------------

use and maintenance of the POCT devices. Each pathology specialty must advise the committee on the clinical and analytical suitability of evaluated devices pertinent to their specialty.

5.6 If there is a difference of opinion (within the pathology specialty or between pathology and the clinical unit) on the suitability of a proposed POCT device, the POCT Committee chairperson will arrange a meeting of stakeholders. If additional evidence for implementation of the proposed POCT solution is required a pilot trial will be considered with full agreement of clinical protocols. In the event of ongoing disagreement, escalation will be through the accountability line (section 5.3, Appendix 6) and ultimately to the Pathology Board.

5.7 Individual Clinical Directorates are responsible for demonstrating a clinical or economic need for Point of Care Testing. Other individuals or departments, including Pathology, may identify the value to patients and to the institution of specific POCT devices or procedures.

5.8 The Business Manager/General Manager of the directorate in which the device is to be used is responsible for the preparation of the business case (including cost benefit analysis) for the use of the POCT device. Appendix 2 (Business Case Proforma) may assist with this process.

5.9 The business case for the use of each POCT device will be examined by the POCT Committee, which will advise SPS and the Clinical Unit of the merits of the case. Approval of the business case is required prior to implementation.

5.10 Following consultation with the clinical unit, the Trust Chief Executive and relevant Clinical Director will be informed of any Clinical Units performing POCT which has not been approved by the POCT Committee.

When non-approved POCT devices are identified within the Trusts the POCT Specialty Lead must be informed to risk assess the situation.

Giving consideration to service provision, patient safety and previous experience of the particular device, the POCT Specialty Lead may take any of the following actions:

- Immediately remove the POCT device from service and work with the clinical unit to agree an alternative solution from the central laboratory.
- Immediately remove the POCT device from service and work with the clinical unit to agree timescale for approval and re-implementation of a POCT device.
- Organise immediate training, competency checking and validation of the POC testing to enable the service to continue whilst a business case is prepared and POCT Committee approval is sought.

5.11 Under the direction of the POCT Committee, the POCT Manager and the Clinical Unit Manager are responsible for the *appraisal* and *introduction* of the device and for the *establishment* of quality assurance, Health & Safety and maintenance practices and procedures. They are responsible for formally identifying and recording who is responsible for ordering reagents, consumables and requesting maintenance.

5.12 A designated Clinical Unit Manager is responsible for ensuring the proper day to day use of each device and ensuring *adherence* to documented quality assurance practices and procedures. The POCT Team must be advised of any trained operators whose competency to use a device is in question. This may be managed through the Link Person.

5.13 A designated Link Person will be assigned to each device to oversee its day to day use (keeping up to date records of operators they have trained), liaise with other users of the device and with the laboratory.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 7 of 36
-----------------	------------------------------	------------------------	---------	--------------

5.14 Only named, trained and Certificated Operator(s) in the clinical unit should be authorised to use a device(s).

5.15 Certificated Operator(s) must comply with documented reporting and quality control procedures and advise the requesting clinician of any contra-indications or applicable limitations to using the specific POC test.

5.16 The POCT Manager is responsible for the maintenance of complex devices, quality assurance practices and procedures, and for monitoring the quality of the service. They are responsible for issuing a 'permit-to-work' certificate prior to servicing or repair of equipment, once the device has been decontaminated.

5.17 All quality control practices and procedures should be in accordance with quality assurance practices and procedures prescribed by the POCT Committee/POCT Specialty Lead. The Pathology Department and POCT Committee must have ready access to Quality Control data.

5.18 A named individual; the trainer, (Healthcare Scientist, specialist nurse, ward Link Person or a Nurse Educator) will be responsible for training users of new devices, for refreshing and re-certificating existing users and for ensuring the register of certified users is updated.

5.19 The requesting clinician is responsible for acceptance and interpretation of the POCT results and subsequent management of the patient. If the requesting clinician or certified operator doubts the validity of the POCT result, a sample must be sent to the laboratory for confirmation.

6. Policy

6.1 Standards

6.1.1 A clinical or economic need for POCT must be established and a business case prepared prior to acquisition of the device (Appendix 2 shows the information required).

6.1.2 For requests within the secondary care Trusts, the business case for POCT devices **must** include consultation with SPS. A cost benefit analysis must be included and a signed funding authorisation form submitted (see Appendix 3).

6.1.3 After establishing clinical/economic need and cost effectiveness following presentation of a business case to the POCT Committee, mutual agreement between SPS and the Clinical Unit Directorate must be reached on the: -

- responsibility of the laboratory in the management of the device and connectivity
- arrangements for the delivery and implementation of the service
- financial arrangements for purchase, operation and maintenance of the device
- quality assurance, health & safety and maintenance procedures
- training of appropriate laboratory and non-laboratory staff
- action which should be taken in the event of analytical errors or the misuse of the device.

This should take the form of a service level agreement and/or contract.

6.1.4 The appraisal of new POCT devices must include a pilot study (Appendix 4) or sufficient supporting information to establish the numeric relationship with existing assays, the accuracy and

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 8 of 36
-----------------	------------------------------	------------------------	---------	--------------

reproducibility of results and safe working practices. Suitability of the device for specific clinical use must be assessed and reviewed (eg: paediatrics).

6.1.5 SPS will not approve or support devices deemed by the POCT Committee to present unacceptable clinical risk.

6.1.6 Use of eye-readable POCT devices will only be considered if there is no suitable machine read alternative and the clinical benefits outweigh any risk of misinterpretation.

6.1.7 Procurement of new devices must comply with Trust procedure across all organisations and in addition to consideration by the POCT Committee, may involve discussion with the Trust Medical Devices/Equipment groups, Pharmacies and the relevant Supplies/Procurement Departments.

6.1.8 Quality assurance and maintenance practices and procedures must be in place before commencement of the use of the device.

6.1.9 All test results from calibrations, controls and patient samples must be recorded contemporaneously. Details must include the name of the patient, hospital number, NHS number (where available), date and time of analysis, sample type, analyser ID, result (with units) and operator ID. The batch number of reagents in use must also be recorded. The device Quality Control book may be used or other procedures put in place to enable full audit trails in the event of a product recall. This information should be recorded and stored electronically whenever facilities are available. Patient confidentiality must be maintained at all times

6.1.10 Evidence should be collected to ensure all reagents are being stored at the correct temperature once in the POC location.

6.1.11 Where achievable, results from POCT devices should be integrated with the laboratory record. Procedures should be in place to clearly identify those results generated at the POC and these results must not be overwritten by the laboratory generated results on the same specimen.

6.1.12 A named individual, the trainer, (healthcare scientist, specialist nurse, ward link person or a nurse educator) will be responsible for training users of new devices and for refreshing and recertificating existing users.

6.1.13 Tests and procedures should only be performed by staff who have been trained and designated as certified users. When barcodes or passwords are issued to certified users these are for the individual's personal use only.

6.1.14 Staff training should include how the device is used, quality assured and maintained. Health & safety and data security issues should be included. Trained staff will be certified as operators.

6.1.15 The POCT Team will oversee training, quality assurance, maintenance practices and procedures and will maintain a current register of devices and certified users.

6.1.16 A designated individual (link person) should be nominated in the clinical area to take responsibility for the day to day running of the device and for ensuring only trained staff use the device.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 9 of 36
-----------------	------------------------------	------------------------	---------	--------------

6.1.17 If a device is faulty or is not used/cared for appropriately within the secondary care Trusts the **Pathology Department will, after discussion with the Clinical Unit, remove the device from service.** Within primary care Trusts or other community sites action will be taken as detailed in the specific SLA.

6.1.18 If devices within the secondary care Trusts are used inappropriately by certified users their passwords will be disabled, further training instigated and/or Trust disciplinary procedures followed. Within primary care Trusts or other community sites action will be taken as detailed in the specific SLA.

6.2 Cost Benefit Analysis

- There must be a clear definition of the problem that the device would solve so that a full examination of all possible solutions can be made.
- The pathology department must be involved in the production and evaluation of the cost benefit analysis.
- A full business case must be produced for secondary care sites detailing all the financial consequences of the purchase. These will include the direct costs of running, maintenance, consumables, quality control, IT connectivity and service contract. The cost benefit analysis must include the full indirect costs for pathology involvement, including support, training and QC/QA monitoring, IT infrastructure as well as the inevitable cost of replacement.
- Consideration must be given to any refurbishment or capital development required to meet the Health & Safety requirements for the POCT device.
- The cost benefit analysis must recognise the need for any device to be compatible with existing equipment, both in the laboratory and in other areas of the hospital. The pathology department must be consulted about the compatibility of all devices.

6.3 Register of POCT equipment

6.3.1 To effectively monitor the wide range and large number of POCT devices, the POCT Team should keep a database of the location and function of all devices. This register should provide information on the range of tests and types of devices used within the Trusts.

The register should include the following information:

- Device name, serial number, supplier (contact name and phone number) and purchase date
- Date of installation
- Location (Clinical Unit)
- Designated Trainer
- Unit Clinical Manager
- Link Person (contact name & phone number)
- Dates of service and details of service contracts

The register should facilitate device standardisation and therefore simplify staff training, reduce repair and maintenance costs and simplify back-up.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 10 of 36
-----------------	------------------------------	------------------------	---------	---------------

6.4 Aim

To manage the introduction and regulate the use of POCT and thereby prosper a cost efficient and clinically effective analytical service, under the supervision of qualified staff from an Accredited Pathology Department (CPA/UKAS).

6.5 Objectives

6.5.1 To ensure POCT is adopted only where it has proven clinical value or other patient/service benefit and offers value for money.

6.5.2 To ensure the appraisal, introduction and use of POCT devices is carried out in full consultation with Surrey Pathology Services (SPS) through the POCT Committee(s).

6.5.3 To ensure personnel using POCT devices are given the appropriate training.

6.5.4 To ensure full quality assurance and maintenance practices and procedures are in place before and during the use of the device.

6.5.5 To ensure the use of the device complies with all appropriate regulations, codes of practice and Health & Safety guidelines.

6.5.6 To ensure that the policy is adopted and complied with throughout the Trusts and other managed sites.

6.6 Medico-Legal Considerations

6.6.1 The Professions Supplementary to Medicine Act 1960 requires Medical Laboratory scientists to be properly educated, qualified and trained in order to protect patients. This underlying principle should apply to all staff performing Point of Care Testing.

6.6.2 Responsibility

- The operator and the Clinical Unit are responsible for using the device properly, for carrying out the tests, for evaluating, reporting and acting on the results.
- The operator is responsible for assigning the correct patient ID to all POC test results and for the correct manual transfer of results into other clinical systems/records.
- The operator has full responsibility for ensuring that their user password/barcode remains confidential.
- SPS is responsible for ensuring that the device is installed correctly, quality assurance procedures are in place, appropriate arrangements have been made for user training and certification and that appropriate standard operating procedures have been prepared and are maintained.
- The Trusts each provide indemnity for staff provided they follow formal standard operating procedures and are trained and certified to operate the device.

6.6.3 In-patient self-testing

Hospital in-patients may perform self-testing POCT in order to continue to manage their chronic disease (eg diabetes) using their own devices and consumables as they would do at home. The patient may administer their own medication based on their own test results if this has been agreed with their clinical team.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 11 of 36
-----------------	------------------------------	------------------------	---------	---------------

If a Trust employee is to administer medication or advise the patient in this respect for the patient's immediate treatment, their actions must be informed by POCT performed on Trust equipment that is supported by the POCT Team and compliant with all required QA processes as detailed in this policy. Refer to guidance given by the Joint British Diabetes Societies for In Patient Care Group Guidelines: Self-management of diabetes in hospital, March 2012.

6.6.4 The provisions of the Data Protection Act must be incorporated into the practices and procedures of POCT.

6.6.5 For medico-legal reasons, adequate and appropriate data must be recorded to ensure the chronological relationship between test results, quality control results, device status and training is retained. The data must be recorded either in a logbook or electronically on the instrument / data manager in accordance with the SOP.

6.6.6 The providers of a Pathology service from a CPA or UKAS accredited laboratory have a duty to ensure that the service is carried out with reference to national and local quality assessment schemes. POCT falls within this duty.

6.7 Health & Safety

6.7.1 The following legislation applies to POCT sites irrespective of location or size:

- Health & Safety at Work Act 1974
- Consumer Protection Act 1987
- The Management of Health & Safety at Work Regulations 1999
- Control of Substances Hazardous to Health Regulations 2002
- Safe working and the prevention of infection in clinical laboratories and similar facilities 2003,
- Advisory Committee on Dangerous Pathogens. (2005)
- Biological agents: Managing the risks in laboratories and health care premises
<http://www.hse.gov.uk/biosafety/diseases/bbv.pdf>
- List of biological agents <http://www.hse.gov.uk/pubns/misc208.pdf>
- Workplace exposure limits: EH40 document (last update 2011)
<http://www.hse.gov.uk/pubns/priced/eh40.pdf>

6.7.2 Staff performing POCT must be aware of the microbiological hazards of the patient samples, the chemical hazards of reagents and the physical/electrical hazards of devices.

6.7.3 Staff must observe the precautions for safe working practices. Operators are responsible for maintaining a clean and tidy working environment for POCT to reduce risks at all times.

6.7.4 Risk assessment following Trust guidelines should be carried out before devices are commissioned. The infection control team / medical microbiologist must be involved in decisions on the placement and safe maintenance of devices.

6.7.5 Standard operating procedures must include protocols for routine decontamination of devices, safe disposal of biological materials and safe handling of all specimens and spillages. A 'permit-to-work' certificate, providing evidence of appropriate decontamination, must be issued by the Link Person or POCT Team before service or repair of equipment.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 12 of 36
-----------------	------------------------------	------------------------	---------	---------------

6.7.6 Devices should be sited to prevent unauthorised use and ensure that safety regulations are not contravened. The testing location must be approved by the POCT Manager in accordance with the specification in Appendix 5 and allow access to laboratory staff for maintenance.

6.7.7 All spillages or leaks of specimens should be dealt with in accordance with the local Infection Control Policy and detailed in SOPs/guidelines.

6.7.8 All accidents or incidents with POCT devices must be reported to senior staff on the Clinical Unit (including the Link Person) and to the POCT Manager. An Adverse Incident Report form or DATIX entry must be completed by staff on the Clinical Unit following Trust Policy & Procedures and copied to the POCT Manager. Incidents involving user error or a device malfunction must all be reported. If patient specimens are implicated these should be retained for further investigation by the POCT Team.

6.7.9 All identified non-conformities associated with POCT will be recorded on the SPS non-conformity record by a member of the POCT Team and acted upon in accordance with established SPS process.

6.7.10 The POCT Manager must immediately inform the SPS POCT Specialty Lead of any incidents that require reporting to the Adverse Incident Centre at the MHRA.

6.7.11 Reports of device malfunction should be confirmed by the POCT Team or relevant diagnostic department and also reported to the Operational Risk Management Group of SPS.

6.7.12 Any device being considered for POCT must have a CE mark (although it is acknowledged that this does not guarantee that it is fit for purpose and of suitable quality).

6.8 Quality Assurance

Many bodies have a role in the assurance of pathology quality: NHS England, CQC, MHRA, NHS Trusts and Foundation Trusts, Commissioners of pathology, and UKAS. The Pathology Quality Assurance Review chaired by Dr Ian Barnes (2014) has emphasised the importance of robust QA processes for POCT as well as for central laboratory testing.

6.8.1 All POCT users must be acquainted with the relevant Department of Health Medical Device Alerts (see Section 14 References) and the requirement to comply with agreed QA procedures.

6.8.2 Internal Quality Control:

This is a means of validating results before they are issued. All QC results must be recorded and retained for at least 10 years.

The QC procedures will be device dependent but can include:

- use of material which mimics a patient sample to check that results fall within agreed limits
- use of an optical or electrical test system to check performance of measurement device.

Frequency of QC testing will be defined for each device in the SOP following a risk assessment by the POCT Manager or POCT Specialty Lead. The device manufacturer's recommendation will be taken as a minimum requirement.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 13 of 36
-----------------	------------------------------	------------------------	---------	---------------

6.8.3 External Quality Assessment (EQA):

Where available, participation in an appropriate EQA scheme is required for all POCT devices. If a suitable EQA scheme is not available alternative options that add value will be considered (eg: regular comparison of POCT results to laboratory test).

EQA involves the analysis of samples received from the Pathology Laboratory, or external body.

- they should be distributed to the POCT site periodically by the appropriate department or external body, to whom results should be returned.
- the sample should be handled in a manner as similar as possible to that of a patient sample.
- whenever possible, the trained operator should process the EQA samples. Where there is a requirement for specialised EQA sample preparation/presentation or time constraints this may be performed by the POCT Team in order to derive optimum value from the EQA scheme.
- the results must be recorded with date and time of analysis, device used and operator identification. The results must be reviewed by the POCT Team at regular QA meetings and where necessary appropriate action taken. Results must be retained for a minimum of 5 calendar years.

6.8.4 Test results and device data:

Results from patients and controls should be recorded with specified device performance data to enable a full audit trail.

Whether recorded electronically or manually, this must include:-

- device name and identification number
- patient ID: name, hospital number and NHS number if available
- type of specimen
- date and time of analysis
- the results obtained
- the name of the operator
- calibration details if appropriate
- quality control results
- batch number of reagents/cartridges/QC when batch number has been changed.

Personal bar codes should be used whenever possible for electronic data entry.

Personal barcodes must not be shared.

Devices with electronic audit trail facilities must be purchased if available as an option on a selected product.

6.8.5 Interpretation of results

- Performance limits and clinical limitations must be established and documented in the SOP.
- If results are to be interpreted by staff other than the patient's medical practitioner, guidelines for interpretation and advice should be described in the SOP and should be included in the training. This should cover abnormal results and referral guidelines.

6.9 Operation and Maintenance

6.9.1 A Standard Operating Procedure (SOP) must be written by a senior member of the POCT Team for each POCT device, which must comply with CPA/UKAS standards and be subject to regular revision. A controlled copy of the SOP (and Service Level Agreement) is available to all Trained

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 14 of 36
-----------------	------------------------------	------------------------	---------	---------------

Operators on their Trust Intranet. A User Quick Reference Guide should be kept near the device for ease of access.

6.9.2 The SOP should follow the standard Pathology format whilst giving due consideration to specific requirements of the end user group.

6.9.3 Modifications to use of any device outside the parameters of the SOP (and manufacturer's instructions) are not permitted (refer to MDA/2010/001 issued January 2010 regarding off-label use of medical devices).

6.9.4 The SOP (or SLA) should include the following information :-

- Clinical relevance/Purpose of examination
- Principle and Method of Examination
- Specimen Requirements (including type of container and additives)
- Patient preparation
- Procedural steps
- Reagents, standard or calibrants and Internal quality control materials
- Procedure for obtaining consumables including reagents, controls, calibrators batteries etc
- Calibration (including metrological traceability)
- Internal quality control procedures
- COSHH and Risk Assessment information
- Recording and calculation of results
- Reporting reference limits
- Alert/Critical values, where appropriate
- Reportable interval of analytical results
- contra-indications, interferences and limitations of the device and technique
- Performance characteristics and measurement uncertainty
- Potential sources of variation
- Responsibilities of personnel (including clinical interpretation)
- procedure required to perform routine maintenance and decontamination
- how to deal safely with specimens, spillages and accidents
- the safe disposal of biological materials
- a list of error messages and basic troubleshooting in case of instrument malfunction
- the procedure for advice and guidance if a problem is unresolved, (contact telephone numbers must be included)
- a statement of who is responsible for removing a device from service if it is not being used properly or if it is not performing satisfactorily.
- alternative arrangements for analysis in the case of device failure.
- References

6.9.5 A device maintenance log must be kept near to the device. It should contain:

- details of malfunctions
- details of problems encountered
- details of any maintenance procedures performed on the device.

6.9.6 All trained operators are required to complete the maintenance log when necessary. The maintenance log will be reviewed regularly by the POCT Team who will bring persistent issues to the attention of the Clinical Unit Manager.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 15 of 36
-----------------	------------------------------	------------------------	---------	---------------

7. Training

Much of the success of POCT depends on the effectiveness of the training of non-laboratory staff.

7.1 The designated trainer is responsible for the routine training of all staff required to use the device.

7.2 All POCT training will be performed in accordance with the SPS POCT Training Policy, with due regard to each Trust's Medical Devices Policy and the device manufacturer's instructions for use.

7.3 A comprehensive training manual should be prepared by the POCT Manager/Training Officer that describes the process and content of training and the arrangements for competency checking and re-certification for all POCT devices.

A central source of training records should be held by the POCT Team.

7.4 The training programme should include:

- The context and clinical utility of POCT
- Theoretical aspects of the measuring system
- Awareness of pre-analytical factors, eg. obtaining the correct specimen, the importance of clinical contraindications, sample handling, stability of sample and reagents. Patient preparation is an important factor to be considered.
- Assessment of the skills necessary to use the device (analytical procedure), perform quality control checks and record relevant data.
- Quality Assurance
- Limitations of the measuring systems
- Response to results outside predefined limits
- Documentation, maintenance and reporting of results
- Infection control and COSHH
- Decontamination and troubleshooting procedures, including guidance available from the laboratory.
- Requirement for Operator to be familiar with and refer to the full SOP and POCT Policy on the Trust Intranet

7.5 POCT device operators should be certified upon successful completion of a training module, for the appropriate period of time and for any relevant conditions.

7.6 Competency should be assessed following training and periodically thereafter. Records of competency checks should be held by the POCT Team.

8. Stakeholder Engagement and Communication

8.1 This policy has been produced following consultation with members of the SPS POCT Committee (representatives from Pathology Specialties, Trust Clinical Departments, Clinical Risk/Patient Safety, IT, Quality Managers and Primary Care), the SPS Pathology Executive group, SPS Clinical Governance group, ward managers, Clinical Directors, medical devices groups and clinical risk groups at all Trusts served by SPS.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 16 of 36
-----------------	------------------------------	------------------------	---------	---------------

9. Approval and Ratification

This policy has been ratified by the SPS POCT Committee, SPS Clinical Governance group and SPS Executive group and ratification will be sourced from the Trust Executive Committees at each organisation.

10. Dissemination and Implementation

10.1 This policy will be disseminated through global emails at each Trust site, in Trust newsletters and will be published on all Trust Intranet sites.

10.2 During training of staff to use POCT devices they will be informed of the policy and where to access it.

10.3 It is the role of all members of the Trust POCT Committee to raise awareness of this policy in both primary and secondary care.

11. Review and Revision Arrangements

11.1 This policy will be reviewed by the SPS Specialty lead for POCT every 3 years, or before this time if there are any significant changes to national guidelines for POCT, Trusts' policies, professional guidelines, Health & Safety policies or departmental business plans.

12. Document Control and Archiving

12.1 This is a Trust-wide document and archiving arrangements are managed by the Quality Department at each Trust, who can be contacted to request master/archived copies. The Quality Departments will be responsible for ensuring the documents available on the Trust Intranet remain current.

12.2 Document control and archiving will also be performed by SPS under their established Quality Management System in accordance with CPA/UKAS requirements.

13. Monitoring Compliance with this Policy

Measurable Policy Objective	Monitoring /Audit Objective	Frequency of Monitoring	Responsibility for performing the monitoring	Monitoring reported to which groups/committees, inc responsibility for reviewing action plans
This policy will be reviewed by the author annually to ensure that it remains valid and in date	Review number of non-conformities /incidents logged	Annual	POCT Specialty Lead	SPS POCT Committee SPS Clinical Governance Committee

14. Supporting References and Evidence Base

(Available from the Chairperson of the POCT Committee)

MHRA Device Bulletin: Management and Use of IVD Point of Care Test Devices.
DB2010(02) February 2010

Pathology Quality Assurance Review January 2014
Chaired by Dr Ian Barnes, NHS England

NHS Health Check programme standards: a framework for quality improvement
Public Health England February 2014

Point of Care Testing – Requirements for Quality & Competence
British Standard BS EN ISO 22870:2006. Issued February 2006.

Medical laboratories – Particular requirements for Quality and Competence
British Standard BS EN ISO 15189:2012. Issued November 2012.

Clinical Pathology Accreditation (UK) Ltd: Standards for the Medical Laboratory. November 2010

Clinical Pathology Accreditation (UK) Ltd: Standards for POCT facilities.
April 2010

National Patient Safety Agency: Patient Safety Alert: Actions that can make anticoagulant therapy safer.
NPSA/2007/18 Issued 28 March 2007

Joint British Diabetes Societies for In Patient Care Group Guidelines: Self-management of diabetes in hospital, March 2012

Briggs C, Guthrie D, Hyde K, Mackie I, Parker N, Popek M, Porter N, Stephens C. Guidelines for point of care testing: haematology.
British Journal of Haematology 142:6;904-915 September 2008

Institute of Biomedical Sciences: Point of Care Testing (Near Patient Testing): Guidance on the involvement of the clinical laboratory. 2010.

Point of Care Testing. AACC Publication by Christopher Price & Jocelyn Hicks. 1999
AACC Press ISBN 1-890883-23-9

Point of Care testing: Making Innovation Work for Patient Centred Care
AACC Publication by Christopher Price & Andrew St John. 2012.
ISBN 978-1-59425-143-6

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 18 of 36
-----------------	------------------------------	------------------------	---------	---------------

Department of Health/Medicines & Healthcare products Regulatory Agency Medical Device Alerts

www.dh.gov.uk

<http://www.mhra.gov.uk>

Medical Device Alert: Lancing devices – including Roche Accu-chek softclix, softclix II, softclix plus and multiclix lancing devices.

MDA/2005/063. Issued 28 November 2005.

Medical Device Alert: Medisense Optium Xceed, Therasense Freestyle Mini and Therasense Freestyle blood glucose meters manufactured by Abbott Diabetes care.

MDA/2006/018. Issued 13 March 2006.

Medical Device Alert: Freestyle, Freestyle Mini and Medisense Optium Xceed blood glucose meters manufactured by Abbott Diabetes Care.

MDA/2006/035. Issued 8 June 2006

Medical Device Alert: Blood glucose meters: LifeScan 1 Touch Ultra 2: Potential to misread results due to indistinct decimal point.

MDA/2006/054 Issued 18 September 2006

Medical Device Alert: Lancing devices used in nursing homes and care homes: Devices implicated in transmission of hepatitis B.

MDA/2006/066 Issued 6 December 2006

Medical Device Alert: Point of care blood glucose measurement systems: Hemocue. Potential for unreliable blood glucose readings when testing samples from pre-term neonates.

MDA/2007/032. Issued 24 April 2007

Medical Device Alert: Single-use capillary blood sampling device: Microtainer®

Safety Flow Lancets manufactured by BD Preanalytical

Systems. Product codes 366354, 366355 and 366358.

MDA/2007/049 Issued 11 June 2007

Medical Device Alert: Pregnancy test kits: Clearview HCG, product code 500158, lot number HG0050. Potential for incorrect results.

MDA/2007/052 Issued 12 June 2007

Medical Device Alert: Point of care and home-use blood glucose meters:

Roche Accu-Chek and Glucotrend; Abbott Diabetes Care

FreeStyle. Overestimation of glucose results with treatments containing maltose, xylose or galactose.

MDA/2007/058 Issued 19 July 2007

Medical Device Alert: Point of care blood glucose measurement systems:

HemoCue Glucose 201+ and HemoCue Glucose 201 RT. Ability to generate erroneous 0.0 mmol/l result.

MDA/2007/059 Issued 2 August 2007

Medical Device Alert: Home use blood glucose meters: Boots brand blood glucose monitoring system. Display may be damaged if dropped.

MDA/2007/077 Issued 15 October 2007

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 19 of 36
-----------------	------------------------------	------------------------	---------	---------------

Medical Device Alert: Blood glucose meters and test strips: Medisense Optium, Optium Xceed meters, Boots brand meters, 1 Touch Ultra test strips. 1 Touch Ultra test strips may generate incorrect results when used in conjunction with the other meters.
MDA/2008/006

Medical Device Alert: Blood coagulation test: Smartcheck INR system (Unipath Ltd).
Risk of inaccurate results.
MDA/2008/009

Medical Device Alert: Pregnancy test kits: Clinitest hCG cassette lot Nos 97552 and 97574 (Siemens).
Recall due to potential for false negative results.
MDA/2008/043

Medical Device Alert: IVD POC test for PSA (Innovacon Inc USA, Surescreen and Fortress Diagnostics). Potential for false negative results.
MDA/2008/085

Medical Device Alert: Pregnancy test: Clearview hCG (Unipath). False positive results may be observed if results interpreted beyond 3 mins.
MDA/2009/054

Medical Device Alert: Home test kits: PSA (Simply Health & Fortel, Biomerica Inc USA).
Risk of false negative results.
MDA 2009/069

Medical Device Alert: Urine test strips: Uritest 13G (URIT Medical Electronic). Potential for misdiagnosis.
MDA/2009/070

Medical Device Alert: Medical devices in general and non-medical products. Off label use of medical devices.
MDA/2010/001

Medical Device Alert: Blood glucose meters: 5 second Contour (Bayer). May show falsely high readings when testing from neonates.
MDA/2010/030

Medical Device Alert: Accucheck Inform and Inform II (Roche). When battery runs low it may not upload information correctly and units can change from mmol/l to mg/dl which could have disastrous results.
MDA/2011/011

Medical Device Alert: Nova Stat Strip Glucose: May generate consecutive error codes for multiple samples from the same patient which could mask abnormal glucose levels.
MDA/2011/044

Medical Device Alert: iStat potential for 20% elevation on INR results.
MDA/2012/025

Medical Device Alert: Cleverchek glucose meter giving falsely low results if strip underfilled, high results if overfilled.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 20 of 36
-----------------	------------------------------	------------------------	---------	---------------

MDA/2012/027

Medical Device Alert: Diagnostic test strips and cassettes for urinalysis, pregnancy testing, menopause testing and opiates testing. Sales suspended due to concerns about the manufacturer's quality systems.

MDA/2013/012

Medical Device Alert: Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces. All manufacturers. Can damage plastic surfaces if incompatible and compromise ability to decontaminate.

MDA/2013/019

Medical Device Alert: Home blood glucose meters – Lifescan OneTouch Verio Pro and Verio IQ. Software fault at glucose levels of 56.8 mmol/l and above (low result or no result displayed)MDA/2013/022

Medical Device Alert: INRatio® and INRatio®2 PT/INR coagulation monitor and test strips used at home and at point of care. Manufactured by Alere.

MDA/2015/012

Appendices

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 21 of 36
-----------------	------------------------------	------------------------	---------	---------------

Appendix 1: Summary of Actions and Responsibilities

Issue	Actioned by	Responsible for ensuring action	Evaluated by
Cost benefit analysis & Business case	Business/General manager of Clinical Unit	POCT Co-ordinator, POCT Manager, POCT Specialty Lead	POCT Committee, Trust management
Health & Safety SOPs	POCT Co-ordinators, Control of Infection Officer	POCT Manager	POCT Committee, H&S Committee
Training & Certification	POCT Training Officer, Designated trainer	Clinical Unit Manager, device operators	POCT Training Officer, POCT Committee
Operational SOPs	POCT Manager, POCT Co-ordinator	POCT Manager	UKAS
Routine Operation, competency	Certified users (clinical unit)	Clinical Unit Manager	Clinical Unit Manager, POCT Team
Recording results	Certified users (clinical unit)	Clinical Unit Manager	Clinical Unit Manager POCT Team, POCT Specialty Lead
Maintenance & support	Designated trainer , POCT Team	POCT Co-ordinator	POCT Manager, POCT Specialty Lead
Quality Control & EQAS	Certified users (clinical unit), POCT Team	POCT Co-ordinator	POCT Manager, POCT Specialty Lead, Pathology Specialty, POCT Committee
Maintenance of records	Link Person (list of users), POCT Team (devices & users)	POCT Team	POCT Co-ordinator, POCT Manager
Budgetary arrangements	Clinical Unit, POCT Manager	Pathology finance advisor	POCT General Manager

Appendix 2: POCT Business Case Proforma

Surrey Pathology Services

Business case for implementation of Point of Care Testing Device(s)

NHS Trust	
Clinical Unit	
Proposed device	
Proposed analyte(s)	
Date	
Prepared by (name & designation)	

All Point of Care Testing (POCT) devices must be procured and managed in accordance with the Trust POCT Policy and the business case prepared following consultation with the POCT Manager or POCT Specialty Lead.

This generic document has been produced to ensure all relevant information is gathered at the first attempt. Please expand the text boxes to give fully detailed answers, which will expedite processing and ultimately provision of your POCT device, if approved by the Trust POCT Committee.

Overview

Why is the current central laboratory diagnostic service not adequate to meet your needs?

How many POCT devices are required?

Where will the device(s) be located/stored/used?

Is there an IT wall port available for use in this locality?

What is your expected annual workload for patient tests?

Only formally trained and certificated operators are permitted to use POCT devices.

How many staff members will require training to use the device(s)?

What operational benefits would the POCT device give to patients and staff?

Are any other sites (wards or other Trusts) using this POCT device successfully?
If yes, please give details and the benefits derived.

Will any other Trust departments or health care services benefit from your use of this POCT device? If yes, please give details.

Clinical Need

What clinical benefits would the POCT device give to patients and staff?

Is the device required in order to satisfy any NICE or other professional guidelines/recommendations? If yes, please give details.

How would this POCT solution fit into any existing or new clinical protocols?
Please attach a copy of any relevant clinical protocols.

What are the clinical risks when managing these patients with the current system?

What would be the clinical risks if managing patients with the proposed POCT solution?

If this POCT proposal is implemented, would any confirmatory or follow up testing from the central laboratory be required on the same patient samples?

If yes, please give details.

Equipment, Facilities & Reagents required

The POCT Manager, following full discussion with the clinical unit, will provide details of equipment, facilities and reagents required.

Facility	Required
Dedicated POCT Room	YES/NO
IT Ports (state number)	YES/NO
Power points (sockets, state number)	YES/NO
Air Conditioning	YES/NO
Refrigeration for consumables	YES/NO
Ambient temperature monitoring	YES/NO

Any necessary refurbishment will be organised and funded by the requesting clinical unit (in discussion with the POCT Manager) following approval of the business case by the POCT Committee.

All reagents (including control solutions) will be purchased centrally, cross-charged to the clinical unit and managed by the Pathology POCT Team who may need to perform a full evaluation of the proposed device(s) before approval can be given. A pilot trial of the device may also be indicated.

Laboratory Support

All POCT devices within the Trusts are provided under the terms of the Surrey Pathology Services POCT Policy: The POCT Team will manage all devices under a service level agreement and endeavour to ensure the devices are available for use at all times.

Internal Quality Control (IQC) and External Quality Assessment (EQA) will be facilitated by the laboratory.

The POCT Team will provide training for staff to use the devices and only trained operators will be enabled on them.

In the event of device failure, Standard Operating Procedures will advise users to access other POCT devices or use the central laboratory.

Cost Benefit Analysis

The POCT Manager will provide the all-inclusive cost per patient test for the POCT solution. This will include the device, reagents, IQC, EQA, connectivity software, POCT Team support and VAT, unless indicated otherwise.

POCT proposal: Cost per patient test

--

POCT proposal: Anticipated financial savings (consider bed days, litigation, lab costs, targets, penalties, Key Performance Indicators etc)

--

POCT proposal: Anticipated savings in staff time and efficiency

--

POCT proposal: Anticipated improvement to the quality of the patient experience and outcomes

--

Costing

Device	Annual patient Workload	Cost per test	Cost per patient test (all inclusive)	Cost per annum

Costs include all POCT Team support and VAT. The cost per patient test includes the requirement to perform regular IQC and EQA testing regardless of the patient workload.

How will the clinical unit fund this POCT proposal? Please indicate if budgetary resource has been identified.

--

This completed business case should be submitted to the chairperson of the Trust POCT Committee. If approved by the POCT Committee, the requesting clinical unit will be responsible for funding the service by authorising Pathology to cross charge.

Appendix 3: POCT Device Funding Authorisation Form

Approval of funding for new POCT Device

To be submitted to the SPS Point of Care Testing Committee, Frimley Health, The Royal Surrey County, Ashford & St Peter's Hospital NHS Foundation Trusts.

NHS Trust	
Clinical Unit	
POCT Device Manufacturer	
POCT Device	
Analytes required	
Agreed location of device	
Identified Link Nurse	

In order to support this POCT initiative with a total quality management system in accordance with Trust POCT Policy and the POCT Service Level Agreement, the Pathology Department will cross charge the Clinical Unit as detailed in the business case and summarised below. The Clinical Unit will be committed to fund this minimum level of activity, which will be reviewed annually. Higher activity will incur additional charges.

Device	Annual patient Workload	Cost per patient test	Cost per annum

Costs include all POCT Team support and VAT.

Clinical Unit Manager Name (please print)		Date
Clinical Unit Manager Signature		
General Manager Name (please print)		
General Manager Signature		
Please provide your cost centre for cross charge		

Appendix 4: Protocol for Pilot Trial of POCT Device

Surrey Pathology Services Protocol for clinical trial of POCT Device Essential Information

Please note: Failure to complete any part of this form will delay the initiation of the trial and the form will be returned to you for completion

NHS Trust	
Clinical Unit(s)	
Proposed device(s)	
Proposed analyte(s)	
Date Protocol submitted	
Protocol submitted by (Name & designation)	
Stakeholder details (Please list all stakeholders with their designation and contact details eg: representation from clinical unit, Pathology specialty, POCT Team, General Managers)	

The SPS POCT Team has agreed to support a clinical pilot trial of this POCT device under the terms of the Trust POCT Policy.

The Clinical Unit will be responsible for funding the trial.

The POCT Team will be responsible for:

- Assessing the proposed area for device and consumable storage
- Ordering/procuring device(s)
- Ordering consumables (including QC & EQA materials)
- Delivering the training
- Competency checking
- Device maintenance
- Documentation including the standard operating procedure (SOP) and audit forms

Clinical staff trained to undertake the pilot study will be responsible for:

- Adherence to SOPs
- Performance of QC and EQA
- Completion of individual audit forms
- Presentation of final audit data and outcomes to inform a business case

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 28 of 36
-----------------	------------------------------	------------------------	---------	---------------

Pilot Trial Details

Patient group to be recruited for trial

Number of device(s) required

Number of POCT tests to be performed (consumables required)

Is back-up laboratory testing required? If yes, give detail

Area on unit where device(s) will be located

Area on unit where consumables will be stored

Number of staff to be trained (please give names & designations, attach a spreadsheet if necessary)

How will the POC test result integrate into the patient pathway (flow diagram if necessary)

Clinical performance indicators to be assessed

Desired outcomes/Success criteria

--

Proposed date of trial commencement:

Duration of trial:

Audit/review dates:

Responsibility for audit/review:

Funding required:

Responsibility for funding:

Protocol agreed

Date:

Specialty lead POCT.....

Clinical Unit Project Lead.....

Appendix 5: POCT Location Specification

The diagnostic procedures for pathology Point of Care Testing involve body fluids and should be considered a hazardous or “dirty” activity.

Many point of care tests will be performed at the patient’s bedside or in the Doctor’s office but when a POCT device is made available for general use within a particular location, there should be a designated area for storage of the device and all essential consumables.

For small, portable devices this may be on a trolley or worktop with easy access to hand wash facilities and any necessary IT equipment.

The sluice may be considered to be a suitable location for POCT devices provided there is adequate space to accommodate them and enable safe operation at a suitable ambient temperature. Consideration must also be given to local circumstances and regular footfall in the sluice area.

POCT devices should not be stored or operated in close proximity to any sterile supplies, clean clothing, food preparation or drug storage areas.

Where POCT devices are installed within a dedicated POCT area the following specification must be followed:

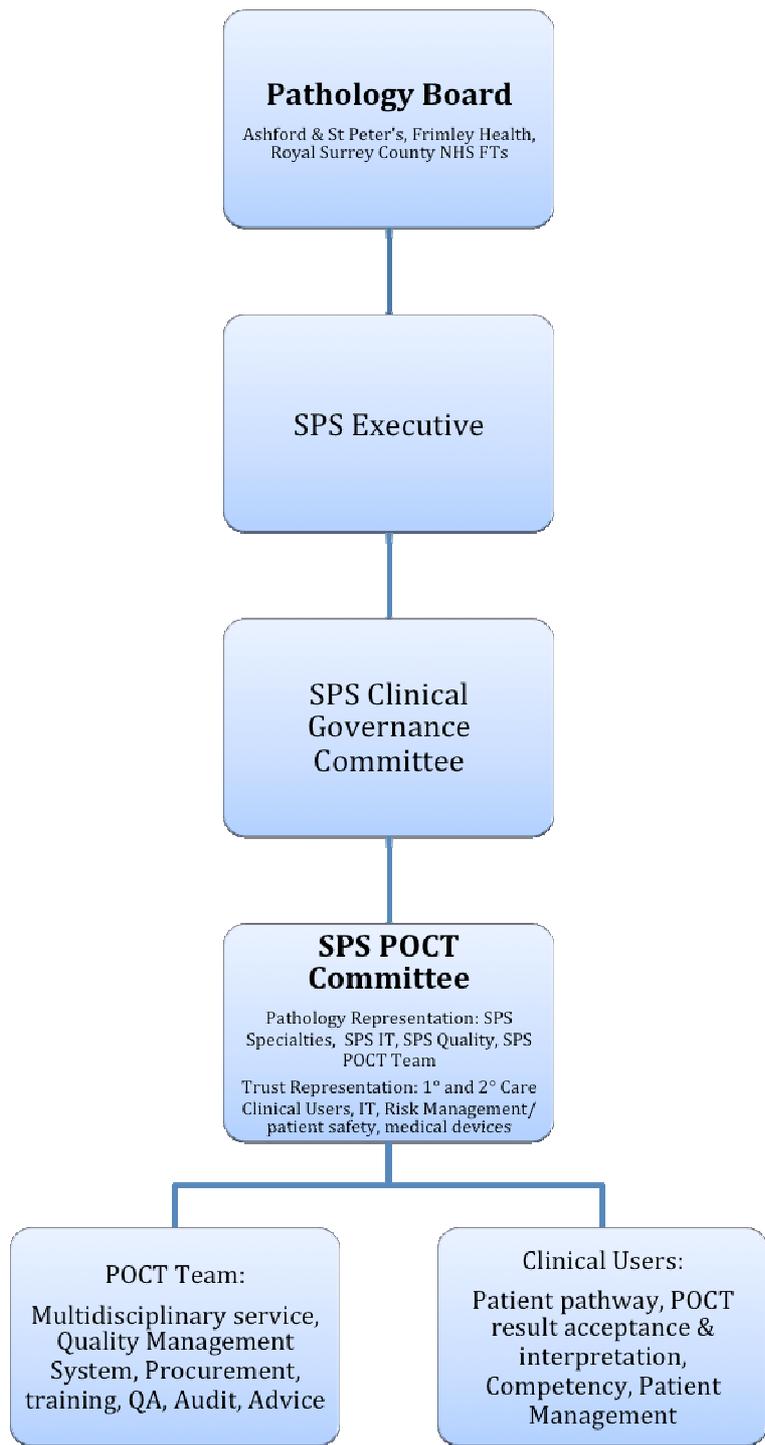
- Dedicated POCT Room or a fixed solid screen between benchtop device and patients in close proximity
- Continuous laboratory grade formica benching with any joints completely sealed
- Continuous plastic splash back on the walls from bench top to ceiling
- No kick boards on any under bench cupboards
- Easy access to hand wash basin (no doors between POCT and basin)
- Dedicated gloves, goggles and eye wash kit
- Clinical waste bin and domestic waste bin
- Adequate electric plug sockets and IT ports at bench height
- Under bench electric plug socket available for fridge
- Under bench fridge (laboratory grade) with temperature monitoring
- Adequate lighting
- Climate control

- No patient access to the room
- No storage of sterile items, drugs, injectable solutions, food, drink or clean clothing
- No patient procedures to be carried out in the room
- No storage of other apparatus unconnected to the POCT
- If consumables are stored on site a system for monitoring storage temperature in real time is required

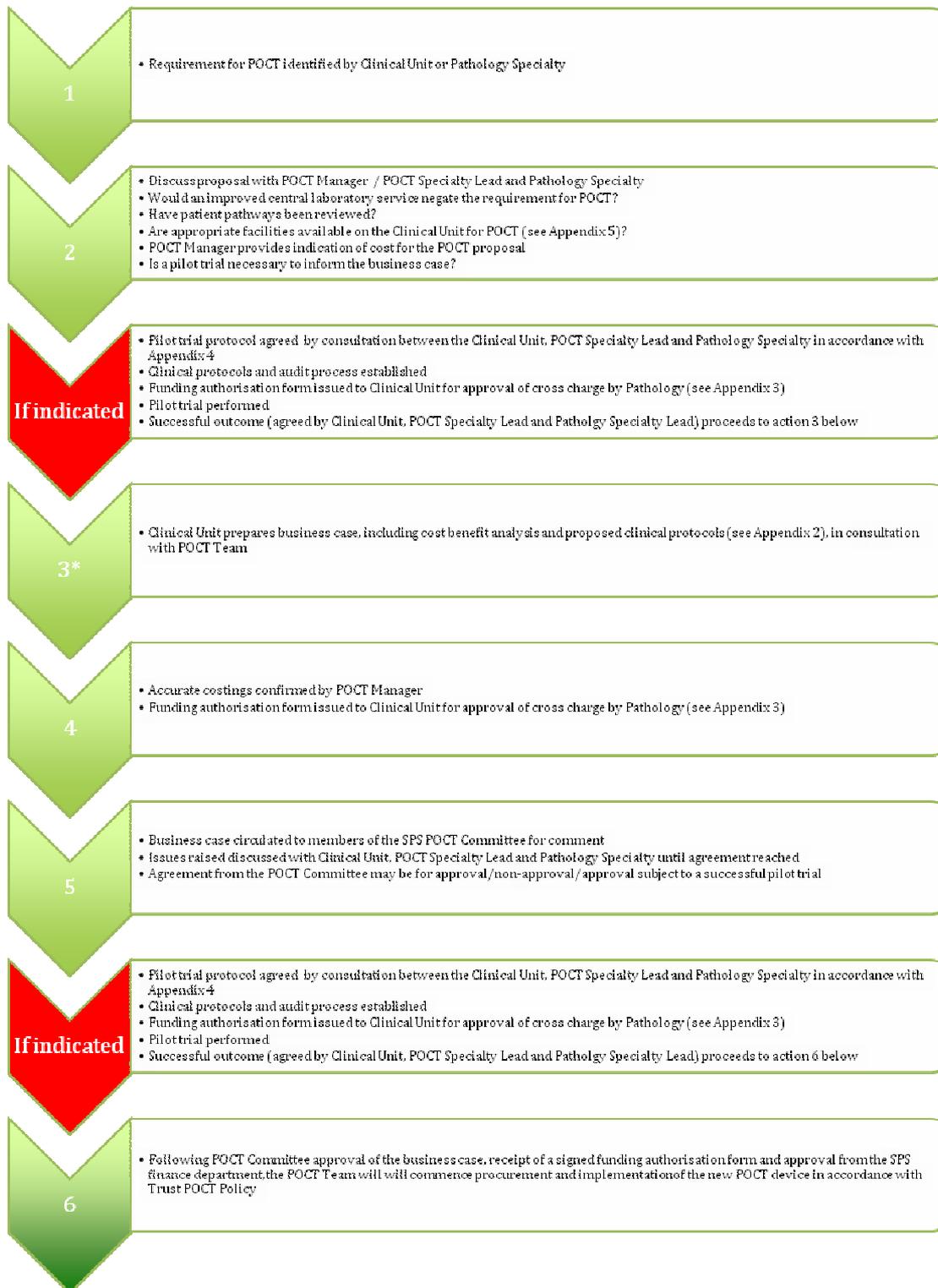
Approval is required from the POCT Manager and Infection Control Team prior to commissioning the room for use.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 31 of 36
-----------------	------------------------------	------------------------	---------	---------------

Appendix 6: POCT Accountability



Appendix 7: Process Chart for POCT requests from secondary care



* Requests for additional blood glucose meters and routine urinalysis devices will not require a business case if due to expansion of the existing service into new areas within the Trusts.

The requesting Clinical Unit will be responsible for funding these devices, which will be issued and managed by the SPS POCT Team in accordance with current SOPs, clinical protocols and Service Level Agreements.

Medical Devices	First Ratified March 2002	Reviewed April 2015	Issue 1	Page 33 of 36
-----------------	------------------------------	------------------------	---------	---------------

Appendix 8: Equality Impact Assessment

Equality Impact Assessment Summary

Name and title: Kerry Whiting, POCT Specialty Lead

Policy: POCT Policy

Background <ul style="list-style-type: none">Who was involved in the Equality Impact Assessment
The equality impact of this document was discussed and assessed by the POCT Committee.
Methodology <ul style="list-style-type: none">A brief account of how the likely effects of the policy was assessed (to include race and ethnic origin, disability, gender, culture, religion or belief, sexual orientation, age)The data sources and any other information usedThe consultation that was carried out (who, why and how?)
All aspects of the POCT policy and required processes were considered by members of the POCT committee. No instances could be envisaged where any particular staff or patient group would be disadvantaged by enforcement of this policy.
Key Findings <ul style="list-style-type: none">Describe the results of the assessmentIdentify if there is adverse or a potentially adverse impacts for any equalities groups
This policy does not discriminate against any race, ethnic origin, disability, gender, religion/belief, age group or sexual orientation.
Conclusion <ul style="list-style-type: none">Provide a summary of the overall conclusions
This policy does not discriminate against any race, ethnic origin, disability, gender, religion/belief, age group or sexual orientation.
Recommendations <ul style="list-style-type: none">State recommended changes to the proposed policy as a result of the impact assessmentWhere it has not been possible to amend the policy, provide the detail of any actions that have been identifiedDescribe the plans for reviewing the assessment
N/A

Appendix 9: Checklist for the review and approval of documents

To be completed (electronically) and attached to any document which guides practice when submitted to the appropriate committee for approval or ratification.

Title of the document: POCT Policy

Policy (document) Author: Kerry Whiting

Executive Director: Ian Fry

		Yes/No/ Unsure/N A	<u>Comments</u>
1.	Title		
	Is the title clear and unambiguous?	Y	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Y	
2.	Scope/Purpose		
	Is the target population clear and unambiguous?	Y	
	Is the purpose of the document clear?	Y	
	Are the intended outcomes described?	Y	
	Are the statements clear and unambiguous?	Y	
3.	Development Process		
	Is there evidence of engagement with stakeholders and users?	Y	
	Who was engaged in a review of the document (list committees/ individuals)?		This policy has been produced following consultation with members of the SPS POCT Committee (representatives from Pathology Specialities, Trust Clinical Departments, Clinical Risk/Patient Safety, IT, Quality Managers and Primary Care), the SPS Pathology Executive group, SPS Clinical Governance group, ward managers, CDs, medical devices groups and clinical risk groups for all Trusts.
	Has the policy template been followed (i.e. is the format correct)?	Y	
4.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	Y	Referenced to National POCT Guidelines and ISO standards
	Are local/organisational supporting documents referenced?	Y	
5.	Approval		
	Does the document identify which committee/group will approve/ratify it?	Y	This policy has been ratified by the SPS POCT Committee, SPS Clinical Governance group and SPS

		Yes/No/ Unsure/N A	<u>Comments</u>
			Executive group ratification will be sourced from the Quality/Clinical Governance or Trust Executive Committees at each organisation.
	If appropriate, have the joint human resources/staff side committee (or equivalent) approved the document?	N/A	
6.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Y	This policy will be disseminated through global emails at each Trust site, in Trust newsletters and will be published on all Trust Intranet sites. It is also referenced during POCT training sessions.
	Does the plan include the necessary training/support to ensure compliance?	Y	All training is provided by the POCT team.
7.	Process for Monitoring Compliance		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Y	Compliance is monitored through the POCT audit plan and non-conformity/incident reporting.
8.	Review Date		
	Is the review date identified and is this acceptable?	Y	
9.	Overall Responsibility for the Document		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Y	
10.	Equality Impact Assessment (EIA)		
	Has a suitable EIA been completed?	Y	

Committee Approval (insert name of Committee)

If the committee is happy to approve this document, please complete the section below, date it and return it to the Policy (document) Owner

Name of Chair	Suzanne Rankin	Date	11th June 2015
----------------------	-----------------------	-------------	----------------------------------

Ratification by Management Executive (if appropriate)

If the Management Executive is happy to ratify this document, please complete the date of ratification below and advise the Policy (document) Owner

Date: 11th June 2015