Guidelines for
Safe and Effective Management and Use of

Point of Care Testing

Blood gases, co-oximetry, lactate electrolytes • Cardiac biomarkers, renal markers, Bilirubin • Cholesterol, Triglyceride and HDL • Albumin • Blood glucose (includes self-testing devices) • Stool occult blood • Alcohol and Toxicology (paracetamol, drugs of abuse) • Intra-operative PTH measurement • Urinalysis (with or without a reader) • Infections (Chlamydia, HIV) • Haemoglobin A1c Anticoagulant therapy monitoring (includes self-testing devices) • Detection of pregnancy and ovulation (includes self-testing devices)

ACBI
IRISH MEDICINES BOARD
FACULTY OF PATHOLOGY
ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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Approved by the
Academy of Medical Laboratory Science, Association of Clinical Biochemists in Ireland, Irish Medicines Board and RCPI Faculty of Pathology

November 28, 2007

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Foreword

It is an honour to be invited to write a foreword for such an important set of guidelines that will, I'm sure, have a significant impact on further driving effectiveness and safety in the use of point of care testing.

Point of care testing can add a significant benefit to the early diagnosis and treatment of patients within a variety of settings. However, every clinician and manager within a department and healthcare facility using point of care testing has a duty to ensure and assure, that its use is safe, accurate, appropriate and effective. This duty extends from the clinical and laboratory settings to the board room.

For these arrangements to be in place, it is fundamental that the effective leadership, behaviours, governance and management arrangements are embedded within and between the services that provide point of care testing – not only to enhance the care for patients and safeguard them against the risk of inappropriately governed point of care testing, but to protect and support staff in their use.

These guidelines outline the steps required to put in place such mechanisms - steps that should be embedded into the ways of working and the general clinical governance arrangements across a healthcare facility.

I strongly recommend that all individuals, both clinicians and managers, with a responsibility for delivering and providing point of care testing services, and as an extended multi disciplinary team, should undertake a baseline of their service against these good practice guidelines and, where gaps exist, move towards implementing the necessary changes.

Finally, I would like to commend the members of the Point of Care Testing Consultative Group, chaired by Dr Gerard Boran, for the passion, commitment and extensive work that have driven the production of these good practice guidelines.

DR TRACEY COOPER
Chief Executive Health Information and Quality Authority

Chairman's Foreword

Point of care testing (POCT) refers to a laboratory medicine service using small analytical devices (including test kits and analysers), provided near to the patient rather than in the traditional environment of a clinical laboratory. The repertoire of tests available has expanded considerably in recent years, as has the technological reliability of the devices. However, there are concerns that incorrectly performed tests or inappropriately interpreted results could put patients at risk, particularly as most POCT operators are not trained laboratory scientists.

The professional organisations associated with laboratory medicine and the Irish regulatory body had concerns with the delivery of POCT in Ireland and recognised the need to address this important area. This led the Dean of the Faculty of Pathology of the Royal College of Physicians of Ireland to invite the Association of Clinical Biochemists in Ireland, the Academy of Medical Laboratory Science and the Irish Medicines Board (the regulatory agency for medical devices in Ireland) to form a Point of Care Testing Consultative Group in 2006. The terms of reference of this group were to produce guidelines for safe and effective management and use of POCT in Ireland and to disseminate the guidelines to the major stakeholders.

It is recommended that these guidelines should be adopted by those responsible for POCT in Irish hospitals. The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT services in Ireland, which in turn wilI deliver considerable benefits and safeguards for patients. An outline framework for primary care and for community pharmacists and the *in-vitro* diagnostic medical device IVD industry is also included.

I would like to thank the members of the Consultative Group who gave their time generously, and I would also like to acknowledge the cooperation of the hospital laboratories who provided details of their procedures.

GERARD BORAN (Dean, RCPI Faculty of Pathology)
Chairman, on behalf of the Point of Care Testing Consultative Group

Membership of the POCT Consultative Group

Mr. John Collier	*Academy of Medical Laboratory Science*
Mr. Tadhg Hurley	*Academy of Medical Laboratory Science*
Dr. Helen Grimes O'Cearbhaill	*Association of Clinical Biochemists in Ireland*
Dr. Nuala McCarroll	*Association of Clinical Biochemists in Ireland*
Dr. Jan Guerin	*Irish Medicines Board*
Ms. Ann O'Connor	*Irish Medicines Board*
Dr. Gerard Boran	*RCPI Faculty of Pathology*

Executive Summary

A Point of care test (POCT) service may be defined as a quality-assured pathology service using analytical *in-vitro* diagnostic medical devices (IVDs) i.e. test kits and analysers, located near to the patient rather than in a clinical laboratory.

It is now possible to provide a rapid test result in a timely manner in the immediate vicinity of the patient such as in the Emergency Department or the Intensive Care Unit and other designated areas of the hospital. The rapidity of obtaining a result can increase clinical effectiveness and contribute to improved outcomes for patients, but it is imperative that the result provided by the device is accurate and reliable. The improved reliability and range of POCT devices is resulting in their increasing use in community clinics, GP surgeries and the home environment.

The aim of this document is to provide guidance for safe and effective management and use of POCT, using IVDs that are fit for their intended purpose and used by a competent individual on the correct patient, giving quality results which become part of the patient record. A faster result is only safe if it is an accurate result.

The major risks arise from poor operator competency; lack of proper supervision, governance and accreditation of the POCT service; failure to use quality assurance schemes; inappropriate testing by inexperienced personnel and uncertainty on how to act on results. However, users must realise that at present, POCT is not a replacement for the conventional laboratory service, but rather a supplement to it. In situations where critical clinical decisions are made on POCT results, verification by the central laboratory may be required by the local POCT policy.

All IVDs that are used for POCT are regulated by the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC. The Irish Medicines Board (IMB) is designated as the Competent Authority for medical devices in Ireland. Its role is to ensure that all IVDs sold on the Irish market comply with the Essential Requirements of the IVD Directive. There is a statutory obligation on the manufacturers to notify the IMB of all adverse incidents involving IVDs. Direct user reporting, although not mandatory, is strongly encouraged and

there is a requirement to report to risk management groups in accordance with local hospital policy.

Effective clinical governance is an essential component of POCT and is best delivered by establishing a multidisciplinary POCT Steering Group, which will usually be chaired by a Laboratory Consultant.

The POCT Steering Group should be accountable to the organisation's executive management team, who must recognise the need for appropriate resourcing. A POCT manager, usually a laboratory scientist, is key to the overall operation. Link nurses are also required at ward level and a nurse coordinator for these is recommended in large organisations. Space available must be adequate to accommodate the equipment, consumables and documentation. The location must be chosen to minimise risks to the health and safety of staff and patients.

The Steering Group will appoint Operational Teams led by a POCT Manager, to oversee the day-to-day operation of POCT services, including training of operators, quality and competence assurance, maintenance, stock management and financial control, IT connectivity, health and safety. All POCT services should be documented in appropriate standard operating procedures (SOPs).

POCT services should only be introduced in consultation with the POCT Steering Group and have the approval of the Laboratory Consultant from the appropriate discipline. All new proposals must be justified by a case of need and supported by a full business case cognisant of evidence-based improved patient care.

Key Recommendations

The following summarises the fifteen key recommendations in this guidance document, which are necessary for the implementation and management of safe and effective POCT.

It is recommended that every hospital in Ireland should have a POCT policy consistent with these guidelines.

1. Clinical governance is an essential part of any POCT service and is best delivered through a multidisciplinary POCT Steering Group. Representatives from the appropriate laboratory disciplines play a vital role in this group.

2. The POCT Steering Group should develop an organisation-wide policy to ensure that all POCT is carried out according to:
   (a) Relevant European and National legislation
   (b) Laboratory and hospital accreditation standards
   (c) Hospital or HSE requirements, e.g. data protection, medical records
   (d) Risk management requirements

3. POCT requests should be evaluated by the POCT Steering Group to ensure that clinical need and effectiveness are defined before a POCT service is introduced and that quality objectives are defined and subsequently evaluated.

4. POCT should not be considered when the laboratory can provide a result in a timely manner appropriate to the clinical condition.

5. Only IVDs that are approved by the POCT Steering Group should be used for POCT. This requirement should apply to all IVDs irrespective of whether they have been purchased, loaned, gifted or leased to the organisation.

6. POCT Operational Team(s) with relevant personnel should be appointed to oversee the day-to-day operation of POCT. Each Operational Team must be adequately resourced to enable them to implement, monitor and audit the day-to-day POCT policy.

7. The clinical laboratory has an essential role in the leadership and co-ordination of POCT.

8. Standard operating procedures should be developed and implemented for POCT, in compliance with manufacturers' instructions and relevant standards.

9. Only trained fully competent staff may undertake POCT.

10. POCT IVDs should be password-protected and only accessible by certified users.

11. Quality assurance, both internal and external, is key to assuring the accuracy and reliability of a POCT service.

12. Connectivity allows the central control and management of POCT analysers and facilitates the exchange of information from a remote site to the hospital information system and the patient permanent record. Connectivity should be resourced to a level which avails of the latest technology including electronic healthcare record and unique patient ID.

13. All adverse incidents that occur with POCT IVDs should be reported to the designated hospital committee, the manufacturer and the Irish Medicines Board as appropriate.

14. The POCT Steering Group should review and monitor quality objectives as required.

15. The POCT Steering Group has authority to withdraw and/or suspend service in the event of a safety-related or performance issue or lack of clinical effectiveness.

The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT services, which in turn will deliver considerable benefits to the Irish health service and to patients.

1.0 INTRODUCTION

Advances in analytical technology and in the healthcare services have led to significant development of and demand for POCT, that is testing performed near to the patient rather than in a centralised laboratory. Some POCT devices have been used in the hospital environment, general practitioner surgeries and even in the home for many years, (e.g. urine and glucose dipsticks and meters). More recently the range of analysers and tests available has expanded considerably, and the technology has become easier to use and more robust. It is now possible to provide a rapid test result in a timely manner in the immediate vicinity of the patient such as in the Emergency Department or the Intensive Care Unit. The rapidity of obtaining a result can increase clinical effectiveness and contribute to improved outcomes for patients, but it is imperative that the result provided by the device is accurate and reliable. The improved reliability and range of POCT devices is resulting in their increasing use in community clinics, GP surgeries and the home environment.

1.1 Scope

The aim of this document is to provide guidance for the implementation and management of a safe and effective POCT service within the hospital environment, and to provide a framework for its extension into other settings. It is intended to assist those responsible for the delivery of POCT, and to ensure that risks to patient health and safety are minimised. **It is recommended that every hospital in Ireland should have a POCT policy consistent with these guidelines.**

1.2 Definition

A POCT service may be defined as a quality-assured pathology service using analytical devices (including test kits and analysers), provided near to the patient rather than in the traditional environment of a clinical laboratory.

Point of care tests currently marketed encompass all of the laboratory medicine disciplines. Table 1 provides examples of POCT currently in use in a hospital setting. The types of sample used for POCT include whole blood, urine, serum, stool and saliva. Table 2 provides examples of POCT currently in use in a community setting.

TABLE 1
Examples of applications available on POCT devices in a hospital setting

Blood gases, co-oximetry, electrolytes, lactate
Cardiac biomarkers, renal markers, Bilirubin
Cholesterol, triglyceride and HDL
Intra-operative PTH measurement
Blood glucose (includes self-testing devices)
Alcohol and toxicology (paracetamol, drugs of abuse)
Urinalysis (with or without a reader)
Haemoglobin A1c
Albumin
Anticoagulant therapy monitoring (includes self-testing devices)
Detection of pregnancy and ovulation (includes self-testing devices)
Infections (Chlamydia, HIV)
Stool occult blood

TABLE 2
Examples of applications available on POCT devices in a community setting

Blood glucose (includes self-testing devices)
Urinalysis (with or without a reader)
Cholesterol, triglyceride and HDL
Anticoagulant therapy monitoring (includes self-testing devices)
Detection of pregnancy and ovulation (includes self-testing devices)

1.3 Risks/Benefits

Analytical results are provided more rapidly and effectively with POCT due to an improved turnaround time. However, there are concerns about the reliability of results obtained by non-laboratory trained personnel. Incorrectly performed testing or inappropriately interpreted results could put patients at risk. In some situations it may be more appropriate to have analyses performed in a clinical laboratory. The provision of POCT should

not be considered when the laboratory can turn around a result in a timely manner appropriate to the clinical condition. The cost per test of POCT generally exceeds that of the clinical laboratory so inappropriate or excessive testing can significantly increase costs. Staff costs for POCT can be substantial but are rarely identified as such in hospital budgets. Higher POCT costs may however be offset by more efficient use of resources in other areas of healthcare delivery.

Advances in technology and legislative control have resulted in more reliable instruments. The major risks arise from poor operator competency, lack of proper supervision, governance and accreditation of the POCT service, failure to use quality assurance schemes, inappropriate testing by inexperienced personnel and uncertainty on how to act on results. However, users must realise that at present, POCT is not a replacement for the conventional laboratory service, but rather a supplement to it. In situations where critical clinical decisions are made on POCT results, verification by the central laboratory may be required by the local POCT policy.

2.0 REGULATORY REQUIREMENTS

2.1 The IVD Directive

The majority of analytical devices (e.g. test kits and analysers) that are used for POCT fulfil the definition of an *in-vitro* diagnostic medical device (IVD). Broadly, an IVD is a device intended by a manufacturer for use for the *in-vitro* examination of specimens derived from the human body to provide information regarding a physiological, pathological or therapeutic state.

All IVDs are regulated by the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC and related Irish Regulations. The IVD Directive became mandatory in December 2003 and was implemented in Ireland via the Statutory Instrument S.I. No. 304 of 2001, European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001.

All IVDs available on the European market must meet the Essential Requirements in Annex I of the IVD Directive and this is demonstrated by the display of a CE mark. The Essential Requirements of the IVD Directive aim to ensure that IVDs do not compromise the health and safety of

patients and users and are designed to achieve the performance specified by the manufacturer for its intended purpose. This legislation introduces common regulatory requirements dealing specifically with the safety, quality and performance of IVDs across Europe.

The Irish Medicines Board (IMB) is designated as the Competent Authority for medical devices in Ireland. Its primary role as a Competent Authority is to ensure that all IVDs sold on the Irish market comply with the IVD Directive.

There are some IVDs that were on the market prior to the implementation of the IVD Directive and therefore do not bear a CE mark. This exemption only applies to IVDs that were manufactured and put into service prior to December 2003.

2.2 Risk assessment of IVDs used for POCT

An *in-vitro* diagnostic medical device is classified on the basis of the risk associated with the device and the relative dangers to the public and/or a patient treatment/diagnosis by an IVD failing to perform as intended. The IVD Directive requires manufacturers to perform a risk assessment for all devices. This risk assessment should consider the use of an IVD at point of care and any additional safeguards that should be applied considering that the device is used outside the conventional laboratory setting and by individuals who are not professionally trained in laboratory techniques.

The Essential Requirements in Annex I of the legislation also specify the information to be supplied by manufacturers with an IVD, to ensure it is used in a safe and proper manner. Paragraph 8.1 of this Annex states that this information should consider the training and knowledge of potential users. Manufacturers should therefore ensure that this requirement is met for IVDs used for POCT an environment distinct from the laboratory setting.

2.3 Adverse incident reporting

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects. In a POCT environment this may involve the health and safety of patients, users or other persons. For example, an incorrect result could lead to a delay in treatment, a life-threatening illness or injury or a serious deterioration in the state of

health, or even death. Any adverse incident involving an IVD should be reported by the hospital to the manufacturer.

Each hospital should have a clearly stated policy to ensure a competent system exists to enable such reporting to the:

1. Manufacturer,
2. IMB,
3. POCT Steering Group,
4. Risk management and State Claims Agency.

The manufacturer has a legal requirement in accordance with article 11 of the IVD Directive 98/79/EC to report all adverse incidents that occur with IVDs on the Irish market to the IMB.

Direct reporting of adverse incidents by users to the IMB is not mandatory but is encouraged. It is important that users are aware of the reporting requirements for adverse incidents under the IVD Directive and the key role they play to ensure that all incidents that occur on the Irish market are reported and investigated by the manufacturer. A form for reporting adverse incidents is included in Appendix 9.1.

2.4 Certification and accreditation of POCT

POCT may be certified to standards developed by the International Organisation for Standardisation (ISO) – the main standard is ISO 22870:2006. This gives specific requirements applicable to POCT and is intended to be used in conjunction with ISO 15189 (the main standard for quality and competence in medical laboratories). Patient self-testing in a home or community setting is excluded, but elements of ISO 22870:2006 can be applicable. An accreditation body such as Clinical Pathology Accreditation (UK) Ltd (CPA), which incorporates the ISO standards and is currently recognised in Europe, may accredit POCT. It is anticipated that accreditation of clinical laboratory services will become mandatory in Ireland and that this will include POCT services.

3.0 CLINICAL GOVERNANCE

Clinical governance is a systematic approach to maintaining and improving the quality of patient care and controlling clinical risk. It is an essential part of any POCT service and is best delivered by establish-

ing a multidisciplinary POCT Steering Group (see Clinical Governance diagram in Appendix 9.2).

3.1 Responsibility for POCT services

The POCT Steering Group will be accountable for the delivery of all POCT services. The Chairperson of this group will usually be a Laboratory Consultant or other appropriate laboratory professional. Laboratory Consultants from participating disciplines will provide direction for their particular POCT service. A person with overall co-ordinating responsibility must be designated for each POCT service, whether existing or proposed. This will usually be a laboratory scientist from the appropriate pathology discipline and will be a member of the POCT Steering Group.

The POCT Steering Group should be accountable to the organisation's executive management team. A formal link with the local Pathology Directorate is desirable. A template for the POCT Steering Group including terms of reference can be found in Appendix 9.3. Note that the existence of this governance structure does not negate the responsibility of the individual analyst to work in a competent manner. The onus is on the Nurse Manager or Head of each unit to ensure that all authorised operators have been trained and demonstrated competence. The individual conducting the analysis is accountable for the results they generate using POCT devices.

3.2 Terms of reference of the POCT Steering Group

The POCT Steering Group should have the objectives set out in Table 3.

TABLE 3
Objectives of the POCT Steering Group

1. Provide clinical governance for POCT services through the development and implementation of an organisation-wide POCT Policy
2. Establish POCT Operational Team(s) to deal with the day-to-day running of individual POCT services
3. Advise the senior management team on all aspects of POCT, including risk, benefits, resources required, new proposals and present and future strategy

3.3 POCT Steering Group membership

The minimum recommended membership is shown in Table 4.

TABLE 4
Minimum membership of the POCT Steering Group

A Laboratory Consultant from participating pathology disciplines
A senior management representative
A senior scientist from participating pathology disciplines
The Manager of each or all POCT Operational Teams
Clinical Risk Manager
Senior Medical representatives from participating services
Senior Nursing Representatives from participating services
IT representative
Risk Manager

Additional members may be included or co-opted (e.g. pharmacy, supplies, engineering, infection control) depending on the needs of the local service.

3.4 Role of the POCT Steering Group

The role of the POCT Steering Group is described in Table 5.

TABLE 5
Role of the POCT Steering Group

To evaluate and approve all new, gifted, loaned and existing POCT IVD devices within the organisation
To ensure that only approved IVDs are used for POCT
To ensure that the IVD is suitable for its intended use and is clinically effective
To ensure that IVDs are procured and commissioned in an appropriate manner and according to hospital policy
Through the hospital asset register, to establish a register of all approved POCT sites and IVDs used at these sites within the organisation

continued overleaf ▶

To ensure that devices for POCT fulfil the requirements of national legislation, the IVD Directive, laboratory and hospital accreditation standards and other relevant standards

To comply with HSE requirements in relation to data protection, patient confidentiality and risk management

To ensure that there is a procedure to document all patient results appropriately and to transfer them to the permanent hospital record. Results should be traceable to the location where the analysis is performed

To ensure that the POCT IVD is operated only by trained and competent users

To define criteria for taking action against unsatisfactory performance, inappropriate use and poor quality practices and for withdrawal of the IVD where appropriate

To review overall POCT IVD performance and trends identified through audit and quality assurance

To ensure that there is adequate support and appropriate use of resources for POCT

To support the POCT Manager(s) and Operational Team(s)

3.5 POCT Operational Teams

One or more POCT Operational Teams may be appointed by the POCT Steering Group to oversee the day-to-day operation of POCT services. One or more POCT Managers may lead the teams.

The developmental phase of establishing Operational Teams may be led by a Senior Scientist, who may in the established phase of POCT hand it over to a specifically appointed Laboratory Scientist as POCT Manager.

3.6 The role of the POCT Operational Team

The role of the teams is described in Table 6.

TABLE 6
Role of the POCT Operational Teams

To develop standard operating procedures for pre-analytical, analytical and post-analytical processes for each POCT device
To develop a system for training, certification and registration of operators which includes maintaining a register of certified trained users and provision of secure operator identity codes for the POCT service
To implement and monitor a quality assurance programme, both internal and external (where available), for the IVD
To validate and compare the POCT method with the current laboratory method and provide comparative data for review by the POCT Steering Group
To ensure that audits are conducted and appropriate corrective action is implemented where necessary
To ensure that the adverse incident reporting policy is adhered to
To establish a procedure for service and maintenance of IVDs in accordance with manufacturers' instructions.
To advise the POCT Steering Group regarding the need to recall or withdraw IVDs in the event of a safety or performance issue until appropriate remedial action is taken

3.7 Governance issues and the IVD industry

It is strongly advised that IVD industry representatives present proposals initially to the POCT Steering Group preferably through the Chairman, or through the POCT Manager, instead of approaching individual end users directly.

It will be the responsibility of the individual contacted to inform the relevant specialties concerned. No POCT device should be put in place by the IVD industry without the prior approval of the POCT Steering Group.

The IVD industry has a role in supporting the Operational Team with commissioning, operator training, development of documentation, auditing and ongoing operation of POCT services and equipment.

3.8 Primary care

General practitioners should be aware of the expertise in POCT available from the local hospital laboratory service and should make use of this by obtaining advice before commissioning any POCT in their practices. The local hospital laboratory should provide support and quality assurance monitoring and should be willing to do this, resources permitting. Particular attention should be given to the use of nationally recognised units of measurement, standardised methods and comparability of results with the local laboratory.

3.9 Community pharmacists

Community pharmacists should be aware of the governance issues set out in this document and their universal applicability. POCT carried out in pharmacies has implications for other healthcare providers in primary care and hospitals. The same quality standards should apply in pharmacies as elsewhere. Hence, pharmacists should give consideration to discussing their plans with the local pathology service and GPs. Particular attention should be given to the use of recognised units of measurement, standardised methods and comparability of results with the local laboratory.

4.0 COMMISSIONING POCT SERVICES

POCT services (both new proposals and existing services) should only be introduced in consultation with the POCT Steering Group and have the approval of the Laboratory Consultant from the appropriate discipline. All new proposals must be justified by a case of need and supported by a full business case. The commissioning process is illustrated in Appendix 9.4 and an application form suitable for new POCT proposals is included in Appendix 9.5. This should include an assessment of all options available to deliver the required pathology service, including the costs of all staff involved, training, quality assessment schemes, equipment, reagents used, servicing and repairs. A specification of requirements (suitable for tender) and a scheduled implementation plan should be presented.

It is acknowledged that increased costs associated with POCT may be offset by clinical benefits and/or cost savings achieved elsewhere in the

organisation. It is also the case that improvements in turnaround time to the central laboratory frequently obviate the need for POCT.

4.1 Resources

It is important to recognise that adequate resources are required for the implementation and on-going support of POCT. A POCT Manager is key to the overall operation. Link nurses are also required at ward level and a nurse coordinator is recommended for large organisations. Depending on the extent of POCT services, it is envisaged that the POCT Manager post would require input of a minimum of 1 whole time equivalent, who would preferably be a laboratory trained Senior Scientist. A further 1 whole time equivalent designated nursing post would also be required to coordinate the day-to day operation of POCT at ward level.

4.2 Space

Space available must be adequate to accommodate the equipment, consumables and documentation. The location must be chosen to minimise risks to the health and safety of staff and patients. It should have sufficient electrical sockets and network points for the equipment. The environment should be controlled to comply with legislation and manufacturers' recommendations. A dedicated refrigerator and possibly a freezer for reagent storage should be available, if required. A safe sturdy area to locate a centrifuge may also be required if serum separation is necessary. Equipment should be arranged to allow for operation in a manner that supports high quality work, quality control, quality assessment, result documentation and maintenance. Provision must be made for safe disposal of sharps, clinical and non-clinical waste, and confidential information.

Space requirements will vary for particular tests or groups of tests but should be defined by the laboratory discipline.

5.0 IMPLEMENTING POCT SERVICES

The POCT Operational Teams are responsible for implementing POCT services. All POCT services should be documented in appropriate standard operating procedures, which should be approved by the POCT Steering Group.

5.1 Training

All staff involved in POCT must be trained and competent in the use of the IVD. The training and certification of POCT users should be overseen and monitored by the POCT Operational Team. Only staff whose training and competence has been established and recorded should be permitted to perform POCT. The topics described in Table 7 should be included in the staff-training programme for POCT.

TABLE 7
Components of a POCT staff training programme

Instructions on safe working practices
Principles of operation of the IVD
Review of the manufacturer's instructions for use, limitations of the IVD and interpretation of results
Review and understanding of error messages, interpretation and appropriate responses
Calibration and quality control requirements, to include performance, appropriate record keeping and required actions for failed results
Patient preparation, sample collection and handling according to health and safety regulations and the manufacturer's stated requirements
Appropriate responses to, and recording of patient results
Facilitating the assignment of operator identification numbers to trained certified POCT users
Inclusion in the register of certified trained users and notification of the programme for retraining and monitoring
Action on improper and unsafe use of a POCT IVD
Procedure for recording of adverse incidents with IVD

Many of the vendors have established training programmes, which they will modify and deliver to suit local needs. Advantage could be taken of e-learning programmes.

5.2 Quality assurance programme

Quality assurance is an integral component of any POCT service and includes all the measures taken to ensure the reliability and accuracy of the patient result. It is important that all POCT IVDs are included in a quality assurance programme and that this is operational prior to patient testing at each site. The quality assurance programme should be overseen and monitored by the POCT Operational Team and appropriate action should be taken if quality standards are not adhered to. The role of the laboratory is integral to the implementation and management of the analytical quality assurance for POCT. Table 8 illustrates the elements which should be considered.

TABLE 8
Elements of quality assurance

Performance and documentation of appropriate quality control and / or calibration
Correct patient identification
Selection of the appropriate test
Obtaining a satisfactory sample and sample integrity
Performance of the test in accordance with the manufacturer's instruction
Correct interpretation of the result and appropriate action taken
Recording of the test result in the patient record

5.3 Internal quality control

Internal quality control (QC) is a means of determining that the IVD is technically performing correctly at that specific time and that the patient result is reliable before it is released and acted on.

The SOP for each IVD should outline the material to be used, specify the frequency at which the internal QC is performed and define the acceptable limits for the QC material prior to testing a patient sample. All POCT users should be educated as to the essential requirement for the QC procedures, appropriate action to take in the event of substandard quality

control, and the implications when quality control is not performed according to the stated protocol.

5.4 External quality assessment

External quality assessment (EQA) is a means of determining how a particular IVD is performing in comparison to similar IVDs at different sites and to other IVDs or other laboratory analysers. The EQA material is a sample of an unknown value, which may be provided by an external quality assessment scheme such as the Irish EQA (IEQAS), the UK EQA (UK-NEQAS), or the Welsh EQA (WEQAS) or alternatively prepared by the laboratory or manufacturer for provision to all POCT sites within the organisation. The laboratory should be responsible for the implementation and management of the EQA and provide feedback to the POCT Operational Team. Monitoring and maintenance of EQA results is best managed by interfacing POCT devices to a single data server accessible to the laboratory and POCT manager. Internet interaction with external quality assessment schemes suppliers has the advantage that the Operator and the POCT Operational team may view results.

5.5 Recording results and audit trail

A maintenance and incident logbook should be maintained for each POCT device to record details of maintenance, faults, repairs and corrective action. The POCT Operational Team should nominate an individual who is responsible for responding to issues logged and recording the corrective actions taken in this logbook. Such an action can be electronically recorded.

All patient results must be recorded in the patient's permanent record and patient identification details must be complete. The POCT operator identity should also be included with the patient result to allow full traceability for POCT. A permanent record of all quality control data should be maintained.

5.6 Maintenance and service

The maintenance and servicing of POCT devices is essential to ensure a functional and reliable POCT service within the organisation. It is important therefore that the POCT Operational Team identifies persons to be responsible for the day-to-day care of an IVD for each POCT site and that this is communicated to users. Responsibility for other maintenance

should be clearly identified by the POCT Operational Team and could be the device's manufacturer/supplier, the Clinical Engineering staff and/or appropriate laboratory staff. All such maintenance and servicing should be conducted in accordance with the manufacturer's instructions. It is recommended that a register, based on the Hospital Asset Register for all IVDS used at POCT, be used to update the maintenance and servicing records for these devices, as appropriate.

The day-to-day maintenance of a POCT device may include some of the following elements:

- Ensure that the IVD(s) is kept in good and safe working order
- Ensure good stock control of all reagents, consumables and controls within their shelf-life
- Temporarily withdraw any IVD/test from the POCT service that is not performing to the manufacturer's specification and ensure that it is not used again until the appropriate remedial action has been taken and the POCT Steering group has been informed
- Suspend/withdraw any POCT service in the event of a safety issue as directed by the POCT Operational Team

5.7 Competence/proficiency testing of POCT Operators

The POCT Operational Team should assess the competence of new POCT operators and should periodically re-assess existing POCT operators. This may be done by observing an operator carrying out an actual test and assessing performance against the SOP. Deviations observed in technique from that specified in the SOP should be corrected immediately, in which case the operator can be re-certified as competent. Defects in theoretical knowledge should be addressed by appropriate educational sessions.

The advantage of this approach is that all aspects of actual POCT practice can be observed, assessed and corrected (e.g. specimen collection, analysis, interpretation of results and further action). The assessment should be conducted as a peer-based practice improvement measure rather than an examination.

Competence/proficiency testing is supplemental to the standard laboratory quality assurance measures. Ideally, all POCT operators should be assessed and re-certified annually, or more frequently where usage of POCT is low.

5.8 Retention of records

Records of instrument maintenance, faults and corrective action, training records, quality control records and medical records should all be retained for the length of time specified in the National Hospitals Office (NHO) *Code of Practice for Healthcare Records Management*.

5.9 Connectivity

Connectivity between disparate computer systems and POCT analysers is an essential component for provision of an effective POCT service within an organisation. In particular, it allows POCT IVDs to be controlled and managed centrally and facilitates exchange of information from the remote POCT site to the laboratory/hospital information system. Key goals are given in Table 9.

Connectivity requirements have been described in the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) – POC Connectivity-Approved Standard (POCT1-A2, the 2005 draft modification of POCT1-A), a co-operative effort of providers, manufacturers and representatives of CIC, NCCLS, HL7, IEEE, CAP, FDA, JCCLS and the IFCC.

The objective of the standard is to allow seamless multi-vendor interoperability and communication between POCT devices, data concentrators and clinical information systems. The CLSI asserts that this standard provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of POCT devices to communicate bi-directionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

Also available from CLSI is a proposed *Guideline on "Implementation of POC Connectivity for Healthcare Providers (POCT2-P)"* which discusses the requirements of a connectivity-compliant device, and describes information that users should request from the supplier. The development of POCT1-A in 2000 was a US initiative, but in 2001 a European initiative was convened to internationalise the standard.

Co-operative development has led to a modified and updated 2005 standard draft POCT1-A2, and some vendors' recent POCT IVDs are compliant with the standard, whilst others plan to implement it in their

future POCT IVDs. Adopting this as an ISO, CEN and IEEE standard is an unparalleled move in the history of standardisation, and so there are still some administrative obstacles to be resolved.

The standard has incorporated agreement on Device and Access Points, the device-messaging layer and Observation Reporting Interfaces. The device interface governs the flow of information between devices and Observation Reviewers. The Observation Reporting Interfaces describes messaging between Observation Reviewers (typically POCT Data Manager, though a laboratory information system may also serve as Observation Reviewer) and Observation Recipients (typically a laboratory information system or Clinical Data Repository).

TABLE 9
Key IT connectivity goals

Positive identification of patient samples and patient demographics to the system
Operator ID to allow traceability of results. Ideally the staff member's bar-coded staff ID card or similar device should be used
Audit controls, logs, and accountability
Password protected access to the system, login procedures and monitoring, and automatic logoff settings
Ability to distinguish POCT results from other results on the laboratory information system
Integration of all results generated from POCT devices with the laboratory information system and appropriate clinical information systems
Generation of positively identified hard copy of results
Appropriate data storage and backup
Remote monitoring of POCT QC and IVD performance from the clinical laboratory
Remote ability to temporarily block certified individuals who are not conforming to the stated QC protocol
On-board decision support for order entry, and interpretation tailored to the analyser and particular test
Checking for data integrity

The extent to which this can be achieved depends on the particular POCT device, the number of devices and the local healthcare IT services available. Use of laser technology to read bar-coded patient identification on patient armbands, user identification badges and reagent/control consumables has greatly reduced the risk of incorrect patient identification, uncertified user and incorrect reagents/controls. Incorrect transcribing of results or failure to record results is also being eliminated by the ability of devices to transmit results to the laboratory information system.

5.10 Health and safety

An audit of hazards associated with the IVDs needs to be completed. Special attention must be given to avoidance of contamination of devices and the surrounding environment and disposal of waste including sharps. Protocols for decontamination of devices and their immediate environment should be available. All testing must be carried out in accordance with Health and Safety Regulations.

6.0 CONCLUSION

Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result in a timely manner in the immediate vicinity to the patient. This may lead to increased clinical effectiveness and improved outcome for patients. However, this is only true if the result delivered is accurate and reliable.

It is important, therefore, that hospitals have a clearly defined and well-structured approach to POCT to ensure that it is performed in a safe and appropriate manner and conforms to acceptable analytical and clinical standards.

Because there is a paucity of information regarding evidence-based support for POCT in clinical management, it is incumbent on users to establish that their proposed POCT service will be effective at a local level. There is a need for well-designed studies to evaluate clinical effectiveness of POCT in relation to patient outcome.

This guidance document has been approved by the Faculty of Pathology, the Association of Clinical Biochemists in Ireland, the Academy of Medical Laboratory Science and the regulatory agency for medical devices in Ireland, the Irish Medicines Board.

It is recommended that these guidelines should be adopted by those responsible for POCT in Irish hospitals.

The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT service, which in turn will deliver considerable benefits to the Irish health service and to patients.

7.0 GLOSSARY AND ABBREVIATIONS

In-vitro Diagnostic Medical Device (IVD)

According to the IVD Directive 98/79/EC an IVD is defined as any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures

CE Mark

The CE mark that appears on an IVD or on its packaging means that the device satisfies the relevant essential requirements of the IVD Directive 98/79/EC and is fit for its intended purpose as specified by the manufacturer.

CEN

European Committee for Standardisation

Competent Authority

The Competent Authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the Medical Devices Directives are carried out in that particular Member State.

CAP

College of American Pathologists

CIC

Connectivity Industry Consortium, formed by the IVD industry to address connectivity solutions for POCT IVDs.

CLSI

Clinical Laboratory Standards Institute (USA), formerly the National Committee for Clinical Laboratory Standards (NCCLS)

FDA
Food and Drugs Administration (USA)

IEEE
Institute of Electrical and Electronic Engineers

IFCC
International Federation of Clinical Chemistry

ISO
International Organisation for Standardisation

JCCLS
Japanese Committee of Clinical Laboratory Standards

POCT1-A, POCT1-A2, POCT-2P
This is the internationally accepted connectivity standard described in the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) POC Connectivity Approved Standard (POCT1-A2, the 2005 draft modification of POCT1-A). This was a co-operative effort of providers, manufacturers and representatives of CIC, NCCLS, HL7, IEEE, CAP, FDA, JCCLS, and the IFCC. POCT1-A2 is the latest iterations of the standard in 2005, and POCT-2P is a proposed guideline on implementation of POCT connectivity standards for healthcare providers.

8.0 KEY REFERENCES

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Clinical Governance of Point-of-Care Testing: The Role of the Point-of-Care Testing Committee. Irish Medicines Board Newsletter. Vol. 1 Number 15, 2006.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices

S.I. No. 304 of 2001 European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001

IMB Guidance Note 11: Guidance Note on the Introduction to the *In-vitro* Diagnostic Medical Devices Legislation

IMB Guidance Note 18: Guidance Note on Adverse Incident Reporting for *In-vitro* Diagnostic Medical Devices

ISO 22870: 2006 Point of care testing (POCT) – Requirements of quality and competence

ISO 15189: 2003 Medical laboratories – Particular requirements for quality and competence

Point of Care Connectivity; Approved Standard-Second Edition (POCT1-A2) www.clsi.org

Implementation of Point-of-Care Connectivity for Healthcare Providers; Proposed Guideline (POCT2-P) www.clsi.org

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9.0 APPENDICES

Appendix 9.1 Adverse Incident Report Form

IRISH MEDICINES BOARD

MEDICAL DEVICE INCIDENT USER REPORT FORM

If you have experienced problems with a medical device, please complete this form and send it to the Irish Medicines Board, Medical Devices Department, Earlsfort Centre, Earlsfort Terrace, Dublin 2 or contact us by telephone at 01-6764971 or by email vigilance@imb.ie

SECTION 1: CONTACT DETAILS OF REPORTING ORGANISATION	
Name of Organisation:	**Fax Number:**
Address of Organisation:	**Contact Name:**
	Position:
Telephone Number:	**Email Address:**
Can the Irish Medicines Board provide your contact details to the manufacturer, as they may need to contact you in order to carry out an investigation ☐ Yes ☐ No	

SECTION 2: DEVICE DETAILS	
Name of device and model number:	
Kind of device (e.g. pacemaker):	
Serial number / batch number / lot number:	
Where did you get the device?	**Name of the person who supplied the device:**
Name and address of the manufacturer:	**Name and address of the distributor:**

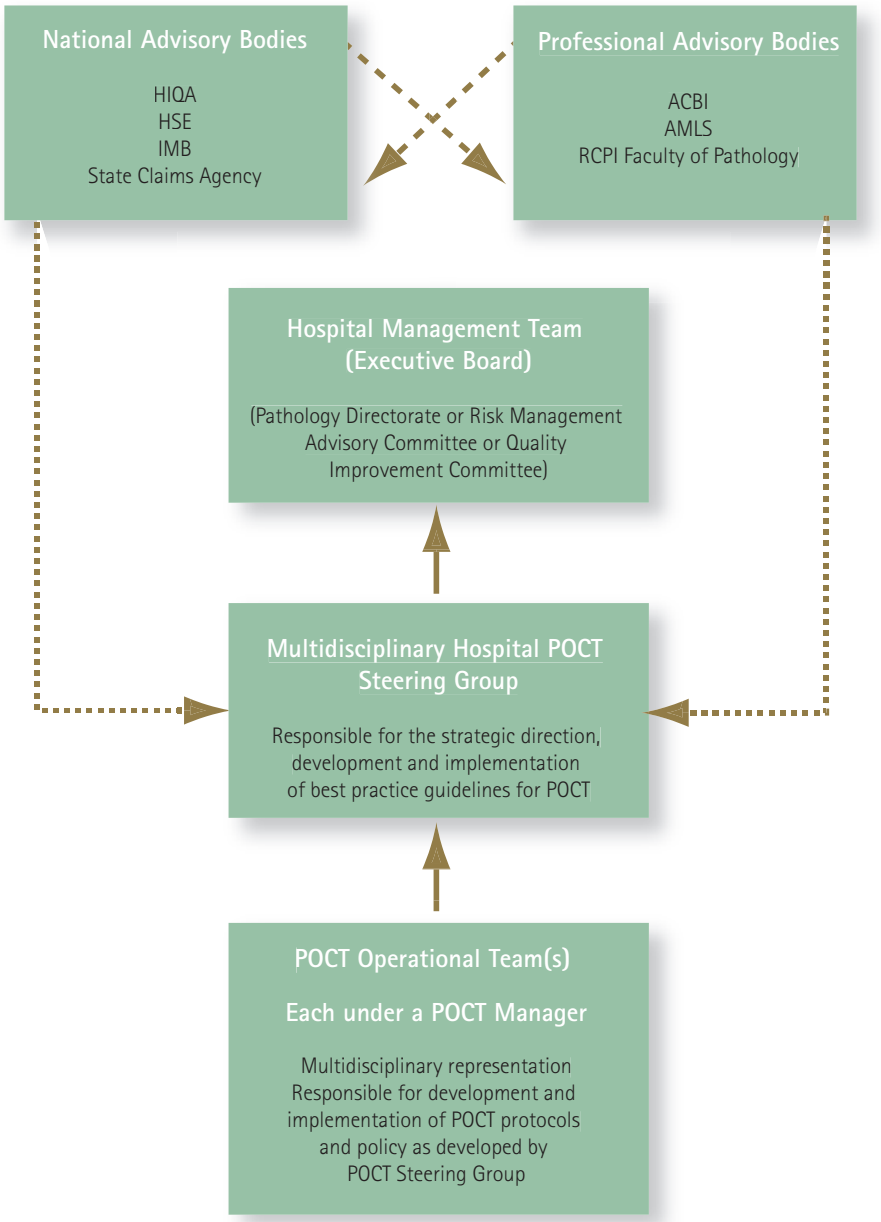
SECTION 3: INCIDENT DETAILS
What went wrong with the device?

Was an injury suffered?	Yes ☐	No ☐
If yes, specify who and what injuries were suffered?		
Have you contacted the manufacturer?	Yes ☐	No ☐

Signature:	**Date of Report:**

The Irish Medicines Board investigates all incidents reported to us in order to identify any faults with medical devices and to prevent similar incidents happening again. Please note that the Irish Medicines Board may contact the manufacturer of this medical device to request they carry out an investigation.

Appendix 9.2 Clinical Governance for POCT



Appendix 9.3 POCT Steering Group Template

1. Terms of Reference

1.1 The Steering Group will advise the management team on all aspects of POCT.

1.2 The Steering Group will provide clinical governance for the POCT service by ensuring that the organisation's systems and processes for monitoring and improving the quality of POCT services are in accordance with best practice.

1.3 The Steering Group will develop and recommend policies and procedures for the proper conduct of POCT, will be responsible for the review and commissioning of POCT services and may recommend or commission focused research or development on aspects of POCT.

1.4 The existing range of POCT services will fall within the remit of the Steering Group, including *[list of analyses: e.g. blood gas analysis, blood glucose monitoring, pregnancy testing, and other analyses requiring instrumentation]*. A survey will determine the extent and risk category (low/medium/high) of existing POCT including manual tests/dipsticks.

1.5 To review existing POCT services and receive proposals for new POCT services; and to assess the case of need and clinical effectiveness for patients compared with other options for service delivery; and to make recommendations as to their appropriateness, taking account of:–

Indications, contraindications and workload implications for POCT
Suitability, accuracy, limitations and scope of testing for clinical needs
Risk management and risk stratification of the various devices
Financial implications
Health and safety implications
Ability to audit quality and clinical effectiveness

1.6 To implement a quality assurance programme for POCT including systems for internal and blind-sample external quality assessment and adverse incident reporting, and taking into account:

Operator training
Machine calibration and maintenance
Correct interpretation of results
Correct recording of results, including integration with IT systems
Health and safety requirements

1.7 To implement an education programme for clinical users of POCT and to keep a list of trained operators.

2. Membership

2.1 The **minimum** membership shall be [number locally defined], (quorum [number locally defined]) and shall serve for [duration defined locally] years.

The **minimum** Steering Group membership should consist of: –

- A Laboratory Consultant from participating pathology/laboratory medicine disciplines
- A Senior management representative
- A Senior scientist from participating pathology/laboratory medicine disciplines
- The Manager of each or all POCT Operational Teams
- Clinical Risk Manager
- Senior Medical representatives from participating services
- Senior Nursing Representatives from participating services
- IT representative

2.2 Other members may be co-opted as necessary.

2.3 In the event of an appointed member being unable to attend, a deputy may attend in his or her place.

2.4 Dr [name of nominee], [job title], is nominated as the first chairperson for a defined period.

3. Meetings

3.1 The Steering Group shall meet on a **quarterly** basis.
3.2 Additional meetings may be convened at the discretion of the Chairperson to deal with urgent or specific matters.

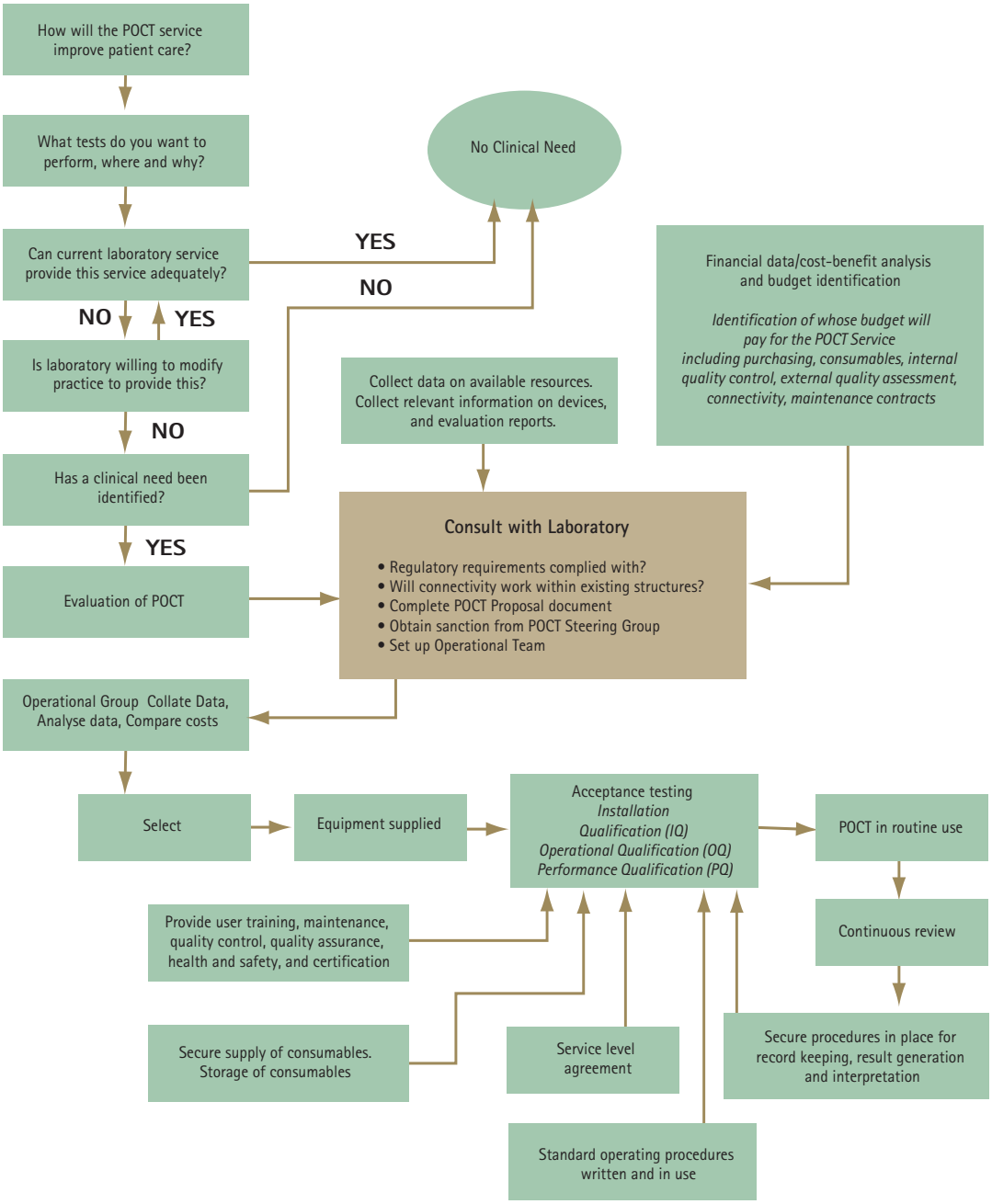
4. Operational Teams

4.1 The Steering Group may appoint Operational (Working) Teams to deal with specific issues and with defined terms of reference. These groups will meet on an *ad hoc* basis according to the needs of the specific project.

5. Reporting and Review

5.1 The Steering Group will report to the Executive Management Team
5.2 This document and the terms of reference will be reviewed every 2 years to gauge effectiveness.

Appendix 9.4 POCT Commissioning Flow Chart



Appendix 9.5 Application Form/Proposal for POCT Service

1. What test(s) do you want to perform?

2. Is the test available in the laboratory?

Yes	No

3. State the clinical need for POCT rather than being supplied by the existing laboratory service?

4. Why is the laboratory unable to meet your requirements?

5. What benefit will the POCT service offer to staff and patients that is not provided by the laboratory?

6. What workload is envisaged in terms of specimen numbers/month?

Space

7. Where do you want to locate the POCT; is it a safe working environment?

8. What size area is available for POCT?

9. What is the distance to the nearest sink?

10. What space is available for storage of stock items?

11. Is the room air-conditioned?

Yes	No

12. Can an engineer have easy access to instruments?

Yes	No

Equipment

13. Has a suitable device/instrument been identified?

No
Yes (give model number and supplier)

14. Has the laboratory agreed with the choice?

Yes	No

15. What is the life expectancy of the device?

16. Is there data in existence to show the comparison of the proposed POCT with the laboratory method?

Yes	No

17. Has a risk assessment been completed? If so please attach

Yes	No

Costs/Risks associated with Device/Equipment

18. What is the capital cost of the instrument including VAT?

19. What is the annual consumables cost?

20. What is the maintenance/servicing cost after guarantee?

21. Is the cost of interfacing the device to the laboratory computer included in the cost?

Yes	
No	If no, what is the cost to interface?

22. Is the cost of software and hardware to monitor and control the device from the central laboratory included?

Yes	No

23. Have you funds sanctioned to cover these costs?

Yes	No

24. Does it have to go to EU tender?

Yes	No

25. Is it CE marked?

Yes	No

26. Can the device be decontaminated?

Yes	No

27. What are the infection control issues?

28. What are the Health and Safety issues?

Maintenance of the Device

29. What response time is guaranteed in the maintenance contract?

30. Is this a 7 day week, 24 hour response?

Yes	No

31. What are the implications for other support departments e.g. Pathology, Biomedical Engineering?

32. Has out of hours support been agreed with the named Support Departments?

Yes	No

33. Is the proposed equipment compatible with similar results produced elsewhere in the hospital?

Yes	No

34. Does the device have a UPS (Uninterrupted Power Supply Unit)?

Yes	No

Responsible Personnel

35. Who will be the designated person in charge of the device day to day?

36. Who will perform the test(s)?

37. Will you have designated staff to cover absences of the designated person responsible for the device and for performing the test(s)?

Yes	No

38. Is the instrument password-protected?

Yes	No

39. Who takes responsibility for issuing and maintaining passwords?

40. Who takes responsibility for Internal Quality Control programme of users?

41. Who takes responsibility for External Quality Assessment?

42. Who takes responsibility for clinical action based on the POCT result?

Interfacing and Patient Record

43. Can the instrument be monitored through designated software in the central laboratory?

Yes	No

44. Can the device be interfaced with the laboratory computer?

Yes	No

45. How will the patient record be stored?

46. Do you need IT support?

Yes	No

47. Has the IT department agreed to your requirements?

Yes	No

Clinical Governance

48. Are you compliant with the hospital POCT policies?

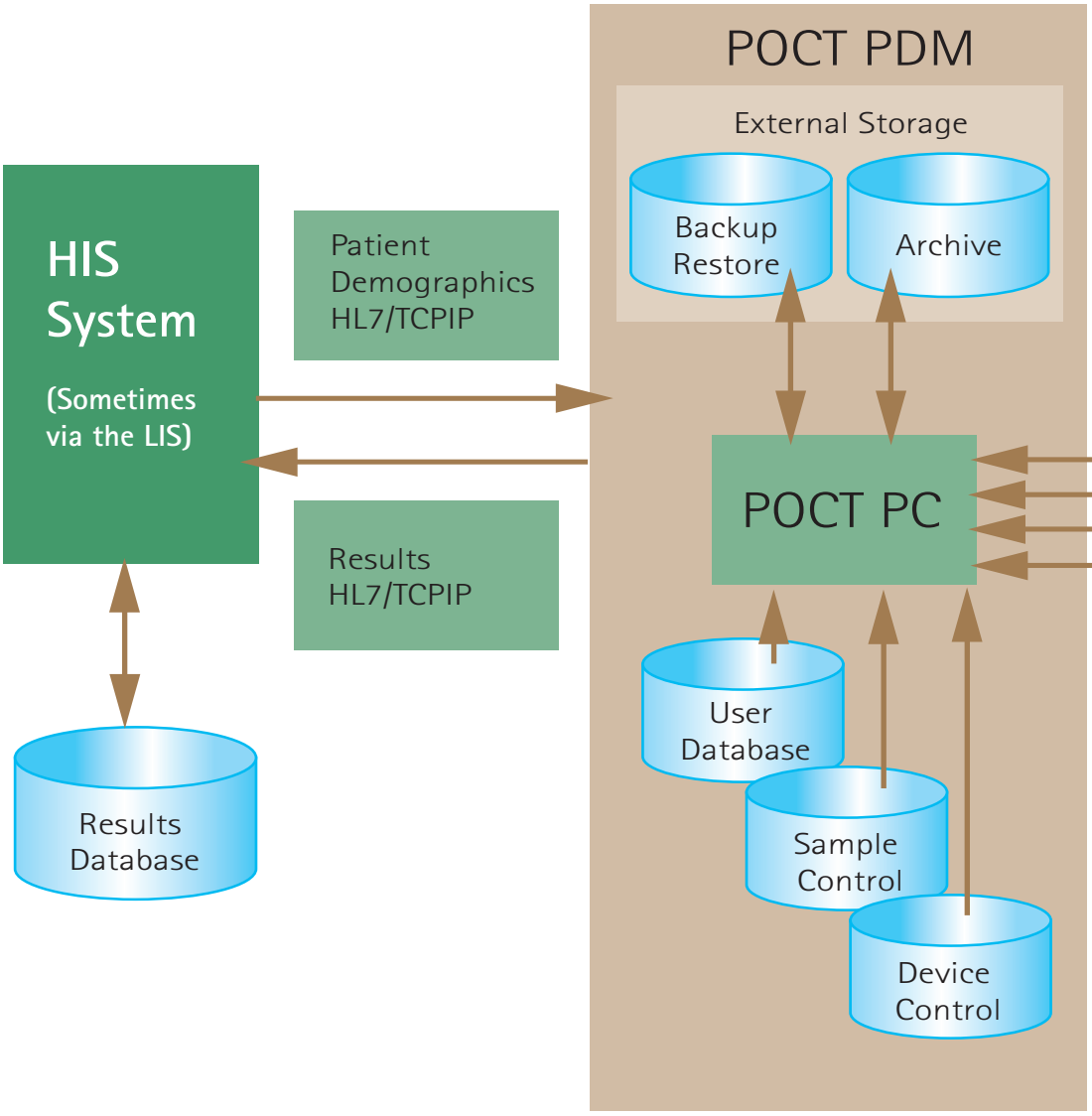
Yes	No

Signatures

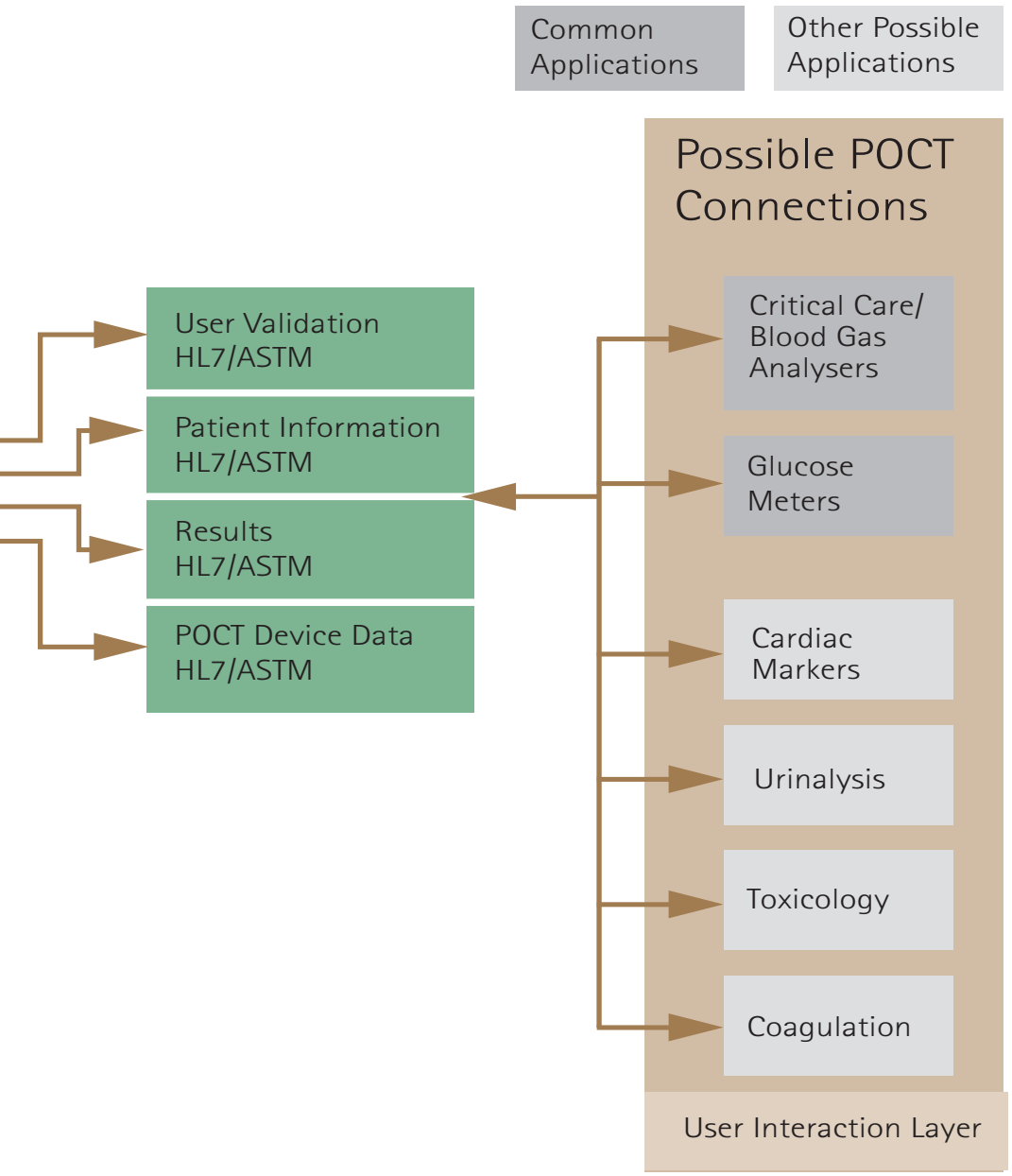
---------- ----------
Clinical Director or Division Head Date

---------- ----------
Laboratory Consultant Date

Appendix 9.6 IT Connectivity Diagram



POCT: Point of Care Testing
PDM: Patient Data Manager
HIS: Hospital Information System
TCP/IP: Transmission Control Protocol / Internet Protocol
ASTM: American Standard for Testing and Materials
HL7: Health Level Seven


Common Applications
Other Possible Applications
Possible POCT Connections
User Validation HL7/ASTM
Patient Information HL7/ASTM
Results HL7/ASTM
POCT Device Data HL7/ASTM
Critical Care/ Blood Gas Analysers
Glucose Meters
Cardiac Markers
Urinalysis
Toxicology
Coagulation
User Interaction Layer