POINT OF CARE TESTING POLICY

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Responsible Lead Executive Director:	**Deputy Director of Acute Services**
Development & Approval Group or Team	
Endorsing Body:	**Acute Services Divisional Management Team**
Governance or Assurance Committee	**Acute Clinical Governance and Risk Management Group**
Implementation Date:	**August 2023**
Version Number:	**1.3**
Review Date:	**September 2026**
Responsible Person	**Principal Clinical Scientist**

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CONSULTATION AND DISTRIBUTION RECORD	
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CHANGE RECORD			
Date	**Author**	**Change**	**Version No.**
May 2018	Risk Department	GDPR statement added into section 3	1.0
Sept 2020	G O'Reilly	Document updated	1.1
Sept 2023	G O'Reilly	Stakeholder list updated New ISO standard (ISO 15189:22) included and referenced Updated RCPath guidance on POCT testing included and referenced	1.2

		Section 4.1.3 Accountability- the POCT Committee will report to the Lab Management Group. Section 4.4 Training- updated to state that barcode sharing is prohibited. Cascade trainers included in the list of staff approved to provide training Section 4.6 Health and Safety- reference to Control of Infection service updated to Infection Prevention and Control (IPC) service Out of date references from further reading section removed	
Jan 2025	G O'Reilly	Further reading section- added updated reference for records management: code of practice for health an social care. Removed reference to superceded document- Annex B "The Management, Retention and Disposal of Personal Health Records.	1.3

1. INTRODUCTION

Point of Care Testing (POCT), also known as near patient testing, involves performing an analytical test in the immediate vicinity of the patient outside a conventional laboratory setting. POCT can be used for screening, diagnostic or monitoring purposes to facilitate local decision making, improve patient safety and improve patient flow. POCT is performed across NHS Lanarkshire (NHSL) in both Primary and Secondary Care.

POCT encompasses a wide range of devices and practices with varying degrees of complexity. Examples of POCT devices currently used in NHSL include blood glucose meters, blood ketone meters, blood gas analysers, blood cholesterol meters, urinalysis test strips (urine dipsticks), urine pregnancy tests and INR meters.

POCT results are often used to inform acute clinical decisions and it is vital that confidence can be placed in results and thus minimise risk to patients.

The objective of this policy is to ensure that all POCT activity within NHSL is performed to acceptable analytical and clinical quality standards and adheres to clinical governance requirements in accordance with MHRA guidance[1], the International Standard for POCT (ISO 15189:2022)[2] and Scottish Government Policy[3, 4].

2. AIM, PURPOSE AND OUTCOMES

The purpose of this policy is to ensure that Point of Care testing of patient samples in NHSL is carried out safely, effectively, accurately and is cost effective. The policy is based on guidance issued by the MHRA[1], The Royal College of Pathologists (RCPath)[5], the Institute of Biomedical Science (IBMS)[6] and the United Kingdom Accreditation Service (UKAS, ISO 15189:2022)[2].

This policy excludes devices classified under the Active Implantable Medical Devices Directive[7] or The Medical Devices Directive[8].

This Policy will set out the following:

- The Terms of Reference of NHSL POCT committee, with appropriate representation from all stakeholders, who would be responsible for overseeing the operation of this policy and for providing professional advice on POCT matters
- The requirements that must be satisfied, and considerations taken into account, when setting up a POCT facility
- The responsibilities of Staff and Clinical Directors for the management of POCT in their area
- The need for continual review of POCT testing services and withdrawal of the service if required.

3. SCOPE

3.1 Who is the Policy intended to Benefit or Affect?

This policy will be of benefit to:

- All patients who have POCT performed across NHSL
- Staff who perform POCT in the knowledge that they will do so in an controlled and safe environment
- Clinical services wishing to introduce new POCT tests
- NHSL Board. To provide the confidence that POCT is carried out safely, effectively, accurately and is cost effective.

3.2 Who are the Stakeholders

NHSL has consulted with the stakeholder listed in Section i) to produce this policy, setting out guidance on the development, implementation and monitoring of POCT.

"NHS Lanarkshire take care to ensure your personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot.nhs.uk or ask a member of staff for a copy of our Data Protection Notice."

4. PRINCIPAL CONTENT

4.1 POCT Committee

4.1.1 Role of the Committee

The POCT committee shall be responsible for minimising risk to patient care by ensuring that all analytical devices within NHSL conform to the guidelines of the MHRA[1], the EU In Vitro Diagnostics Device Directive[9], ISO 15189[2], and the Royal College of Pathologists[5].

The assessment of need will be made by the POCT Committee after consultation with appropriate staff. POCT facilities should be considered when the following conditions are met:

- The patient care/ pathway will be adversely affected by the time taken to obtain a result from the laboratory
- The laboratory turnaround time cannot be reduced to acceptable levels by special laboratory-based emergency services
- When a reliable result can be produced by non-laboratory staff in the Ward or Clinic area within the time scale required (24 hours per day, if required).

POCT should lead to a clinical and /or an economic benefit. For example, the rapid decision may be required to avert a life-threatening crisis, to confirm or exclude a diagnosis, or to use

a test result as a means of improving compliance with therapy as part of a disease management program. An example of this would be administration of glucose in a child following insulin overdose. A POCT glucose result could be used to initiate therapy prior to a laboratory result being available. Prompt treatment could minimise the risk of permanent complications.

The provision of POCT facilities must not prejudice the availability or reliability of laboratory tests to other clinical services.

The committee and users will review the continuing need for POCT.

The committee will establish a system for continual audit and assessment of POCT.

Where there is persistent failure to comply with NHSL POCT Policy, the Committee will consult as necessary but will have the authority to suspend testing and remove any related equipment if required.

4.1.2 Terms of Reference

The composition of the laboratory POCT committee shall include representatives from Biochemistry, Haematology, Microbiology and the Anticoagulant Service. Key link personnel will be co-opted as required fromNursing, Infection Control, Procurement and Information Technology.
Where necessary, the POCT committee will establish sub-groups to deal with the introduction of new equipment, policy development and monitoring of specific POCT processes (e.g. blood glucose monitoring) working with clinical services (diabetes, Emergency Care, obstetrics, neonatal, primary care etc.) as appropriate.

4.1.3 Accountability

Clinical Directors and Managers should also be aware of their responsibility for clinical governance and the medico-legal implications of an erroneous result – especially if the equipment is not used in strict accordance with the manufactures guidelines. Lines of accountability should be clearly written into service level agreements and procedures.
The POCT committee will report to the Laboratory Manangement group.

4.2 Introduction of POCT Processes and Procurement

All proposals for the introduction, extension or replacement of POCT processes and or/ equipment must be formally submitted to the committee. This procedure will apply irrespective of whether any proposed equipment has been loaned, gifted, hired or purchased.

Where a proposal is approved, the POCT committee (or one of its subgroups) will work with the relevant clinical and managerial staff through production of the business case, procurement and commissioning stages. The evaluation should provide details of the capital cost of the equipment, the revenue costs of consumables, the cost of Quality Assessment material and scheme registration (see Section 4.8), repair and maintenance costs, details

of staff costs to perform the test and the availability of laboratory and other staff to support the facility on site or the cost of provision of additional staff to provide this support.

The POCT co-ordinator (a Healthcare Scientist within a laboratory specialty) will be responsible for training (running sessions or organising participation), risk assessment (auditing correct use of POCT etc.) and disseminating information to user level and back to the committee.

The committee will formally sign off the procedure as compliant with NHSL Policy. A formal service level agreement must be agreed between the Laboratory and the clinical service.

4.3 Selection of Equipment

The selection of POCT equipment and consumables shall be made by the POCT committee in conjunction with the clinical service and procurement. The selection must take into account published evaluation reports, ease of use by non-laboratory staff, benefits of standardisation between POCT and laboratory testing across NHSL, accuracy and imprecision, health and safety and running costs. Verification testing should be carried out in conjunction with the laboratory and should include comparing results with those from previous testing (i.e. previous POCT and/or laboratory testing) and gold-standard method.

All POCT devices shall be CE marked[1].

The POCT co-ordinator will keep an up to date record of all POCT equipment. The records should include location, installation date, device serial number, training dates, maintenance schedules and checks of quality performance.

4.4 Training

Only those staff that have been trained and assessed as competent shall be permitted to carry out POCT. Training will be recorded on a central database by the POCT co-ordinator. Only staff members, whose names are maintained on this list, may operate the equipment. The sharing of user barcodes is strictly prohibited. Training will be provided by laboratory staff, designated cascade trainers or equipment manufacturer representatives with input from the POCT co-ordinator. Trained staff will also receive continued support, regular updates and assessment of on-going competence. The frequency of this will vary depending on the individual test and its associated risks.

The training shall include:

- Basic principles of the measurement including performance characteristics
- Demonstration of proper use of the instrument in accordance with the manufacturer specifications including the intended purpose of the device and limitations of use
- Interpretation of results including response to results outside predefined limits
- Demonstration of the consequences of improper use
- Instruction in sample requirements/ collection, including health and safety aspects
- Instruction in the importance of documenting all data generated by the device
- Appropriate calibration and quality assurance procedures
- Storage of reagents (including expiry dates) and samples

- Actions to be taken in the event of fault or instrument breakdown
- Practical experience of the procedures, including a series of analyses that satisfy the instructor that the trainee is competent, must be completed prior to analysis of a patient sample.

Training shall be provided for existing staff and as part of the induction for new staff. All training shall be formally documented in individual staff training records by the Nurse Manager. Training shall be updated on a regular basis and competence re-assessed.

4.5 Standard Operating Procedure (SOP)

There must be a SOP in place and available wherever POCT is performed.

It is essential that any SOP that gives instructions for use reproduces the manufacturer's instructions for use and that all existing copies are updated as appropriate. The SOP must also include patient preparation, sample collection, analytical technique, quality control, quality assessment, result recording, and safe disposal of samples and consumables. These should be written in conjunction with the POCT co-ordinator. [Liability under the Consumer Protection Act (1987)[11] will only remain with the manufacturer or supplier if the user can demonstrate that the equipment has been used in strict accordance with the manufacturer's instructions.]

4.6 Health and Safety

POCT users and managers must recognize the potential hazards of handling and disposing of body fluids, chemical waste and sharps outside of a laboratory setting.

The Infection Prevention and Control (IPC) service may be asked to assess the suitability of the equipment and site to be located. Identification of suitable sites for testing will include assessment of physical security, confidentiality and hygiene standards.

Needle stick injuries and cross infection are obvious risks in POCT. Appropriate health and safety standards must be rigorously applied to protect both the patient and operator. Users, in collaboration with laboratory staff including the IPC service, should agree detailed protocols for patient comfort and safety, the collection and handling of specimens, the disposal of 'sharps' and body fluids, and the routine decontamination of equipment and working surfaces.

Appropriate guidance will be incorporated into the SOP and COSHH assessment which will include the procedures for decontamination. A certificate of decontamination must be available prior to a manufacturer's representative working on the equipment.

4.7 Record Keeping

A record of all results produced by the equipment, including patient results, calibration data, and quality control data shall be maintained in a format agreed with the laboratory. The record should include:

- Identification of the sample e.g. CHI / Hospital number, patient's name and ward (or quality control sample)

- Date and time of sample
- The result
- Identification of the operator.

A record should be maintained adjacent to the measuring facility, or electronically, for assessment and retention by the laboratory. In addition, all the above information should be maintained in a permanent record in the patient's case notes. Networked IT support, where possible, will be employed to facilitate record keeping, audit trails and faster troubleshooting. In the event of recall of POCT devices/ reagents, records must be in place to identify individual patients to be reviewed.

4.8 Quality Assurance

Quality assurance is an essential component of POCT to ensure that results are reliable.

It ensures optimal accuracy of results through regular monitoring of operator performance, reagents and equipment. Quality assurance procedures in POCT should be applied to the same standard as in the routine laboratory setting. It also encompasses operator training and review of overall performance.

Suitable Quality Assessment schemes shall be defined by the laboratory. This will include two components: internal quality control and external quality assessment. Both must be undertaken to ensure reliability of results.

Internal Quality Control (IQC)
The analysis of an appropriate control material, often supplied by the manufacture, before patient sample analysis, can provide reassurance that the system is working correctly. Internal quality control material must be used regularly to an agreed time scale. Some POCT devices incorporate electrical or optical checks, which form part of the internal quality control procedure. A written protocol on IQC procedures, including the recording of results, and the limits of acceptability, must be available to staff performing the tests. If results fall outside agreed limits then analysis of patient samples must cease until appropriate advice is sought and analytical performance is restored.

There must be a permanent record of all IQC results.

External Quality Assessment (EQA)
POCT devices will be registered in an EQA scheme (where available) and must perform adequately as part of Clinical Governance.

EQA involves the analysis of samples with unknown values from an external source. Results are subject to peer group assessment and statistical analysis to compare results across laboratories. This provides a retrospective indication of the POCT device's performance but does not assess the actual sample collection. EQA schemes may be operated by the manufacturer or by a dedicated supplier e.g. National External Quality Assessment Scheme.

The Clinical Laboratories will be responsible for assessing the performance of each device in an EQA scheme. 100% compliance with EQA is expected. A flow chart on how poor compliance and poor performance will be escalated is detailed in Appendix 1.

There must be a permanent record of all EQA results.

4.9 Installation, Supply of Consumables, Maintenance and Repair

The Clinical Laboratories should liaise with the clinical users and arrange the installation and commissioning of the POCT facility. Where the equipment is to be connected directly to the patient, the Medical Physics Department must carry out a full acceptance test which will include testing the electrical safety of the equipment prior to completion of the commissioning process. The equipment shall be included on the laboratory inventory.

On purchase, formal arrangements should be in place for calibration and maintenance of the equipment, in accordance with the supplier instructions. Reagents and consumables must be used in accordance with the supplier instructions. Acceptance testing will be performed in conjunction with the committee and relevant laboratory specialty.

Planned preventative maintenance and repair should be arranged by the laboratory. Where equipment is connected directly to the patient, electrical/electronic repair, carried out by a manufacturer, should be checked by the Medical Physics Department prior to re-connection to the patient. When equipment is in need of routine service or repair, alternative arrangements for testing should be made in advance with the local laboratory. [Failure of proper maintenance and calibration of equipment may lead to misleading and possibly dangerous results.]

4.10 Assessment of Performance

Before results from the equipment are used in patient care, the laboratory must ensure that results are accurate and comparable with those produced by the routine laboratory.

The laboratory specialty will provide a protocol for the clinical user incorporating the regular calibration and quality assessment checks and will agree with the clinical user a procedure whereby laboratory assistance is obtained when those checks fall outside specified limits.

The degree and frequency of quality assessment procedures will be at least that which exists for the same test performed in the routine laboratory. The laboratory specialty, in association with the clinical user, will be responsible for the assessment of the quality of performance of the POCT service. Where performance of the service is deemed by the laboratory to be unsatisfactory, the latter should notify the Consultant or other senior clinical user as soon as possible and should contact the POCT co-ordinator. The clinical user should cease to use the facility immediately until the quality of performance is considered, by the laboratory, to be satisfactory.

4.11 Accreditation and Quality Management

Accreditation is an external audit of the ability of a laboratory to provide a high quality service. In the UK, UKAS defines standards of practice and independently assesses compliance. These standards of practice encompass any POCT service that may therefore

be included in an inspection. By having compliance with national standards independently confirmed, POCT providers are able to give reassurance to users of their service.

POCT systems will be monitored by quality audits reviewing specific areas such as POCT device workload, reliability, internal quality control results, EQA performance, cleanliness, compliance with quality control protocols and recording of patient results. POCT audits will be registered within the Clinical Laboratories using the Quality Management Systems in place. The Quality Co-ordinator of the service will be responsible for the quality of the service and report any problems to the Laboratory Quality Manager.

There will be an annual review of POCT which shall include a review of the clinical need, the clinical effectiveness and the cost effectiveness of POCT. Opportunities for improvement will be identified.

4.12 Information Technology

It is recommended that POCT devices are integrated into Laboratory Information Management systems (LIMS) for onward transmission to SCI store and hospital Patient Management Systems (PMS), wherever possible, in order to maintain a complete record of results. The NHSL Information Management & Technology Department (IM&T) will be consulted when there are any IT implications. Networked IT support, where practical, will be employed to facilitate recordkeeping, audit trails and faster troubleshooting.

4.13 Adverse Incident Reporting

Clinical Incidents shall be reported through DATIX. These shall also be reported to the POCT co-ordinator, who will report to the POCT committee and, where necessary, to the MHRA.

5. ROLES AND RESPONSIBILITIES

Clinical Directors and Managers should also be aware of their responsibility for clinical governance and the medico-legal implications of an erroneous result – especially if the equipment is not used in strict accordance with the manufactures guidelines. Lines of accountability should be clearly written into service level agreements and procedures.

6. RESOURCE IMPLICATIONS

Resource implications and cost- effectiveness will be reviewed for each service by the POCT committee annually.

For services which do not comply with the POCT policy, the requirement for additional resources will be established and recommendations for improvement or removal of the service made by the POCT committee.

7. COMMUNICATION PLAN

The endorsed policy will be launched using the weekly Staff Briefing and will be available on the NHS Lanarkshire Corporate Policies website.

8. QUALITY IMPROVEMENT – Monitoring and Review

The policy has been developed in consultation with all stakeholders and following national guidance.

The policy will be reviewed by the POCT committee in 3 years (36 months) or sooner if there is a significant change which required a review of this document.

The committee will establish a system for continual audit and assessment of POCT by the POCT co-ordinator. The committee will review the continuing need for POCT.

Where there is persistent failure to comply with the NHSL POCT Policy the Committee will consult as necessary but will have the authority to suspend testing and remove any related equipment.

9. EQUALITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire's EQIA [x] (tick box)

10. SUMMARY or FREQUENTLY ASKED QUESTIONS (FAQs)

The purpose of this policy is to ensure that point of care testing of patient samples in NHSL is carried out safely to minimise risk. All areas with existing point of care equipment should have ongoing support and input from the relevant laboratory disciplines. All new requests for point of care testing equipment should be directed to the Point of Care Co-ordinator for discussion and approval at the Point of Care Testing Committee.

11. REFERENCES

1. **Management and Use of IVD Point of Care Test Devices.** Medicines and Healthcare Regulatory Authority DB2010(02)
2. **Medical Laboratories - Requirements for quality and competence** BS EN ISO 15189:2022.
3. **Driving Improvement, Delivering Results: The Scottish Healthcare Science National Delivery Plan 2015-2020.** The Scottish Government (2015)

4. **Review of the Use of Point of Care Testing in Primary and Secondary Care in Scotland.** A report by a Short Life Working Group of the Scottish Medical and Scientific Advisory Committee. The Scottish Government (2011)
5. **Point of Care Testing: National Strategic Guidance for at Point of Need Testing**. The Royal College of Pathologists (2023)
6. **Professional Guidance**: **Point of Care Testing.** Institute of Biomedical Science (2004)
7. **The Council Directive 90/385/EEC on Active Implantable Medical Devices.** The Council of the European Communities.
8. **The Council Directive 93/42/EEC on Medical Devices.** The Council of the European Communities.
9. **The Council Directive 98/79/EC on *in vitro* diagnostic medical devices.** The Council of the European Communities.
10. **The Consumer Protection Act 1987** (commencement No. 1) Order 1987 Statutory Instrument 1987 No. 1680 (C.51). ISBN 0 11 077680 1.

Further Reading

1. **Management and Use of IVD Point of Care Test Devices.** Medical Device Agency DB2002(03)
2. **Management of In Vitro Diagnostic Medical Devices.** Medical Device Agency DB2002(02)
3. **The Retention and Storage of Pathological Specimens and Archives**. Royal College of Pathologists, 4th edition 2009.
4. **Safe Working and the Prevention of Infection in Clinical Laboratories - Model Rules for Staff and Visitors.** Health Services Advisory Committee of Health & Safety Commission 1992.
5. **Protection Against Blood Borne Infections in the Workplace:** HIV and Hepatitis - Advisory Committee on Dangerous Pathogens (ACDP) 1995.
6. **Heath and Social Care-** Records Management: Code of Practice.

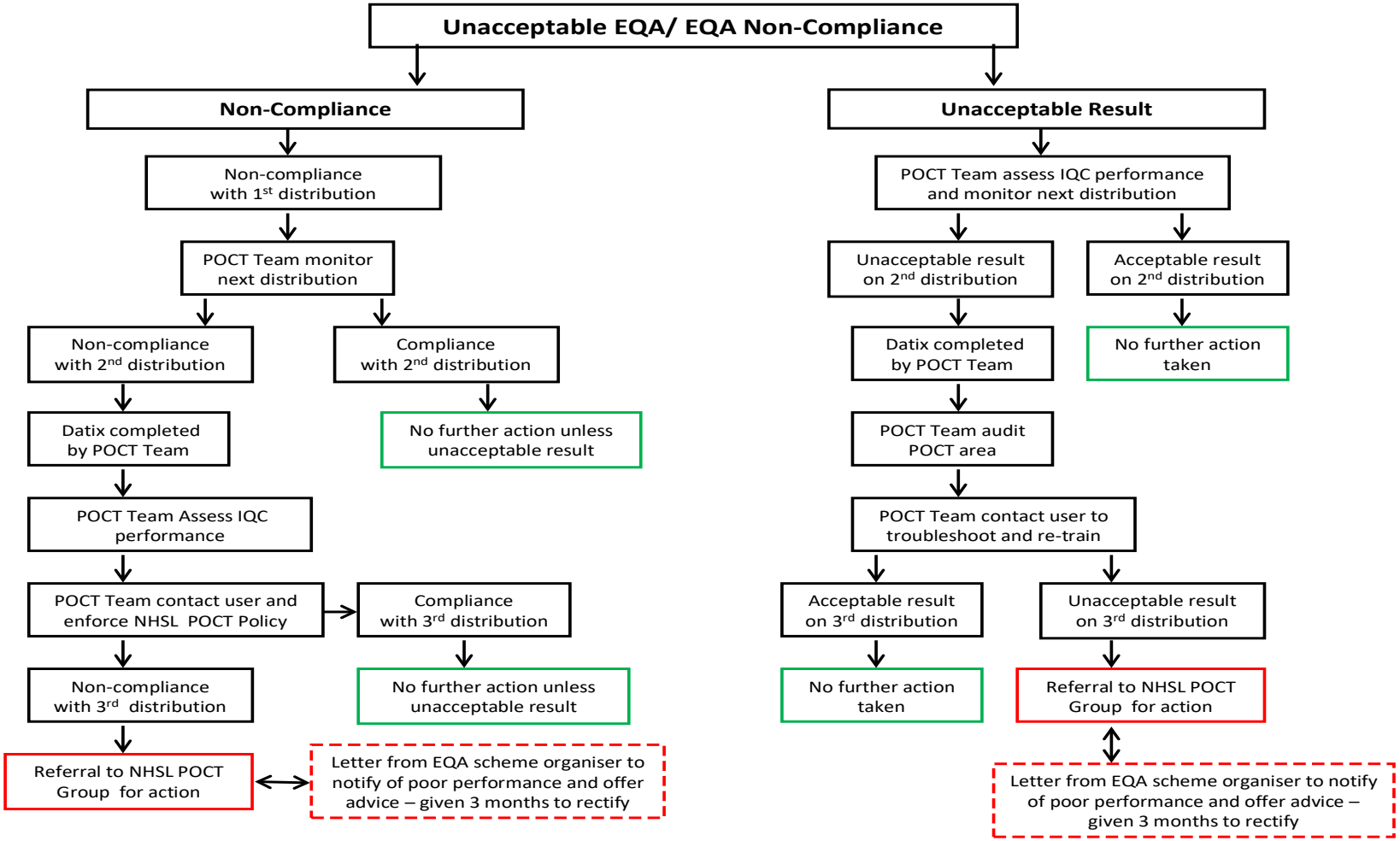
   Records Management Code of Practice for Health and Social Care v4.0
7. Protecting Patient Confidentiality: NHSScotland Code of Practice
   http://www.wdhscp.org.uk/media/1256/revised-code-of-confidentiality-final.pdf

12. CHECKLIST

To be sent to Corporate policies:-

Copy of completed policy
Copy of EQIA
Copy of assurance process document for all policies
Copy of fast-track document if applicable

Appendix 1


Unacceptable EQA/ EQA Non-Compliance
Non-Compliance
Non-compliance with 1st distribution
POCT Team monitor next distribution
Non-compliance with 2nd distribution
Compliance with 2nd distribution
Datix completed by POCT Team
No further action unless unacceptable result
POCT Team Assess IQC performance
POCT Team contact user and enforce NHSL POCT Policy
Compliance with 3rd distribution
Non-compliance with 3rd distribution
No further action unless unacceptable result
Referral to NHSL POCT Group for action
Letter from EQA scheme organiser to notify of poor performance and offer advice – given 3 months to rectify
Unacceptable Result
POCT Team assess IQC performance and monitor next distribution
Unacceptable result on 2nd distribution
Acceptable result on 2nd distribution
Datix completed by POCT Team
No further action taken
POCT Team audit POCT area
POCT Team contact user to troubleshoot and re-train
Acceptable result on 3rd distribution
Unacceptable result on 3rd distribution
No further action taken
Referral to NHSL POCT Group for action
Letter from EQA scheme organiser to notify of poor performance and offer advice – given 3 months to rectify