Policy Directive

NSW GOVERNMENT | **Health**

Managed Point of Care Testing (PoCT) Service

Summary This Policy Directive provides guidance for the safe and effective management and use of PoCT, used by competent individuals using devices that are fit for their intended purpose on the correct patient, giving results which become part of the patient record.

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Applies to Ministry of Health, Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Government Medical Officers, Community Health Centres, NSW Ambulance Service, Public Hospitals, Private Hospitals and day Procedure Centres

Distributed to Ministry of Health, Public Health System, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Health Associations Unions

Audience Medical, Nursing, Laboratory technical and scientific staff, Pathologists, Emergency & ICU Dep, GMs

MANAGED POINT OF CARE TESTING (PoCT) SERVICE

PURPOSE

The purpose of the Managed Point of Care Testing (PoCT) Service Policy Directive is to describe the requirements for a quality assured pathology service using devices located near the patient.

More rapid access to test results provided through the use of PoCT devices can increase clinical effectiveness and contribute to improved patient outcomes. However the result provided by the devices must be accurate, reliable and relevant.

This Policy Directive outlines the requirements for the safe and effective management and use of PoCT. Devices must be fit for their intended purpose and be used by competent individuals on the correct patient. Results become part of the patient record.

The expected outcomes for this Policy Directive are to ensure that:

- PoCT pathology testing is deployed in NSW Health facilities in an accurate, effective and clinically reliable manner supporting safe and optimal care for patients.
- clear standards for the introduction and management of PoCT that maximise patient care and patient safety are provided.
- any associated medico-legal and financial risks are minimised by supporting all operators in implementing PoCT appropriately including those without a laboratory background.
- patients and staff do not suffer avoidable harm or loss.
- staff using PoCT are trained, competent and use safe work practices.
- equipment including facilities and environmental conditions are safe for users.
- compliance with International Standards ISO 15189 and ISO 22870 and any other relevant regulatory requirements so that supervising laboratories achieve and maintain National Association of Testing Authorities Australia (NATA) accreditation for PoCT.
- principles of quality management and continuous improvement for PoCT are applied.

MANDATORY REQUIREMENTS

The mandatory requirements are described in the Procedures at Attachment 1.

IMPLEMENTATION

Effective clinical governance is an essential component of PoCT. This Policy Directive describes a co-operative framework involving both NSW Health Pathology services and local healthcare facility staff.

The multidisciplinary PoCT Clinical Advisory Committee provides governance oversight.

The NSW Health Pathology Operational Team where the PoCT device is situated provides operational oversight of the PoCT Service including laboratory assigned supervision. The local healthcare facility performs testing at the point of care.

Customer Service Charters must specify:

- appropriate use of devices.

- roles and responsibilities for managing the PoCT service.

- measures for compliance with the requirements of this Policy Directive and any other relevant requirements.

NSW Health Pathology provides an electronic management solution for PoCT devices to support clinical governance and accreditation objectives by:

- electronically transmitting a patient result to the Laboratory Information System (LIS) in which they then become part of that patient medical record.

- monitoring both operator and device performance.

- allowing for remote management of devices including preventing device operation if the competency of the operator has not been assessed or reassessed within appropriate intervals.

- supporting e-learning for ongoing competency assessment.

Public Health Organisations (PHOs) and NSW Health Pathology must ensure that all relevant staff comply with this Policy Directive.

REVISION HISTORY

Version	Approved by	Amendment notes
PD2018_028 (July 2018)	Deputy Secretary, Population and Public Health	Minor editing throughout.
PD2015_028 (August 2015)	DDG approval	Removed two appendices Updated Appendix 1. Minor editing throughout. No major content changes.
PD2014_003 (January 2014)	DDG approval	New policy

ATTACHMENT

1. Managed Point of Care Testing (PoCT) Service: Procedures

Managed Point of Care Testing (PoCT) Service

NSW GOVERNMENT | **Health**
PROCEDURES

CONTENTS

1   BACKGROUND

The driving forces increasing the demand for PoCT include clinician demand for best practice treatments, the need for more rapid results and advances in technology resulting in new devices.

PoCT is performed in many locations throughout NSW Health facilities including Emergency and ICU departments and clinics and other settings.

Advantages of PoCT include:

- improved equity of access

- greater satisfaction for patients who require care in rural and remote communities or who are unable to travel from home

- improved patient compliance with testing due to the convenience of PoCT and, in some instances, more simple sample collection

- more rapid provision of test results particularly the reduced time between collection and analysis.

This ensures more timely treatment reducing the risk of harm and increasing the likelihood of more effective healthcare outcomes.

1.1   About this document

This document applies to all approved PoCT services and equipment incorporated into the NSW Health Pathology's Managed PoCT Service and covers the management and use of these devices irrespective of who performs the test.

The process for approval of devices is detailed in the PoCT Device Commissioning Flowchart (Attachment 1).

1.2   Key definitions

Point of Care Testing (PoCT) is defined as pathology testing performed in close proximity to a patient by a healthcare worker and usually outside the precincts of a traditional laboratory. Other terms commonly used to describe PoCT include:

a)   Near patient testing (NPT)

b)   Bedside testing

c)   Physician office testing

d)   Extra-laboratory testing

e)   Disseminated laboratory testing.

Managed PoCT Service is defined as an organisational framework that delivers an integrated PoCT service according to defined standards to provide results in a short period of time because of clinical urgency.

Operator refers to registered medical practitioners, nurses, midwives, and other healthcare workers including laboratory staff.

Quality Assurance is the process of assuring that diagnostic services have been performed in an appropriate and approved manner adequate to meet an agreed standard of medical care.

1.3 Abbreviations

APA	Approved Pathology Authority
APP	Approved Pathology Provider
ARTG	Australian Register of Therapeutic Goods
eMR	Electronic Medical Record
EQA	External Quality Assurance
ISO	International Organization for Standardization
ISO 15189	International Standard -Medical Laboratories – Requirements for quality and competence - Requirements for quality and competence
ISO 22870	International Standard - Point-of-care testing (POCT) - Requirements for quality and competence
IT	Information Technology
KPI	Key Performance Indicator
LIS	Laboratory Information System
NATA	National Association of Testing Authorities, Australia
NPAAC	National Pathology Accreditation Advisory Council
NPT	Near Patient Testing
NSWHP	New South Wales Health Pathology
PHO	Public Health Organisation
PoCT	Point of Care Testing
QA	Quality Assurance
QC	Quality Control
RCPA	Royal College of Pathologists of Australasia
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
WH&S	Workplace Health and Safety

1.4 Regulatory Framework

NSW Ministry of Health requires that NSW Health staff comply with all approved jurisdictional policies and legislation regulating and assuring the quality of pathology results.

The [Accreditation of Pathology Laboratories in NSW Health Policy Directive PD2017_011](#) states that accreditation of NSW Health Pathology laboratories is required by the Commonwealth to meet uniform standards of practice, competently perform tests and examinations, and produce accurate and reliable results in order to attract Medicare benefits.

2 MANDATORY REQUIREMENTS FOR A MANAGED PoCT SERVICE

2.1 General

2.1.1 Pathology testing that is performed on approved PoCT devices must conform to this Policy Directive.

2.1.2 PoCT will only be approved for use as an alternative to a laboratory based service if there is a significant demonstrable benefit to patient care or clinical outcomes.

2.1.3 The Managed PoCT Service must comply with all relevant NPAAC Standards and International Organization for Standardization (ISO) Standards ISO 15189 Medical laboratories – Requirements for quality and competence and ISO 22870 Point-of-care testing (POCT) Requirements for quality and competence.

2.1.4 The service must review all requests to establish PoCT and must approve all such services and the devices to be used before PoCT is implemented.

2.1.5 Testing locations performing PoCT must be authorised to provide PoCT testing by the Local Health District (LHD).

2.1.6 Each staff member performing PoCT tests must be trained and assessed as competent. This training and assessment must occur before commencing testing.

2.1.7 PoCT devices must be periodically evaluated for their ongoing suitability.

2.1.8 PoCT devices may be withdrawn and PoCT services suspended if:

- PoCT service testing locations fail to comply with this Policy Directive
- a significant safety issue has occurred
- the instrumentation is misused or operator accreditation or certification is deficient
- there are concerns in relation to accuracy of results
- there is a lack of clinical effectiveness
- the expected benefits for using PoCT are not realised.

Services may be reinstated if evidence of remediation or resolution is provided.

2.2 Service Introduction

2.2.1 Applications to introduce, modify or change POCT services or devices must be submitted on the [Application Form for PoCT Service Form](#).

2.2.2 Implementation of PoCT by NSW Health Pathology must be in collaboration with the LHD or relevant clinical service team and the supporting NSW Health Pathology Operational Team and must be integrated into the clinical framework of the health service.

2.2.3 The application must:

    a) identify if PoCT will replace, or will be in addition to, laboratory testing

    b) identify how PoCT will be integrated in to clinical pathways and guidelines

    c) address the benefits to clinical need and effectiveness

    d) define quality key performance indicators (KPIs).

2.2.4 Only approved devices will be endorsed and supported by this policy and procedure, irrespective of how the devices are financed, for example, purchased, loaned, gifted, leased, etc.

2.2.5 Devices will be commissioned once adequate numbers of competent operators have been trained, assessed and accredited. 'Adequate numbers' of operators will be determined by the management at the requesting test location.

2.2.6 A Customer Service Charter must be agreed and signed before implementation of PoCT services.

2.3 Accreditation

2.3.1 All PoCT services must be accredited by National Association of Testing Authorities, Australia (NATA).

2.3.2 Under Commonwealth legislation, all PoCT devices must be approved for use by the Therapeutic Goods Administration.

2.4 Patient Results

2.4.1 All patient results must be entered into, or transferred to, the appropriate LIS so they become part of the electronic medical record (eMR).

2.4.2 Results from PoCT devices must be clearly distinguishable in the LIS and eMR from results derived from laboratory analysers.

2.5 Networking

2.5.1 All new PoCT devices included in the Managed PoCT service must be:

    a) capable of transferring patient results electronically to the LIS.

    b) linked to NSW Health Pathology's PoCT Management System.

2.6 Supporting Documentation

2.6.1 A copy of the operational procedure for each device must be readily available near the PoCT instrument. Electronic copies are available from the NSW Health Pathology internet.

2.6.2 The procedure must contain:

- principle of examination
- sample requirements

- reagent storage

- calibration procedure (if appropriate)

- testing procedure and use of all related equipment

- maintenance and troubleshooting procedures including device error messages

- result interpretation including critical alert limits and reference ranges

- competency assessment criteria

- response to abnormal or unexpected results

- limitations of procedure including known interferences and limits of detection

- Quality Control (QC) and External Quality Assurance (EQA) procedures and Quality Control Record Sheets

- safe work practice and infection control information

- requirements and processes for recording results

- storage of documentation relating to testing ie printed test results.

2.7 Safety

2.7.1 Only PoCT devices and associated equipment that have satisfied Workplace Health & Safety requirements may be commissioned.

2.7.2 Specimens, reagents and other consumable supplies must be handled and disposed of according to safe work practices.

2.7.3 Devices and associated equipment must be located/stored, used and managed according to safe work practices.

2.8 Quality Control and External Quality Assurance

2.8.1 Prescribed quality control and quality assurance must be performed on all devices for all analytes as specified by the Managed PoCT Service to achieve compliance with the NATA Medical Testing Field Application Document Requirements for Accreditation (2013).

2.8.2 All devices must be enrolled in an EQA program for every analyte/test performed. If a commercial EQA is not available, an internal "interlab" program is mandatory.

2.8.3 Quality control and external quality assurance must be performed by certified operators. It is recommended that a representative sample of staff who use the device participate in the EQA program. All results must be recorded and retained for a period according to NPAAC Requirements.

2.9 Device Maintenance

2.9.1 Maintenance of devices is the responsibility of staff employed at the testing

location performing PoCT.

2.10   Training and Competency Assessment

2.10.1 Initial training for devices must include 'face-to-face' training.

2.10.2 Training must be undertaken by an approved trainer. Knowledge/skill training requirements must include:

- the ability to demonstrate appropriate use of the device.
- pre-analytical requirements such as sample collection, reagent storage requirements, safety and infection control practices.
- the ability to identify results that fall outside of reference ranges.
- device maintenance.
- an understanding of Quality Control (QC) and Quality Assurance Program (QAP).

2.10.3 All staff performing PoCT must be initially assessed for competence by an approved trainer, for all devices they use.

2.10.4 All staff performing PoCT must be reassessed for competence periodically. The interval between re-certification of competency will be dependent on the device type, testing frequency and may be varied if there is any deficiency in performance of PoCT at the testing location. Minimum intervals for re-certification are to be specified in service level agreements.

2.10.5 All training will be followed by competency assessment.

2.10.6 Competency assessment records must be stored on site and retained in accordance with NPAAC Requirements.

2.11   Incident Reporting

2.11.1 Any incident involving PoCT devices must be reported in the NSW Health Incident Information Management System (IIMS) in accordance with the Incident Management Policy.

2.11.2 Any non-clinical issue relating to reagents, devices, quality control, EQA must be reported to the management at the testing location and be made the subject of a corrective action report in accordance with current standards.

2.12 Internal and External Audit

2.12.1 PoCT Services are subject to internal and external audits to assure quality and compliance with accreditation requirements**.**

3 APPENDIX

Attachment 1: PoCT Device Commissioning Flowchart