Policy

Equipment Traceability

NSWHP_PD_017

1. Purpose

This policy:

a) Provides the calibration requirements for the introduction of new or replacement equipment and the management of existing equipment that have a significant effect on the validity of test results

b) Ensures consistency across NSW Health Pathology laboratories in equipment calibration and in-house performance checking which will be dependent on the criticality of the equipment determined by the frequency of use and the test sensitivity of the result. A small error in calibration can cause a large error in the final result

c) Minimises associated medico-legal risks by establishing a traceable chain of calibrations performed by an accredited calibration laboratory with regular in-house performance checks of equipment where performance may affect the quality of test results

d) Ensures compliance with the following International Standards so that NSW Health Pathology laboratories achieve and maintain metrological traceability of equipment:

   i. ISO/IEC 17025 *General Requirements for the competence of testing and calibration laboratories* and
   ii. AS ISO 15189 *Medical Laboratories – Requirements for quality and competence*

e) Provides the requirements to comply with traceability and calibration specifications of equipment used by facilities accredited by the National Association of Testing Authorities (NATA)

f) Is supported by NSW Health Pathology procedures for different types of equipment.

2. Background

The policy improves consistency of approach to metrological traceability of all items of equipment deemed to have a significant impact on the uncertainty of the result.

3. Scope

This policy is mandatory and applies to all NSW Health Pathology laboratories.

4. Definitions

Accredited calibration laboratory: The Scope of Accreditation specifically identifies the appropriate service suitable for the intended need and the accrediting body is covered by the International Laboratory Association Cooperation Mutual Recognition Arrangement (ILAC MRA) for calibration.

Equipment Assurance Program: Facilities are responsible for establishing their own equipment assurance programs. This is to ensure that all equipment used satisfies the need to produce consistent, reliable and, where appropriate, traceable results. In accordance with the NATA General Accreditation Criteria – Equipment assurance, in-house calibration and equipment verification, when establishing an equipment assurance program, consideration must be given to the following:

- History of stability
- Frequency of use
- Accuracy required
- Requirement for traceability of measurement
- Ability of staff to perform in-house checks and
- Successful participation in proficiency testing programs for the testing for which the equipment is used.

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In-house performance check: The measurement of at least one point within a working range of a measuring instrument to confirm that it has not deviated significantly from its calibrated value.

Metrological traceability: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Quality Management System: As defined in the ASQ Quality Glossary, a Quality Management System (QMS) is a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organisation's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Traceable calibration report: A report or certificate documenting that a specific asset, identified by model and serial number, and calibrated in a manner traceable to national or international standards in accordance with AS ISO/IEC 17025.

Working range: The total measuring range for which the manufacturer's performance specifications are given.

5. Policy Statement

5.1 Calibration Reports

a) New or replacement equipment deemed to be critical must have a traceable calibration report prior to being approved for routine use.

b) Equipment requiring repairs or maintenance must have a new traceable calibration report prior to being returned to routine use. In some instances, it may be more cost-effective to purchase a replacement unit with a traceable calibration report and downgrade the older equipment to non-critical.

5.2 Performance Checks

a) Following the introduction of a critical piece of equipment into routine use, the equipment shall undergo periodic in-house, or external, performance checks to re-evaluate its ongoing stability and to determine that it has not been adversely affected by use.

b) External performance checks or calibrations must be conducted by an appropriately accredited facility.

5.3 Equipment Assurance Schedule

a) The laboratory must establish and maintain an in-house, or external, performance checking program to ensure metrological traceability of the measurement results is maintained.

b) The program shall be periodically reviewed and adjusted as necessary to maintain confidence in the status of calibration.

5.4 Retention of Records

The laboratory must maintain records for each item of equipment including:

a) The traceable calibration report and

b) Evidence of the in-house, or external, performance checks including stable or unstable performance.

As a minimum, each asset record shall include:

a) The identity of the asset, that is, the manufacturers name and model number
b) Reference to the current calibration certificate including the period of validity
c) Asset serial number or other unique identifier
d) The current asset location
e) Acceptance criteria, results of all checks, the in-house performance check dates, the due date of the next in-house performance check or the in-house performance check frequency, where possible
f) Details of any damage, malfunction, modifications or repairs carried out and
g) Evidence and/or justification for determining criticality of individual assets.

The asset records and equipment compliance audits conducted as part of a Quality Management System must be retained for the life of the equipment plus one NATA cycle.

6. Roles and Responsibilities

Laboratory staff must comply with this policy.

Laboratory Managers must ensure that

a) Records of calibrations, in-house performance checks and maintenance activities are maintained in the relevant QMS

b) All relevant equipment is included in the equipment assurance schedule covering in-house performance checks, external calibration activities and maintenance activities as required.

The Quality Management Team will monitor compliance with this policy through regularly scheduled audits.

7. Legal and Policy Framework

AS ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories

AS ISO 15189 Medical Laboratories – Requirements for quality and competence

ASQ Quality Glossary

NATA General Accreditation Criteria – Equipment assurance, in-house calibration and equipment verification

NATA General Accreditation Guidance – General Equipment Table

NATA General Accreditation Criteria – Metrological Traceability Policy

8. Review

This policy will be reviewed by 30 June 2023.

9. Risk

Risk Statement	Adherence to equipment traceability standards to validate calibration status safeguards accuracy of reporting, ensures we provide quality and reliable services to our customers and reduces the likelihood of legal or reputational harm.
Risk Category	Clinical Care and Patient Safety

10. Further Information

For further information, please contact:

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11. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Policy Author	Risk Rating	Sections Modified
1.0	28/06/19	Clinical Governance Quality and Risk Committee	30/04/19	Quality Manager, FASS, Edited by Senior Policy Officer	High	New Procedure.
1.1	12/07/2021	Director Clinical Governance	18/05/2021	Quality Manager, FASS.	High	Section 7 – updated links to NATA documents Section 10 – updated policy contact