NSW Health Pathology Quality Manual

NSWHP_CG_012

Contents

Access to the Health Intranet and the Internet is necessary for all links to function properly

1 Introduction

This Quality Manual describes the operation of the NSW Health Pathology (NSWHP) quality management system (QMS) and replaces all previous quality manuals from the separate NSWHP Pathology sectors, including the services provided by the NSWHP Point of Care Testing Service and NSWHP Forensic & Analytical Science Service.

The Clinical Governance and Quality Management Framework of NSWHP including the NSWHP Compliance Management Framework (NSWHP_CG_010) and regulative environment in which it operates can be found in the NSWHP Clinical Governance Framework (NSWHP_CG_009).

NSWHP operates various quality system software and manual platforms which comply with and are embraced by the QMS and this quality manual. These systems encompass, at least, document control, audit management, non-conformity and complaint management, corrective actions and risk management and quality records.

Operational Sector	QMS Delivery Tools
Corporate	NSWHP Intranet Policy Library
East	Various manual systems
FASS	Q-Pulse (instance 1)
North	Pandora
Point of Care	Cubit, CRM, POCCelerator, Aqure
West, Regional & Rural	Q-Pulse (instance 2)
South	IQMS
Statewide Biobank	Various manual systems
BMT Network	Q-Pulse (instance 3)

1.1 Scope of the Quality Management System

The scope of the Quality Management System to which this quality manual applies is the leadership group, their activities and functions and the laboratories of NSWHP. It does not include the Statewide BioBank or the Blood and Marrow Transplant (BMT) Network. The BMT Network of Laboratories and associated Apheresis units are NATA accredited and have a separate Quality Management System and Quality Manual.

The Quality Manual is intended for use by NSWHP to ensure laboratory services meet the needs of users and provide a framework for compliance with the international standards and requirements of

a) ISO 15189:2022 Medical Laboratories-Requirements for quality and competence,
b) ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories,
c) ISO 9001:2015 Quality management systems — Requirements,
d) NPAAC website for NPAAC standards,
e) NATA website for compliance requirements for accreditation,
f) Any other relevant Standards and statutory requirements, including but not limited to those applicable and issued by the
    - RCPA website,
    - Medicare for the granting of an Approved Pathology Authority, an Approved Pathology Laboratory, and Approved Pathology Provider, and of the
    - Australian Therapeutic Goods Administration (TGA) website.

The sections in this document correspond with and reference the relevant clauses of ISO 15189:2022, ISO/IEC 17025 and/or ISO 9001. Copies of these and other standards can be accessed via the NSWHP intranet site at Accessing Standards.

This manual should be read in conjunction with the NSW Health Managed Point of Care Testing (PoCT) Service (PD2018_028) which is available with other PoCT information in NSWHP website PoCT documentation.

It is intended that this Quality Manual links and unifies the previous quality management systems of NSWHP and has dominance over other documents. Where there is conflict, this document has precedence.

All testing and management of NSWHP services are subject to the requirements of the quality management system and this Quality Manual.

1.2 References

a) NSWHP Compliance Management Framework (NSWHP_CG_010)
b) NSWHP Clinical Governance Framework (NSWHP_CG_009)
c) Accessing Standards
d) Australian Commission on Safety and Quality in HealthCare: NPAAC website
e) NATA website
f) RCPA website
g) Australian Therapeutic Goods Administration (TGA) website
h) NSW Health Managed Point of Care Testing (PoCT) Service (PD2018_028)
i) NSWHP POCT documentation

2 New South Wales Health Pathology

In August 2011, a NSW Health report titled ***Future Arrangements for the Governance of NSW Health*** identified the potential value of creating an integrated, state-wide public pathology service to support our public hospitals and health services.

In November 2012, the Director-General endorsed a state-wide model that brought together the four previously separate pathology networks – Pathology North, Pathology West, South Eastern Area Laboratory Services and Sydney South West Pathology Service to form NSWHP. NSWHP is committed to delivering efficient, effective and transparent services for the people of NSW. We have set out important structures, systems, processes and behaviours to help us achieve this in an open, accountable and impartial way.

Our governance structure is underpinned by a range of strategic documents that collectively contribute to robust and strong systems and processes.

In December 2012, the Director-General endorsed the merger of Forensic Medicine services across the state with the former Division of Analytical Laboratories at Lidcombe to create a fifth NSWHP network, the Forensic & Analytical Science Service.

2.1 Governance

NSWHP is responsible for the strategic leadership and decision-making to ensure the people of NSW have access to the public pathology, forensic and analytical science services they need, while operational accountability for the delivery of those services is devolved to operational sectors.

The NSWHP Strategic Leadership Team works to deliver state-wide strategies and benefits, foster greater collaboration, and improve the long-term sustainability of services across NSW.

The NSWHP Board provides strategic advice and support to the executive and is made up of stakeholder representatives including clinicians, pathologists, and scientists who oversee corporate and clinical frameworks designed to ensure the organisation provides sustainable, responsive, efficient, and high-quality services.

NSWHP operates more than 60 pathology laboratories and over 200 collection services, an extensive managed point of care testing (PoCT) service, and delivers forensic services to provide independent, objective analysis to the NSW health and justice systems.

3 Abbreviations

APA	Approved Pathology Authority
APL	Accredited Pathology Laboratory
Cth	Commonwealth
EQA	External Quality Assurance
eMR	Electronic Medical Record
FASS	Forensic & Analytical Science Service
ICT	Information and Communication Technology
ims+	State-wide Incident Management System
IVD	In Vitro Diagnostic Device
OFI	Incident / suggestion captured into the Quality Management System
LHD	Local Health District
LIS	Laboratory Information Systems
NATA	National Association of Testing Authorities, Australia
NPAAC	National Pathology Accreditation Advisory Council
NSWHP	New South Wales Health Pathology
PoCT	Point of Care Testing
QAP	Quality Assurance Program
QMS	Quality Management System
RCPA	Royal College of Pathologists of Australasia
RMO	Registered Medical Officer
ROB	Recruitment and Onboarding
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
WHS	Work Health & Safety

4 General Requirements

4.1 Impartiality

NSWHP is committed to the impartiality and ethical conduct of its laboratory activities and aims to prevent commercial, financial, or other pressures from compromising its impartiality.

All NSWHP employees must comply with the following:

a) NSW Health Code of Conduct (PD2015_049)
Section 4.2.3 Demonstrate honesty and integrity:
"Staff must ensure that their actions and decisions are not influenced by self-interest or considerations of personal gain or other improper motives".
b) NSW Health Conflicts of Interest and Gifts and Benefits (PD2015_045)
c) Corrupt Conduct - Reporting to the Independent Commission Against Corruption (ICAC) (PD2016_029)
d) NSW Health Pathology Fraud and Corruption Control Policy (NSWHP_PD_024)
e) NSW Health Pathology Conflicts of Interest and Gifts and Benefits Procedure (NSWHP_PR_001)

NSWHP employees must evaluate all activities they become aware of which relate either to operations or to individuals within the organisation regarding risk to impartiality or confidentiality. The main evaluation criteria are whether the activity might diminish trust in competence, impartiality, confidentiality, judgement, or operational integrity of NSWHP.

Online registers are available on the NSWHP intranet where staff can: -

- Declare a conflict of interest
- Register a gift or benefit

(See: ISO 15189:2022 Clause: 4.1; ISO/IEC 17025:2017 Clause: 4.1; ISO 9001:2015 Clause(s) 4.2)

4.2 Confidentiality

Procedures are in place to ensure privacy and confidentiality of patient identifying information is always maintained in accordance with the NSW Health Privacy Manual for Health Information and NSW Privacy legislation.

The NSW Health Code of Conduct (PD2015_049) Section 4.5 details how NSWHP staff must maintain the security of confidential and/or sensitive official information.

NSWHP Information Security Management System Framework (NSWHP-CG-011) provides Policies and Procedures to protect against unauthorised access to patient/customer information and safeguard against tampering and loss of data.

NSWHP monitors IT system audit trails for evidence of inappropriate access or use of patient data in accordance with sect 16.3.4 of the NSW Health Privacy Manual for Health Information. Key elements that are retained in system audit trails to support such monitoring may include: -

- Name and ID of employee or contractor
- Position or designation of employee or contractor
- Name and MRN of health record accessed / altered
- Section(s) of the health records viewed / altered
- Date and time access commenced
- Date and time access ceased
- Details of alterations made
- Device ID (eg. MAC ID and IP Address)

This audit trail data may be shared with managers, the relevant Executive Director, the NSWHP Privacy, Right to Information and Records Officer, or NSWHP Human Resources, to facilitate the investigation of confidentiality breaches.

Any risks to confidentiality identified by employees must be reported and resolution sought from managers, the relevant Executive Director, the NSWHP Privacy, Right to Information and Records Officer, or NSWHP Human Resources team as required.

(See: ISO 15189:2022 Clause: 4.2; ISO/IEC 17025:2017 Clause: 4.2; ISO 9001:2015 Clause(s) 4.2)

4.3 Requirements regarding patients

The NSW Health Code of Conduct (PD2015_049) Section 4.6 details that NSWHP staff must maintain professional relationships with patients or clients.

Patients' wellbeing, safety and rights are central to NSWHP operations. Where relevant, patients and users are provided with information relating to the examination services and any costs associated.

Informed consent will always be sought when required and services provided without discrimination.

All staff treat human tissues, body parts, and remains with respect in line with the RCPA's *Ethical and Legal Issues in Relation to the Use of Human Tissue in Australia and New Zealand*.

In the event that NSWHP merges with, or acquires management of, an established laboratory, records and diagnostic specimens shall be retained by the previous owner or transferred to NSWHP to ensure the ongoing integrity of records and retained patient samples. Additionally, if a NSWHP laboratory should close, the records and diagnostic specimens that belong to that laboratory shall be transferred to the parent Category GX laboratory or other suitable laboratory in the network, to ensure the ongoing integrity of records and retained patient samples after the laboratory has closed.

(See: ISO 15189:2022 Clause: 4.3; ISO/IEC 17025:2017 Clause: 4.2; ISO 9001:2015 Clause(s) 4.2)

5 Structural and Governance Requirements

5.1 Legal Entity

NSWHP (ABN 49 382 586 535) is the leading provider of clinically integrated pathology services supporting quality patient outcomes for the public health system of NSW. NSWHP is a division of the Health Administration Corporation established under the Health Administration Act (NSW) and delegated various functions of the NSW Secretary of Health, including the development and implementation of rigorous clinical and corporate governance frameworks that provide sustainable, responsive, efficient, high quality pathology, forensic and analytical science services.

The Strategic Leadership Team is accountable for delivering state-wide strategic initiatives that leverage our economies of scale and integration opportunities across NSW.

NSWHP holds an Approved Pathology Authority (1142) under the *Health Insurance Act (Cth)*.

(See: ISO 15189:2022 Clause: 5.1; ISO/IEC 17025:2017 Clause: 5.1; ISO 9001:2015 Clause(s) 4, 4.1)

5.2 Laboratory Director

Local Pathology Directors of Category GX Laboratories act as the 'designated person', in accordance with NPAAC supervision requirements, and under whose direction and control the laboratory and those under its direction operates. In cases where the GX laboratory has responsibility for regional laboratories, the Designated Person delegates local management responsibilities to Local Pathology Directors based at regional sites.

In addition, Clinical Directors, Supervising Pathologists, Directors of Operations, Senior Operations Manager, Operations Managers and Laboratory Managers operate within their level of delegation and scope of practice to supervise and manage laboratories in accordance with the NPAAC Requirements:

a) NPAAC Requirements for *Medical Pathology Services*
b) NPAAC Requirements for *Supervision in the Clinical Governance of Medical Pathology Laboratories*

There are 6 state-wide Clinical Streams.

- Anatomical Pathology Clinical Stream
- Chemical Pathology Clinical Stream
- Haematology Clinical Stream
- Immunology Clinical Stream
- Microbiology Clinical Stream
- Transfusion Clinical Stream

These Clinical Streams are a critical part of the NSW Health Pathology organisational structure, providing expert advice and assistance to achieve the organisation's strategic directions and initiatives as documented in the NSW Health Pathology Strategic Plan: Towards 2025

In addition to the Clinical Streams are a number of statewide services including: -

- Genomics
- Point of Care Testing
- Pre and Post-Analytical
- Biobank
- Non-Coronial Post Mortem
- Perinatal Post Mortem
- Public Health
- Mass Specrtrometry

(See: ISO 15189:2022 Clause: 5.2; ISO/IEC 17025:2017 Clause: 5.2; ISO 9001:2015 Clause(s) 5.1)

References

1. Health Services Act
2. *Health Insurance Act (Cth)*
3. NSW Health Code of Conduct (PD2015_049)
4. NSW Human Tissue Act
5. NSW Health Organ and Tissue Donation, Use and Retention (PD2022_035)
6. Use of Human Tissue for Research (GL2023_008)
7. RCPA Ethical and Legal Issues in Relation to the Use of Human Tissue in Australia and New Zealand
8. NSW Health Conflicts of Interest and Gifts and Benefits (PD2015_045)
9. NSW Health Records and Information Privacy Act
10. NSW Health Privacy Manual for Health Information
11. NSW Health Pathology Fraud and Corruption Control Policy (NSWHP_PD_024)
12. NSW Health Enterprise-Wide Risk Management (PD2022_023)
13. NSWHP Enterprise Risk Management Procedure (NSWHP_PR_026)
14. NSW Health Pathology Strategic Plan: Towards 2025
15. NPAAC Requirements for *Medical Pathology Services*
16. NPAAC Requirements for *Supervision in the Clinical Governance of Medical Pathology Laboratories*
17. Media Relations Guideline (NSWHP_PG_001)
18. NSWHP Release of Results Policy (NSWHP_PD_016)

5.3 Laboratory Activities

NSWHP provides ready access to competent key employees for clients seeking technical and medical support, including interpretation of examination results, advice on choice of examinations, repeat frequency and specimen type, on a 24-hour, 7-day per week basis. Medical staff specialists are available on-call out-of-hours for consultation.

Medical and scientific staff participate in a range of clinical and multi-disciplinary team meetings, including clinical-pathologic correlation sessions, grand rounds, RMO and registrar training and development meetings, medical education meetings, Quality and Patient Safety Meetings, clinical incident root cause analysis investigations, and other meetings at all levels as requested or desirable.

The NSWHP Test Catalogue provides information to staff, clinicians, and patients, on the examinations offered by NSWHP, testing frequency, turn-around time, collection and transport requirements, referred testing arrangements, method details and result interpretation. Client doctors and specialists are encouraged to visit laboratories to facilitate the consultative process.

NSWHP is committed to working with its clinical referrers to achieve quality use of pathology.

(See: ISO 15189:2022 Clause: 5.3; ISO/IEC 17025:2017 Clauses: 5.3 , 5,4; ISO 9001:2015 Clause(s) 5.1.2)

5.4 Structure and Authority

NSWHP has a governance structure to deliver on the objectives of the Quality System. The NSWHP Governance Structure may change from time to time as it adapts to changing organisational need. To reproduce it here in the Quality Manual could require frequent revision. Readers should view the current Governance Structure on the NSWHP intranet.

(See: ISO 15189:2022 Clause: 5.4; ISO/IEC 17025:2017 Clause: 5.5; ISO 9001:2015 Clause(s) 5.2, 5.3)

5.5 Objectives and Policies

In NSWHP's current strategic plan**,** NSW Health Pathology Strategic Plan: Towards 2025, the Strategic Leadership Team and Board have endorsed eight new NSWHP Strategic Priorities that align with the State priorities: -

01 Keep people healthy and safe
02 Deliver world class services where safety is first
03 Integrate systems to deliver truly connected care
04 Develop and support people and culture
05 Support and harness research and innovation
06 Enable advances in technology, data, and analytics
07 Deliver future-focused infrastructure and strategic commissioning
08 Maintain robust governance and financial sustainability

The definition of success for each objective is included in the plan.

(See: ISO 15189:2022 Clause: 5.5; ISO/IEC 17025:2017 Clause: 5.5; ISO 9001:2015 Clause(s) 5.3)

5.6 Risk Management

Identification of risks.
Employees are empowered to identify potential nonconformities, near-misses and risks as an essential tool towards continuous improvement of processes and are encouraged to report these as non-conformances in the Quality Management System.

Actions taken.
If mitigating action is required, action plans are developed, including a risk assessment, and implemented to reduce the likelihood of nonconformity and to take advantage of the improvement opportunity.

The development and implementation of action plans are monitored and recorded in the relevant nonconformity management system and the plans include the initiation of procedures and application of controls that ensure the effectiveness of prevention of nonconformity. A designated officer is responsible for establishing whether acceptable preventive action has been achieved.

Records
Any risks identified are documented and managed in accordance with the NSW Health Enterprise-Wide Risk Management (PD2022_023) and the NSWHP Enterprise Risk Management Procedure (NSWHP_PR_026) using NSWHP electronic Statewide Risk Register. The NSWHP Strategic Leadership Team has oversight of all documented risks.

(See: ISO 15189:2022 Clause: 5.6; ISO/IEC 17025:2017 Clause: 5.6; ISO 9001:2015 Clause(s) 6.1)

6 Resource Requirements

6.1 General

NSWHP maintains laboratory services throughout New South Wales. The locations of our laboratories and collections centers are listed on our website.

(See: ISO 15189:2022 Clause: 6.1; ISO/IEC 17025:2017 Clause: 6.1; ISO 9001:2015 Clause(s) 7, 7.1)

6.2 Personnel

All personnel have the supervision, training, qualifications, and experience required to carry out their duties, and perform testing safely and effectively. NSWHP ensures that employees performing assigned tasks are competent by training, periodic competency assessments, and by review of their performance as it relates to their role, including verification and scope of practice where relevant.

Specific policies and procedures for the management of personnel are overseen by NSWHP People and Culture and the Medical Workforce Unit.

Recruitment

NSWHP employees have a position description created and/or reviewed during recruitment in Recruitment Onboarding (ROB), NSW Health's electronic system for recruiting and onboarding personnel. Each position has its place in the organisation described by a relevant organisation chart.

Conditions of employment are found at NSW Health Remuneration and Conditions and detail specific requirements for basic and higher qualifications, including training, registration and accreditation requirements for appointment to particular positions.

NSW Health is an Equal Opportunity employer.

Every employee is appointed with the minimum qualifications and experience to perform the duties of their position. Laboratories may retain administrative employee records locally.

New employees undergo mandatory training, site-specific orientation and induction according to the NSWHP Orientation and Induction for New Employees Procedure (NSWHP_PR_027) and should be performed as soon as possible after commencing duties. Orientation includes, at a minimum, the location of staff facilities, access and security arrangements, introduction to employees and colleagues, the use of personal protective equipment and general laboratory safety, an introduction to the QMS and incident reporting, employee sickness and annual

leave policies, privacy and patient/customer confidentiality policies, email and internet policies, no smoking policies and use of software systems such as the LIS.

New employees are made aware of NSWHP's goals through introduction to the strategic and operational plans and RITE values and confirm that they have read and agree to abide by the NSW Health Code of Conduct (PD2015_049).

Personnel have access to hospital medical libraries, the Internet, CIAP and LHD/NSWHP Intranet resources and laboratory collections of textbooks and journals for their professional development. Employees can routinely access the NATA, RCPA and NPAAC websites to obtain technical and related information.

NSWHP has access to Clinical and Laboratory Standards Institute (CLSI) technical standards and guidelines resources via the NSWHP Intranet.

Building Competency and Education

NSWHP views building competency and developing personnel as an essential management responsibility that is vital to meeting the laboratory's missions and future requirements. NSWHP management is committed to providing relevant training and continuing education and development opportunities to optimise personnel effectiveness in an environment of rapidly changing technologies and customer expectations.

The laboratories of NSWHP maintain employees' skills by programs of competency building and competency certification appropriate to their duties. Laboratory competency program records are held as hard-copy or in electronic form in the QMS.

The My Health Learning site provides mandatory and other education to NSWHP employees. Records of education are maintained.

NSWHP has procedures and retains records to: -

1. Determine competency requirements,
2. Recruit and appoint suitable employees NSW Health Recruitment and Selection of Staff to the NSW Health Service (PD2023_024),
3. Build competent employees,
4. Supervise employees NSWHP Supervision Policy (NSWHP_PD_019),
5. Establish employee delegations and authorities NSW Health Pathology Delegations Manual (NSWHP_CG_001),
6. Monitor employee competence,
7. Position descriptions,
8. Training and retraining.

NSWHP authorises appropriate employees to, including but not limited to: -

a) Develop, modify, verify and validate test methods,
b) Provide analysis of results, including opinions & interpretations and statements of conformity,
c) Review, authorise and report results.

Laboratory management is responsible for the formulation of individual development goals relevant to the education and skill requirements of the assigned position. Educational needs are identified through a performance review process and on a day-to-day basis by laboratory management. Attendance at external education opportunities and conferences is recorded in the individual employee personnel records.

Management ensures that competent deputies are identified to carry out the duties of a key position holder and relevant records of authorisation are maintained.

Employee Departure

Employees who are ceasing employment are required to surrender any items supplied by NSWHP, e.g. mobile phones, computers and access cards. Access to the NSW Health network and programs are removed and the employee is offered an exit interview to allow NSWHP to review the reasons for resignation, and to invite suggestions for improvement in recruitment, conditions of employment and areas of dissatisfaction/satisfaction to assist in future planning.

(See: ISO 15189:2022 Clause: 6.2; ISO/IEC 17025:2017 Clause: 6.2; ISO 9001:2015 Clause(s) 7.1.2)

References:

1. NSW Health Remuneration and Conditions
2. NSWHP Orientation and Induction for New Employees Procedure (NSWHP_PR_027)
3. NSW Health Recruitment and Selection of Staff to the NSW Health Service (PD2023_024)
4. NSWHP Supervision Policy (NSWHP_PD_019)
5. NSW Health Pathology Delegations Manual (NSWHP_CG_001)

6.3 Facilities and Environment

NSWHP laboratories, point-of-care sites, collection centres and administrative areas have sufficient space designed to ensure the quality and efficacy of the testing and service provided and ensures the health and safety of personnel, patients and visitors.

All areas have sufficient lighting, ventilation, water, waste and refuse disposal and are deemed safe and satisfactory for testing activities. The temperature and humidity of testing environments are stabilised by air-conditioning.

Patient collection areas provided are private and optimised for collection purposes and comply with the specific NPAAC Requirements.

Accommodation

Space needs are reviewed as part of the QMS management review process during site service development processes. The factors considered, at least, are the

a) Minimisation of the risk of injury and occupational illness,
b) Efficiency of operations,
c) Suitability of tasks carried out therein,
d) Optimisation of the comfort of occupants,
e) Protection of the test materials,
f) Efficient cleaning and maintenance,

g) Minimisation of the risk of processing, storage error or cross contamination,
h) Effective separation of testing from incompatible activities,
i) Communication systems,
j) Staff facilities,
k) Space to accommodate PPE for ready use,
l) Provision of water, waste, computer network and stable electrical services.

Controlled access for unauthorised persons and visitors to testing and critical areas provides security for the testing environment, equipment, patient/customer information.

Facilities for sample collection have separate reception/waiting and collection areas. Consideration is given to patient comfort, privacy and the accommodation of patient disabilities in addition to optimisation of collection conditions.

Storage

Suitable and sufficient storage space and conditions maintain the continuing integrity of records and items being stored i.e. sample materials, documents, equipment, reagents etc and any item that may affect the quality of examination results.

Clinical and evidentiary samples are stored to minimise the risk of loss, sample storage artefacts or cross contamination at least according to the NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material* and other relevant requirements.

Environment

Laboratory and facility management is responsible for ensuring that work areas are clean, functional and well-maintained and that storage and disposal of dangerous materials is in accordance with local government and other regulatory requirements.

Environmental conditions likely to affect the integrity of the testing process, the quality of the sample, storage of testing materials and staff health are monitored. This includes, at least, lighting, temperature, noise levels, dust, fumes, humidity, and sterility. Failure of appropriate environmental conditions for accurate laboratory testing immediately results in the cessation of analysis.

(See: ISO 15189:2022 Clause: 6.3; ISO/IEC 17025:2017 Clause: 6.3; ISO 9001:2015 Clause(s) 7.1.3, 7.1.4, 7.1.5)

6.4 Equipment

NSWHP ensures that testing and measurement equipment is fit for the purpose for which it is being used and is properly used, properly calibrated, well maintained, uniquely labelled and registered in the Quality Management system. See NSWHP Equipment Traceability Policy (NSWHP_PD_017). Equipment is used within its measurement capability.

The performance of equipment is validated, when necessary, and verified on-site before authorisation to commence testing is given by the supervising pathologist. Acceptability criteria for validations and verifications are determined by the supervising pathologist for one-off local installations, or by the relevant discipline Clinical Stream for multi-site equipment roll outs.

Computer software built into equipment for the purpose of collecting, processing, recording, storing and retrieving examination results is validated as part of instrument validations. Where possible, testing instruments are interfaced with the LIS or proprietary middleware to transfer data automatically and minimise the possibility of transcription errors or loss of data. Interfaces are verified prior to commencing work. Discipline managers ensure that any software in use is supported by procedures for maintaining integrity and confidentiality of data, storage and processing of information.

Equipment is operated by authorised and trained personnel. Up-to-date instructions on the use and maintenance of equipment are readily available in the form of work instructions or the manufacturer's operating manual. Deviations from manufacturer's operating instructions are validated before use and registered with the Therapeutic Goods Administration as in-house in-vitro diagnostic devices (see NPAAC Requirements for the *Development and Use of In-house Diagnostic Medical Devices*). Metrological traceability of the calibration standards in use are recorded where applicable.

NSWHP procedures include safe handling information for the equipment as detailed by manufacturer's instructions. New and altered instruments are subject to a risk assessment before use. The risk assessment considers WHS matters including the need for PPE and waste disposal, along with the potential for unauthorised or accidental adjustment that could invalidate results. Any risks identified are mitigated according to a defined risk appetite.

A set of routine checks and maintenance are defined to remove contamination and prevent instrument malfunction, erroneous results, or damage to the instrument, and to ensure continued safe working order. This may include daily, weekly, or monthly tasks. Records of checks and maintenance are kept together with an incident log for recording adverse events, any changes made, and corrective actions taken.

Nonconforming equipment is removed from service, clearly labelled as such, and repaired, stored, or decommissioned and discarded. When equipment is removed for service or repair, the laboratory ensures that it is checked and shown to be satisfactory before being returned to routine laboratory use. When an item of equipment is found to be non-conforming, an assessment is made as to whether any results were compromised for correction and notification.

Reasonable steps are taken to decontaminate equipment prior to service, repair, or decommissioning.

Significant adverse events that are directly caused by equipment items are investigated and notified to the manufacturer / supplier, and where necessary, the Therapeutic Goods Administration. Safety alerts or recall notices that describe the potential for equipment related adverse events are submitted to a central email address (NSWPATH-Recalls@health.nsw.gov.au) for distribution to potentially affected laboratories. Actions taken in response to safety alerts and recall notices are recorded in OFIs logged in the Quality Management System. ims+ is used to record any adverse patient care outcomes. The outcome of investigations and any actions taken are also reported back to the manufacturer / supplier when required.

Included in these requirements are blood bank refrigerators, blood gas analysers and other point-of-care equipment located on-site but outside of the laboratory.

Records

Each item of equipment is uniquely identified and registered on an asset database. The following information is recorded:

1. Identity of the equipment and its software
2. Manufacturer / supplier name, type identification serial and model number
3. Manufacturer / supplier contact person and contact details
4. Date of receipt and date put into service
5. Current location and operational status (e.g. in use, in storage, decommissioned, disposed)
6. Condition when received (new, used or reconditioned)
7. Verification of fitness for purpose with specified acceptability criteria
8. Location of manufacturer's instructions
9. Equipment performance records that confirm suitability for use
10. Service history and major maintenance records
11. Calibration and user checks to confirm metrological traceability
12. Whether the instrument is calibrated, interfaced, alarmed
13. Notes on any damage to, malfunction or repair of the instrument.

Equipment records are retained for at least the life of the equipment plus four years.

(See: ISO 15189:2022 Clause: 6.4; ISO/IEC 17025:2017 Clause: 6.4; ISO 9001:2015 Clause(s) 8, 8.1)

References

a) NSWHP Equipment Traceability Policy (NSWHP_PD_017)
b) NSWHP Risk Assessment Template
c) NSWHP Personal Protective Equipment (NSWHP_PD_015)
d) Clinical and Related Waste Management for Health Services (PD2020_049)
e) NPAAC Requirements for the *Development and Use of In-house Diagnostic Medical Devices*

6.5 Equipment calibration and Metrological Traceability

NSWHP ensures that items of equipment are evaluated, purchased, identified, calibrated, maintained, operated, and serviced in accordance with existing NSW Health and NSWHP policies and the manufacturer's instructions. Discipline supervisors are responsible for ensuring that the equipment in use can provide the accuracy of measurement needed. This is performed by regularly monitoring, maintaining, calibrating, and servicing equipment according to a scheduled program in accordance with the manufacturer's instructions.

NSWHP laboratories monitor, adjust, and review the calibration status of critical measuring devices to ensure confidence in test results and adjust the calibration plan if required. Where possible, such activities are sourced from a NATA accredited provider, or a provider accredited under a scheme with which NATA has a mutual recognition arrangement (MRA), for the activities concerned.

Requirements for equipment calibration and the metrological traceability of results are included in the NSWHP Equipment Traceability Policy (NSWHP_PD_017)

(See: ISO 15189:2022 Clause: 6.5; ISO/IEC 17025:2017 Clause: 6.5; ISO 9001:2015 Clause(s) 8, 8.1)

6.6 Reagents and Consumables

NSWHP laboratories receive, accept and store reagents and consumables according to manufacturer's specifications to ensure they are fit for purpose and to minimise deterioration.

Each new shipment of reagent / consumable that can affect the quality of examinations is verified for performance before use in examinations or before the release of patient results. Any unverified reagents / consumables are segregated from those currently accepted for use. Similarly, reagents / consumables that have been identified as unsuitable for use are stored separately to prevent inadvertent use.

Significant adverse events that are directly caused by reagents or consumables are investigated and notified to the manufacturer / supplier, and where necessary, the Therapeutic Goods Administration.

Records are maintained for each reagent that affects the performance of an examination, including expiry dates, lot numbers, date into service, data showing its initial and ongoing acceptance for use and, if relevant, the date taken out of use.

Reagents prepared in-house include sufficient identification records to allow traceability, including but not limited to the

1. Name of the reagent
2. Concentration when applicable
3. Name of employee who prepared the reagent
4. Expiry or preparation date
5. Storage conditions and hazard warnings as appropriate
6. Unique identifier e.g. batch number.

Safety Data Sheets (SDS), Certificates of Analyses and other batch or lot data information for reagents and chemicals are retained.

Reagents and consumable supplies are segregated and discarded immediately after reaching expiry date.

(See: ISO 15189:2022 Clause: 6.6; ISO/IEC 17025:2017 Clause: 6.6; ISO 9001:2015 Clause(s) 8.2)

References:

1. NSW Health Procurement (PD2022_020)
2. NSWHP Delegations Manual (NSWHP_CG_001)

6.7 Service Agreements

NSWHP's commitment to provide testing services is covered by one or more of the following agreements or documents:

a) Annual Statement of Service with the NSW Ministry of Health in relation to general pathology services,
b) Annual Statement of Service with the NSW Ministry of Health in relation to Specialised Public Health Testing Services,
c) Customer Charters with individual LHDs,
d) Referrals for testing for individual patients,
e) Agreements to perform testing for clinical trials or otherwise for the purposes of ethically-approved research,
f) Memorandum of Understanding between NSWHP and the NSW Department of Communities and Justice,
g) Service Level Agreement between NSWHP and NSW Police,
h) Other services agreements with private companies or public referring authorities.

A laboratory testing scope is established and reviewed in consultation with the relevant LHD, hospitals, clinical services and, if relevant, the local medical community. Account is taken of the local hospital medical and surgical activity, the range of patient conditions treated locally and the distance to alternative services.

Testing not within a laboratory's scope is preferentially referred to another NSWHP laboratory or to an accredited external reference laboratory with the capacity to perform the testing. Reports with results from an external reference laboratory or consultant have the appropriate attribution to that laboratory or consultant.

Testing is not performed that is not within the capacity and resources of that laboratory, but testing performed within the capacity of the laboratory but not within the NATA scope of testing is reported and it is made clear that the results are outside the scope of the laboratory's NATA accreditation.

Customer Charters are established between NSWHP and each of the LHDs which describe the services which NSWHP provides to the LHD and the cooperative arrangements between both parties, including to ensure the delivery of high quality, patient-centred care.

Other testing services agreements, PoCT, clinical trials and commercial testing agreements are approved only after an assessment of NSWHP's capacity to provide or support a service delivering results consistent with patient safety and NSWHP's mandate and delegation.

Customer Charters and other service agreements are periodically reviewed.

(See: ISO 15189:2022 Clause: 6.7; ISO/IEC 17025:2017 Clause: 6.6; ISO 9001:2015 Clause(s) 8.4)

6.8 Externally provided Products and Services

Referral Laboratories

Human Pathology

Pathologists and relevant discipline experts select external referral laboratories for tests not performed within NSWHP laboratories. External consultants may also be required to provide expert opinion on testing. A consultant is selected from their recognition as an expert in their field, including teaching, publications and work within a NATA accredited facility. Following a specific request from a requesting practitioner, an alternative consultant may be engaged after consultation and agreement.

Where possible, a referral laboratory is accredited by NATA, or be a laboratory accredited under a scheme with which NATA has a mutual recognition arrangement (MRA), for the examinations concerned. NSWHP advises customers of the referral of tests through service agreements and contracts. These agreements contain the provision to refer specimens at the discretion of the laboratory and that the laboratory is responsible for all referred work, except in the case where clients or authorities specify which referral laboratory must be used.

Laboratories maintain records of referred specimens, confirm their receipt at the referral laboratory, and monitor the list of referred specimens for outstanding results. With few exceptions, referred pathology test reports are reissued by NSWHP except where the sensitive nature of results requires that the referral laboratory issue a report directly to the requesting agent particularly for Genetics testing as required specifically by Genetics Tests - Charging Policy Clinically Required Specialised-Non-Medicare Benefits Schedule (PD2005_335).

The performance of referral laboratories and consultants is monitored on a regular basis and is part of the annual QMS management review process. Evaluation of external consultants is performed on an on-going basis by review of reports returned to the laboratory, the consultant's continued leadership in the field and employment within a NATA accredited laboratory.

Results received from a referral laboratory are generally reported as received. In some cases additional interpretation is provided by competent NSWHP employees and included in the report with attribution.

FASS

FASS refers some analyses to other units within FASS and within NSWHP. Reports containing results of these analyses are attached to the relevant FASS report.

Externally provided products and services

NSWHP is bound by the NSW Health Procurement (PD2022_020) for all tendering and purchasing. The evaluation of external services and supplies is undertaken by relevant management personnel to ensure that appropriate assessments are conducted to verify suitability. Purchases are approved by managers so authorised in the NSWHP Delegations Manual (NSWHP_CG_001).

Receipt and storage of reagents and laboratory consumables are documented according to receipt of goods procedures. Any actions taken to check compliance of consumables before use are maintained by the laboratories and all suppliers of critical supplies are evaluated and periodically reviewed, at a minimum, in the QMS management review process.

Purchasing from vendors whose products consistently do not meet their stated performance specifications, show undesirably high proportion of instrument downtime or do not provide satisfactory after-sale service is reviewed.

NSWHP ensures that purchasing documents describe the product or service to be delivered accurately to ensure that purchased materials, products, and services are verified (inspected and accepted) against documented and specified requirements.

Purchasing of critical supplies is managed by NSW Health Oracle Purchasing System. A real time monitoring of performance is by communication with HealthShare and feedback on NSW Health Contracts by laboratory management.

Where possible, external services and supplies are sourced from a NATA accredited provider, or a provider accredited under a scheme with which NATA has a mutual recognition arrangement (MRA), for the items concerned.

(See: ISO 15189:2022 Clause: 6.8; ISO/IEC 17025:2017 Clause: 6.6; ISO 9001:2015 Clause(s) 8.2)

Reference:

Genetics Tests - Charging Policy Clinically Required Specialised-Non-Medicare Benefits Schedule (PD2005_335)

NSW Health Procurement (PD2022_020)

NSWHP Delegations Manual (NSWHP_CG_001)

7 Process Requirements

7.1 General

Risks are minimised by having controls in place. Significant changes to protocols in pre-examination, examination and post-examination processes are approved prior to implementation taking into consideration potential harm to patients. Risks and opportunities to improve patient care are captured via risk pathways or as improvement activities.

(See: ISO 15189:2022 Clause: 7.1; ISO/IEC 17025:2017 Clause: 7.1; ISO 9001:2015 Clause(s) 8.3)

7.2 Pre-examination Processes

Collection and specimen reception services are offered at most laboratories. NSWHP provides collection services through hospital collection points, Commonwealth-registered approved pathology collection centres and home collection services.

Test Requesting

Patients and doctors are provided with the information required to ensure testing is reliably carried out in a timely manner on the correct specimen, with the correct patient preparation, in the correct container and preservative and correct identification. Comprehensive test information is available in the online NSWHP Test Catalogue which provides information to NSWHP staff, clinicians, patients, hospital employees and test requestors. Information about NSWHP including collection centres may be found in the NSWHP Internet Site.

NSWHP provides a range of patient information sheets to assist patients and clinicians.

Further advice for test requestors and specimen collectors is available from NSWHP laboratories upon request.

Test requests are made on a request form, through eOrder functionality of an interfaced LHD clinical system, a letter with the doctor's letterhead, or a verbal request followed by a confirmatory written request within 14 days or. A request must contain sufficient information to uniquely identify the patient, the authorised requestor and contact information, the tests required, and preferably pertinent clinical information.

Specimen Collection

Test specimens must have the required minimum unique identifiers e.g. patient's name, date of birth and/or medical record number, and be accompanied by a requisition to which they are traceable. The samples should also have the date and time of collection shown and may also have the patient's signature or initials verifying the identification data are correct. The requestor's identity should also be recorded and retained for collections undertaken by NSWHP collectors.

NSWHP specimen collectors comply with patient identification procedures at the time of collection as outlined in policies: -

- Positive Patient Identification for Collection of Pathology Specimens (NSWHP_PR_092)
- Labelling Requirements for Pathology and Forensic Specimens (NSWHP_PD_023)
- Minimum Patient Identification Requirements for Pre-Transfusion Testing (NSWHP_PD_009)

Collection requirements including volume, specimen container and specimen stability are documented in the NSWHP Test Catalogue as relevant.

Collection procedures and instructions are available at the collection services. Deviations from collection protocols are recorded. Deviations having an impact on patient care are managed through ims+.

Specialised testing requirements and out-of-pocket expenses are explained to patients before collection of samples. Special procedures may require consent to be documented.

Specimen Transport

Specimens are conveyed to a laboratory for testing; transportation occurs within an appropriate time, at an appropriate temperature interval and in a manner that ensures suitability of the specimen for testing according to the Transport of Pathology Specimens to Laboratories (PD2023_001).

Transportation methods also assure safety for the carrier, general public and the receiving laboratory. Laboratories regularly monitor the integrity of specimen transportation with identified risks mitigated.

Specimens are transported in accordance with the Transport of Pathology Specimens to Laboratories (PD2023_001) and NPAAC Requirements for the *Packaging and Transport of Pathology Specimens and Associated Materials*.

Transportation of specimens within NSWHP is tracked via Akuna Tracking System. Transport of specimens will be in line with Delayed, Misplaced and Lost Specimens Management Policy (NSWHP_PD_027).

Specimen Reception and Handling

Patient/specimen details are entered into the LIS including the specimen type and the date/times of collection and receipt, when relevant.

Requests are assigned a unique identifier as an accession or laboratory number and scanned into the LIS.

Laboratory management is responsible for ensuring that correct procedures are followed for receipt, handling, protection and retention/disposal of test items within their laboratory. Periodic reviews of requests and sample volume requirements for phlebotomy are carried out to ensure that neither insufficient nor excessive amounts of sample are collected.

Authorised and competent personnel in specimen reception review requests and samples before sending them to various sections for testing. An additional check of request forms for requested tests, reporting details and the patient demographics is performed by units prior to result validation when required.

Amendments to patient details are noted on the request form and are maintained with the request forms for at least the minimum retention period as per NPAAC guidelines. For routine laboratory tasks, the identification of the person in the laboratory responsible for carrying out the work is documented. These records are maintained electronically in the audit trail of the laboratory's information management system. More comprehensive records may be maintained at divisional level for new, complex, or advanced testing.

Rejection or acceptance of samples for testing are based upon a laboratory Accept /Reject policy. Laboratories maintain records for rejected samples in the LIS. The criteria for handling of unsuitable specimens (e.g. containers leaking or broken, inadequately labelled specimen containers) is also part of NSWHP standard procedures. Compromised precious specimens may be tested and reported on, and where relevant deemed to be in the best interest of the patient.
The customer is informed of any deviation from the request, and pertinent discussions are recorded with the appropriate record. Verbal requests for deviations from the original test list, such as the addition or cancellation of a test, are processed.

Laboratory managers are responsible for ensuring that procedures are documented for prioritising the receipt, labelling, processing, and reporting of urgent test items.

(See: ISO 15189:2022 Clause: 7.2; ISO/IEC 17025:2017 Clauses: 7.1, 7.3; ISO 9001:2015 Clause(s) 8.3)

References

1. NSWHP Internet Site
2. Transport of Pathology Specimens to Laboratories (PD2023_001)
3. NPAAC Requirements for the *Packaging and Transport of Pathology Specimens and Associated Materials*
4. Delayed, Misplaced and Lost Specimens Management Policy (NSWHP_PD_027)
5. Labelling Requirements for Pathology and Forensic Specimens (NSWHP_PD_023)
6. Minimum Patient Identification Requirements for Pre-Transfusion Testing (NSWHP_PD_009)

7.3 Examination Processes

General

The scope of testing for individual NSWHP laboratories can be accessed at the NATA website.

The selection and use of appropriate examination procedures and the requirements (space, skills etc.) are identified and laboratories have the capability and resources to meet these requirements. Proposal for changes to testing methods are approved through the Request for Assay Change Approval (NSWHP_F_048).

Procedures used without modification from the vendor's documentation are subjected to verification by the laboratory before use. Non-standard methods, in-house methods or those methods once validated but subsequently modified are validated and the results are documented. Statewide verification and validation protocols and templates are used where available including for Statewide rollouts of major analysers. In-house in-vitro diagnostic devices are subject to the regulatory requirements including notification to TGA.

Measurement uncertainty is estimated on tests reported as a quantitative value or where a quantitative result is used to determine a qualitative value. This information is updated regularly and when a method change occurs with records kept.

Biological reference intervals and clinical decision points are included on patient reports where applicable and on local intranet and websites.

Test method documentation follows the established NSWHP or laboratory method templates consistent with ISO 15189 or ISO/IEC 17025 either by controlled specific method documents, on-instrument manuals, or reagent package inserts. Inserts provided by manufacturers, other controlled documents, or the manufacturer's operating manual may be used as part of the procedure description if the document describes the procedure as it is performed in the laboratory.

Methods are available to relevant employees at their workstations either in hard-copy or electronic form. Work instructions (abbreviated methods) are permitted provided they correspond to the full procedure that is also available.

Test procedures and the method documentation are reviewed regularly to ensure that they remain current. When changes are made, review will also include impact of information provided on reports, such as reference and therapeutic intervals.

Significant changes to testing procedure or the interpretation of test results are communicated to clients in writing prior to and with new test results.

Verification of Results

Laboratories perform and document internal quality control on key processes (refer to individual laboratory quality control documentation) in such a way as to verify the intended quality of results. The chosen QC materials are intended to react in the examination system as close as possible to actual patient samples.

Internal QC data are reviewed regularly during the testing process and timely corrective action occurs if deficiencies are identified or trends detected. Procedures are in place to prevent the release of results in the event of QC failure.

Medical Testing

Laboratories participate in appropriate external QAP programs if available. Regular review of results is carried out by supervisors of laboratories. Each laboratory testing area is to ensure that a timely, documented response occurs to deficiencies with QAP results and the effectiveness of the response is monitored.

If an EQA program is unavailable, an alternative EQA method including, but not limited to, specimen exchange program, or use of stable specimens from previous runs, certified reference materials or material from a cell or tissue repository is acceptable.

Each laboratory ensures that significant outcomes/trends from QAP review are discussed with employees at departmental meetings and in QMS Management Review meetings.

FASS

Laboratories/sections participate in proficiency testing programs for each major area of tests, measurements and activities that are covered by their scope of accreditation, when there is a proficiency program available. If proficiency testing programs are not available, other ways for monitoring performance are developed. Frequency of these programs depends on the field and the program provided.

Life Sciences: at least once every two years for each major area of test or measurement, where such programs are available.

Legal (including Forensic Science): where proficiency testing program meets the need of the facility, annual participation in at least one test per skill mix is mandatory.

The laboratory's routine test procedures are used when analysing proficiency test samples. Feedback is provided to the relevant staff, and when required, corrective actions are taken and documented.

(See: ISO 15189:2022 Clause: 7.3; ISO/IEC 17025:2017 Clauses: 7.2, 7.7; ISO 9001:2015 Clause(s) 8.5)

References

1. NATA website
2. Request for Assay Change Approval (NSWHP_F_048)
3. NATA ISO/IEC 17025 Application Document, Life Sciences - Appendix
4. NATA ISO/IEC 17025 Application Document, Legal (including Forensic Science) - Appendix

7.4 Post-examination Processes

Medical Testing

Laboratory management maintains procedures for the review and authorisation of release of patient results. The validation and release of results are only undertaken by authorised personnel.

Clinical and interpretive comments and comments relating to technical / scientific limitations of testing procedures are added to reports by trained senior employees according to documented reporting protocols approved by a supervising pathologist or other appropriate authorising officer.

When this procedure involves automatic selection and reporting via software analysis such as the LIS system or middleware connected to the LIS, the review criteria are approved and documented.

Storage and retention of clinical samples is in accordance with the NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material*. Specific timeframes for sample retention are documented further as required.

Safe disposal of clinical samples is carried out in accordance with NSW Health policies for contaminated waste and the applicable requirements for the management of human tissue.

FASS

Each unit has a written procedure for the appropriate and standardised format that should be used for the case files. Only one original case file exists. The report review requirements for each unit is documented.

If a unit is required to issue a Supplementary Report to provide additional or clarifying information, a documented procedure exists for the issuing of such reports. The additional information is clearly identifiable on the Supplementary Report.

Reporting of Results

Medical Testing

NSWHP complies with NPAAC Requirements for *Information Communication* in reporting the results of its medical testing and is formatted to clearly convey test results, interpretations and comments, and patient identification so that this information and data is conveyed for the safe and efficient management of patients. Test reports are issued from a NSWHP LIS in hard copy, by fax, remote printing, and electronic transfer to an LHD eMR system or medical practice software.

Laboratory management is responsible for documenting and following a written procedure for report generation and validation that ensures the correct recording of laboratory examination results. The reports include the necessary information for interpretation of examination results.

Test reports containing results of tests performed by an external laboratory have the testing laboratory clearly identified.

Any NSWHP examination reports displaying the NATA emblem (logo) comply with NATA's document Use of the NATA emblem, NATA endorsement and references to accreditation. The use of the Royal College of Pathologists of Australasia's (RCPA) crest and logo is authorised by the RCPA Board of Directors for NATA/RCPA accredited laboratories.

Where results reported are not included in the scope of accreditation, an appropriate disclaimer will be applied.

Records of medical results reported are retained in accordance with NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material.*

FASS

Each unit has a documented procedure for the review, authorisation and issuing of reports including the authorisation of report copies. Where reports include results from a subcontracted laboratory or facility, including other units within FASS, these reports are attached. All communication regarding requests for copies of reports are recorded in the relevant case file record.

Reports issued electronically are sent in PDF format.

Each unit documents their report authorisation protocols. Protocols describe the requirement for the content of telephone conversations to be documented, facsimile or email transmissions to be retained within the case file, and the procedure for the withdrawal of invalid reports.

It is acknowledged that some methods are not NATA accredited. Where results from these methods are reported on the same report as those from NATA accredited methods, the report includes the following statement:

“NATA accreditation does not cover the performance of this service”.

Unless otherwise stipulated, all reports are issued on the current site specific FASS letterhead.

Release of Results

NSWHP policy NSWHP Release of Results Policy (NSWHP_PD_016) documents procedures for the release of examination results including who may release results and to whom. Procedures include the notification of users of high risk (critical) results, the use of interim reports, the presence of sample interference, verbal notification of results, release of results to patients, and the steps taken to ensure that results reach only authorised recipients. Critical results will be notified as soon as relevant as per NSWHP policy High Risk (Critical) Laboratory Results (NSWHP_PD_10). Procedures are also available to notify users when results are delayed based on the impact to the patient.

The transmission of results conforms with the NSW Health Records and Information Privacy Act and the privacy requirements set out by the Ministry of Health in the NSW Health Privacy Manual for Health Information.

The conditions under which test results are auto verified are documented and validated for use including those indicating an unsuitable specimen or other flags.

When an original report is revised, processes ensure that a revised report, delivered by any medium, is clearly identified as a revision and a detailed reference to the change is shown in the re-issued report. Records of the revision are kept in the reporting system, or an alternate copy kept including the identity of the person responsible for the change and the original report entries.

When a test result is amended a clinician caring for the patient is notified of the revised result. Given that sub-optimal clinical decisions could be made on the basis of the initial result, the details of amendments are urgently communicated using standard critical result notification pathways.

(See: ISO 15189:2022 Clause:7.4; ISO/IEC 17025:2017 Clauses: 7.4, 7.8; ISO 9001:2015 Clause(s) 8.6)

References

1. NSWHP Release of Results Policy (NSWHP_PD_016)
2. NSWHP policy High Risk (Critical) Laboratory Results (NSWHP_PD_10)
3. NSW Health Records and Information Privacy Act
4. NSW Health Privacy Manual for Health Information

5. NPAAC Requirements for the *Communication of High Risk Pathology Results*
6. NPAAC Requirements for *Information Communication*
7. NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material*
8. Use of the NATA emblem, NATA endorsement and references to accreditation

7.5 Nonconforming Work

Laboratory management periodically reviews performance of examinations using quality control and quality assurance results. Any significant findings are acted upon immediately and preventive action instituted.

Employees are empowered and encouraged to report nonconformities including, but not limited to, failure to meet any relevant standard or other mandatory requirement, failure of a procedure or any adverse incident that affects testing or provision of a test result before, during or after testing, including after the release of results. The range of potentially reportable nonconformities is intended to be wide, all-encompassing, and non-restrictive.

Specifically, nonconformity recording systems are intended to capture internal and external problems, suggestions and opportunities for improvement, commendations and compliments, complaints and hazards, near-misses, or risks. A nonconformity may be notified due to single or recurrent incidents involving lack of compliance with existing laboratory policy or procedures or related to inadequately documented policy or procedures.

Variances detected as a result of an internal or external audit, any other planned or ad hoc evaluation or through the QMS management review process are handled through the relevant nonconformity management systems. The system is to ensure that any deviation from normal processing procedures is assessed, corrected where necessary, and recorded, via documented procedures.

NSWHP local QMS systems are used for the management of nonconformities and corrective and preventive actions. The system defines all aspects of incident management including a risk analysis and the identification of responsible employees to assess nonconformity scope, carry out immediate actions including cessation of testing, withholding of reports when there is a risk of harm to patients, authorisation of resumption of testing, assessment of any patient/customer impact significance individually or collectively arising from an incident and initiate and monitor corrective or preventive actions.

Review of individual incidents, frequencies and trends in nonconformities and the robustness and success of the systems is carried out, at a minimum as part of the Quality and Patient Safety Committee meetings and the laboratory's management review process.

(See: ISO 15189:2022 Clause: 7.5; ISO/IEC 17025:2017 Clause: .7.10; ISO 9001:2015 Clause(s) 8.7,10.2)

7.6 Control of Data and Information management

Security issues related to access and use of the LIS are documented and managed by the NSWHP ICT team.

NSWHP laboratories use various LIS to manage testing and to report results. Results are provided by hard-copy, fax, HL7 files download and interfacing with LHD eMR systems. Electronic ordering through the relevant eMR system is available for most pathology laboratories.

Procedures are in place to ensure confidentiality of patient identifying information is always maintained in accordance with the NSW Health Privacy Manual for Health Information and NSW privacy legislation. NSWHP Information Security Management System Framework (NSWHP-CG-011) provides policies and procedures implemented to protect against cybersecurity threats and unauthorised access to patient/customer information and safeguard against tampering and loss of data.

NSWHP defines access and authorities to ensure confidentiality, accessibility, security & retrievability of test results. LIS are hosted in secure data centres both on and off site.

The interface between the instrumentation and the laboratory computer system is continuously tested for results integrity. Validation criteria are established via an algorithm to ensure validity of results. When a result is manually entered in the LIS, laboratories have procedures for manual transcription, error checking and verification. Appropriate corrective action is taken in case of any system failure.

NSWHP laboratories have central and local contingency plans in place to maintain services in the event of downtime or failure of laboratory information systems.

New LIS and other interface and monitoring systems which may influence the quality of test results are verified and validated as reliable for the processing of results.

(See: ISO 15189:2022 Clause: 7.6; ISO/IEC 17025:2017 Clause: 7.11; ISO 9001:2015 Clause(s) 7.4)

References:

1. NSW Health Records and Information Privacy Act
2. NSW Health Privacy Manual for Health Information
3. NSWHP Information Security Management System Framework (NSWHP-CG-011)
4. Electronic Information Security (PD2020_046)

7.7 Complaints

Complaints made by patients or other customers are managed under the NSW Health Complaint Management (PD2020_013) which provides a framework for the registration, investigation, analysis, resolution and escalation of a complaint. Complaints are logged, and associated actions are documented in the NSW Health state-wide electronic incident management system (ims+) using the consumer feedback module (CF).

If a complaint reveals a significant incident the processes for managing critical incidents are used.

(See: ISO 15189:2022 Clause: .7.7; ISO/IEC 17025:2017 Clause: 7.9; ISO 9001:2015 Clause(s) 10.2)

References:

a) NSW Health Complaint Management (PD2020_013)
b) NSW Health Complaint Management Guidelines (GL2020_008)

7.8 Business Continuity – Emergency Planning

Our Business Continuity Management Policy seeks to reduce the likelihood of, prepare for, respond to, and recover from disruptions when they arise, by providing a mechanism to:

- Deliver a systematic, transparent, organisation-wide approach to business continuity
- Enable NSWHP to provide critical services, regardless of a disruption
- Liaise with LHDs Disaster Controller and required stakeholders
- Provide training as appropriate to laboratory staff
- Expedite and return to normal for the full recovery of business operations
- Provide clear guidance for the response and reporting of potential or actual disruptions
- Protect NSWHP from reputational, financial and political risks resultant from a disruption
- Adhere to industry best practice and international standards
- Use post-incident reviews to identify opportunities for improvement

(See: ISO 15189:2022 Clause: 7.8; ISO/IEC 17025:2017 Clause: 7.11; ISO 9001:2015 Clause(s) 6.2, 6.3)

References:

a) NSWHP Business Continuity Management Policy (NSWHP_PD_031)

8 Management System Requirements

8.1 General Requirements

NSWHP is committed to good laboratory practice and ensuring the quality of its services.
To achieve this NSWHP:

a) Maintains a quality management system that continuously improves the effectiveness of the service and is compliant with ISO 15189:2022, ISO/IEC 17025:2017 and ISO 9001:2015.

b) Requires employees to comply with the quality management system requirements and provides training and support for them to do so.

c) Ensures that responsibilities, authorities, and interrelationships are defined.

d) Ensures employees are aware of the organisational objectives and policies, benefits of continual improvement and consequences of non-conformance.

e) Establishes, monitors, and works towards objectives to improve the quality of the service and the quality management system.

f) Maintains effective internal systems of communication to support service provision and the operation of the QMS.

g) Promotes ethical standards of professional practice.

h) Identifies and consults to deliver the best possible service to our customers - patients, clinicians, LHDs, criminal and coronial justice systems, Public Health Units, and other key external customers.

i) Achieves the goal of timely, accurate and cost-effective diagnostic services in accordance with quality standards and customer requirements.

j) Developed its RITE Values (see below) to shape our organisational culture and guide how we interact with one another, our partners, customers, and patients.

Our values

(See: ISO 15189:2022 Clause: 8.1; ISO/IEC 17025:2017 Clause: 8.1; ISO 9001:2015 Clause(s) 7.3)

8.2 Management System Documentation

NSWHP fosters a strong quality culture so that quality becomes the 'way of doing business'. This is achieved via: -

- Clinical Governance framework to minimise clinical risk whilst continuously improving service quality
- Continual improvement
- Preventative action
- Quality objectives with a suite of monthly KPI aiming to reduce risks to patient safety
- Policy library accessible to all staff via the intranet
- Incident and complaints management

All staff have access to all documents in the quality management system and to NSWHP policies and documents.

(See: ISO 15189:2022 Clause: 8.2; ISO/IEC 17025:2017 Clause: 8.2; ISO 9001:2015 Clause(s) 7.5)

8.3 Control of Management System Documents

The documents of the QMS, including this quality manual, external reference documents and Standards, policies and procedures and critical records are retained within secure server-based regional quality software systems. Other documents, such as NSW Health and NSW Health Pathology policies and procedures are accessed via the NSW Health Pathology Policy Library. The NSWHP Policy Framework (NSWHP_CG_003) establishes a defined, clear, identifiable, consistent and enforceable system for the development, approval, implementation and review of NSW Health Pathology documents.

Through the quality software systems, the QMS documents and tools are available to employees of NSWHP in their workplaces and QMS training is provided to the employees of NSWHP.

This quality manual has been prepared in accordance with the requirements of ISO 15189:2022, ISO/IEC 17025:2017 and ISO 9001:2015. The QMS documentation is flexible and adaptable and can be changed in response to user feedback and changing circumstances.

Quality management system document control features of the software ensure that:

a) A list of active documents is maintained.
b) Documents are reviewed and made active for use by a properly authorised person.
c) A record of document authorisation is retained.
d) Documents are uniquely identified with at least the document name and version.
e) Only active authorised documents are available at point of use.
f) Each page is uniquely identified with the document name and/or the document code.

g) Each document page shows page number of page total pagination e.g. "Page 2 of 5".
h) Documents are legible and fit for purpose.
i) Documents are reviewed regularly and updated to retain fitness for use.
j) Obsolete documents are immediately removed from point-of-use.
k) Copies of obsolete documents continue to be stored securely electronically.
l) Uncontrolled documents are not used.

Paper copies may be used where access to computers is unavailable or in “dirty areas”. Document register is maintained in the QMS.

Handwritten amendment practices are specific to the various document control systems in use. The authority to make handwritten amendments and the timeframe for inclusion in a new updated version are described in local QMS procedures.

(See: ISO 15189:2022 Clause: 8.3; ISO/IEC 17025:2017 Clause: 8.3; ISO 9001:2015 Clause(s) 7.5)

Reference: NSWHP Policy Framework (NSWHP_CG_003)

8.4 Control of Records

NSWHP maintains its records for the minimum retention periods outlined in the NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material*, NSW Health Health Care Records - Documentation and Management (PD2012_069) and the *Health Insurance Act (Cth)* and to any other regulatory or operational requirement. This ensures that NSWHP and its quality management system is operating effectively and that NSWHP has the essential documentation to record its critical activities can substantiate the validity of the testing performed, can review performance via a process of management review and can retrieve patient/customer information for a medically/legally relevant period of time, identify critical steps and ensure staff identities are recorded for audit trail.

Retention

NSWHP retains both materials and records for at least the minimum retention periods and disposes of records/materials appropriately depending on confidentiality requirements and hazardous waste management procedures. Quality and technical records are stored in a suitable environment to prevent damage or deterioration and to prevent loss. Records stored electronically are backed up on servers with security protocols to prevent unauthorised access to or amendment of these records.

NSWHP’s various historic document repositories are maintained for the tracking and retention of stored materials/records. In addition, Microsoft Teams and the NSW Health Sharepoint platform has been adopted as an interim central records storage repository that can be accessed by all parts of the organisation until records management can be migrated to a new records system.

Reprinting from LIS allow for results of testing to be reproduced.

Pathology request forms are retained in accordance with the regulatory requirement for the retention of requests for a pathology service as set out in the *Health Insurance Act (Cth)* s23DK, retained either as hard-copy or scanned for electronic storage with a digital signature according to Medicare requirements.

Examination results are stored indefinitely in a live LIS and reports from pathology referral laboratories are stored for a minimum of seven years.

Instrument printouts, laboratory workbooks/worksheets, calibration functions and conversion factors, quality control and external quality assurance records, inter-laboratory comparisons, lot documentation, certificates of supplies, original test observations and calculations, an indication that calculations and manual data transfers have been checked (transcription checks), are kept for a minimum of four years. Instrument maintenance records are kept for life of the instrument plus four years, at least. Superseded examination procedures are stored for at least the minimum retention period. Instrumentation maintenance records are stored either as a hard-copy or electronically in the QMS software.

Historical records derived from QMS activities are stored for at least the minimum retention periods on secure servers. Current records, including nonconformity records, internal problems, complaints and actions taken and records of internal and audit reports, assessments by external bodies and quality improvement action plans are held in the NSWHP QMS systems.

The NSW Health incident management systems (ims+) store clinical, complaints, corporate and work health and safety incident records indefinitely. All QMS and ims+ information is hosted in secure data centres both on and off site.

Employee training records are retained for a minimum duration of employment plus seven years. Employee health records, including immunisation records are retained by the relevant LHD and managed by HealthShare staff health under a service agreement.

Procedures for identification, collection, indexing, access, storage (including location and duration), maintenance and safe disposal of quality and technical records are further detailed in laboratory documentation.

The record system and LIS enables identification and traceability of test materials and personnel.

For testing, laboratories retain original observations, employee and maintenance records and the LIS audit trail to maintain traceability of testing processes. Any result amendment can be traced to previous versions.

Changes to records are signed/authorised and dated in both hard and electronic files. Password protection ensures confidentiality of computerised records.

When mistakes occur in records, the error is crossed out without deletion, erasure, or obscuring the original data with the correct data or information entered alongside. Such alterations to records are signed or initialled and dated by the person making the correction.

(See: ISO 15189:2022 Clause: 8.4; ISO/IEC 17025:2017 Clauses: 8.4; ISO 9001:2015 Clause(s) 7.5)

References

a) NPAAC Requirements for the *Retention of Laboratory Records and Diagnostic Material*
b) NSW Health Health Care Records - Documentation and Management (PD2012_069)
c) *Health Insurance Act (Cth)*
d) *State Records Act*
e) MBS On-Line - Australian Government Department of Health and Aged Care

8.5 Actions to address Risks and Opportunities for Improvement

NSWHP identifies, evaluates and addresses risks and opportunities by mitigation, planning, monitoring and review to ensure that the management system achieves expected results, takes advantages of opportunities, maintains business continuity and achieves improvement.

Organisational risks are managed in accordance with the NSWHP Risk Management Procedure (NSWHP_PR_026). Risks identified from nonconformities, audits, management and other reviews, notifications by the Therapeutic Goods Authority, employees, patients, clinical test requestors, LHD and hospital personnel and from any other source are assessed for severity and managed with the guidance of the NSW Health Enterprise-Wide Risk Management (PD2022_023). Risks and opportunities for improvement are recorded, prioritized, and acted on according to their severity and potential impact on patient and staff safety. The effectiveness of action taken is evaluated.

(See: ISO 15189:2022 Clause: 8.5; ISO/IEC 17025:2017 Clause: 8.5; ISO 9001:2015 Clause(s) 6.1)

References

a) NSWHP Risk Management Procedure (NSWHP_PR_026)
b) NSWHP Risk Appetite Statement (NSWHP_CG_008)
c) NSW Health Enterprise-Wide Risk Management (PD2022_023)

8.6 Improvement

NSWHP continuously reviews its processes and procedures at Executive and laboratory levels to improve outcomes through innovation, and technology. Improvement allows for NSWHP to better achieve timely, accurate and cost-effective diagnostic services in accordance with quality standards and customer requirements.

Both negative and positive feedback is sought from customers to identify opportunities for improvement.

An open-door policy, employee input into QMS management reviews, and engagement with employees about planning for improvements facilitates the communication for engagement with and identification of potential improvements. Quality improvement opportunities offered by service users and service partners are pursued.

NSWHP identifies, evaluates, and addresses risks and opportunities by mitigation, planning, monitoring and review to ensure that the management system achieves expected results, takes advantages of opportunities, maintains business continuity and achieves improvement.

The application of the tools, methodologies and techniques of quality improvement are used in the improvement processes.

Opportunities for improvement are reported using the non-conformance system of the QMS. Improvement activities are prioritised based on the positive and negative risks identified.

The internal audit programs and QMS management review processes are used to systematically review operational procedures and the effectiveness of changes to identify opportunities for improvement. Deficiencies or improvements noted during periodic review are addressed immediately and details of actions are recorded.

As part of NSWHP's commitment to improvement, employees are encouraged to attend further training opportunities specific to their area of work. This may include internal or external training or conference/seminar attendance.

(See: ISO 15189:2022 Clause: 8.6; ISO/IEC 17025:2017 Clause: 8.6; ISO 9001:2015 Clause(s) 10,10.1)

8.7 Nonconformities and Corrective actions

Employees are empowered and encouraged to report nonconformities, being but not restricted to: failure to meet any relevant standard or other mandatory requirement, failure of a procedure or any adverse incident that affects testing or provision of a test result before, during or after testing, including after the release of results. The range of potentially reportable nonconformities is intended to be wide, all-encompassing, and non-restrictive.

Specifically, nonconformity recording systems are intended to capture internal and external problems, suggestions and opportunities for improvement, commendations and compliments, complaints and hazards, near-misses or risks. A nonconformity may be notified due to single or recurrent incidents involving lack of compliance with existing laboratory policy or procedures or related to inadequately documented policy or procedures.

Variances detected as a result of an internal or external audit, any other planned or ad hoc evaluation or through the QMS management review process are handled through the relevant nonconformity management systems. The system is to ensure that any deviation from normal processing procedures is assessed, corrected where necessary, and recorded, via documented procedures.

NSWHP local QMS systems are used for the management of nonconformities and corrective and preventive actions. The system defines all aspects of incident management including a risk analysis and the identification of responsible employees to assess nonconformity scope, carry out immediate actions including cessation of testing, authorisation of resumption of testing, assessment of any patient/customer impact significance, individually or collectively arising from an incident and initiate and monitor corrective or preventive actions.

Review of individual incidents, frequencies and trends in nonconformities and the robustness and success of the systems is carried out, at a minimum as part of the Quality and Patient Safety Committees' remit and the QMS management review process.

NSWHP nonconformity procedures specify that remedial action takes place when a nonconformity is identified. An immediate assessment is carried out to determine the past and potential severity of consequences and risks to the testing, the continuity of service, patients/customers, employees, and any other affected party. For clinical and safety incidents reported in the NSW Health electronic incident management systems (ims+) a Harm Score is assigned. Based on the risk rating, immediate mitigation measures including cessation of testing may be instituted until the root cause is determined.

Laboratories ensure that the appropriate management authorities exist to implement corrective actions when nonconformities have been identified.

Corrective actions

Procedures specify that after determining the root cause of the problem, effective corrective action to address the issue is taken in a timely fashion. Corrective action may include amendment to existing procedures, improved documentation, and employee retraining.

Corrective action is taken to eliminate existing nonconformities to a degree appropriate to the magnitude of the problem and commensurate with the risk encountered to eliminate or minimise the impact on safety, performance, reliability, processing cost, quality-related cost, and customer satisfaction.

Laboratory management monitors and verifies the implementation and effectiveness of corrective action. The monitoring process is maintained in the quality management software and is sufficiently comprehensive to allow appropriate cross-referencing e.g. with the relevant ims+ reference number.

Laboratories ensure that an internal audit occurs in instances where the nonconformity potentially affects the laboratory's compliance with its own policies and procedures, or NPAAC or ISO Standards. Follow-up audits and actions are carried out as per documented procedures.

Management of Critical Incidents

NSWHP uses the NSW Health ims+ as its critical incident management system for investigating and actioning recommendations for critical incidents according to NSW Health Incident Management Policy (PD2020_047) and the NSWHP Critical Incident Procedure (NSWHP_PR_021).

A critical incident is defined as an incident that requires mandatory and prompt notification to NSWHP Executive and would include, but is not confined to, incidents such as:

a) Harm Score 1 and 2 clinical and corporate incidents
b) "Reportable Incidents" as defined in NSW Health Incident Management Policy
c) Significant injury or harm to patient, employees, visitors or contractors
d) Significant concerns or complaints raised about conduct, impairment, or performance of individual clinicians is managed according to NSW Health Managing Complaints and Concerns about Clinicians (PD2018_032).
e) Disaster management/emergency response notifications to the State Pathology Controller requiring action at that level

f) Major disruption to the business or provision of services
g) Significant property or environmental damage or loss
h) Matters of legal significance and/or
i) A serious threat to the financial standing or reputation of NSWHP.

(See: ISO 15189:2022 Clause: 8.7; ISO/IEC 17025:2017 Clause: 8.7; ISO 9001:2015 Clause(s) 10.2)

References

1. NSWHP Compliance Management Framework (NSWHP_CG_010)
2. NSW Health Incident Management Policy (PD2020_047)
3. NSWHP Critical Incident Procedure (NSWHP_PR_021)
4. NSW Health Managing Complaints and Concerns about Clinicians (PD2018_032)

8.8 Evaluations (Audits)

NSWHP conducts regular and ad hoc reviews, audits and surveys on its pre-analytical, post-analytical and laboratory processes, the quality management system, workplace safety, and the needs and requirements of users including the test ranges and collection requirements.

Audits are conducted against applicable internal policies, internal procedures, mandatory external Standards and legislation and applicable guidelines. The results of the actionable findings are managed through the respective nonconformity procedures that include changing processes and updating documentation.

External body auditing of NSWHP laboratories is carried out for NATA/RCPA accreditation by the National Association of Testing Authorities, Australia according to Commonwealth Health NPAAC Requirements and by RCPA for accreditation of training for pathologists.

Media Units at Westmead and St George Hospitals are NATA-accredited in the field of Life Sciences to ISO/IEC 17025:2017. TGA undertakes certification visits to cellular therapy and donor tissues for transplantation screening services operated by NSWHP. The Andrology service at Randwick is accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia.

Facilities at FASS are accredited under ISO/IEC 17205 in the Life Sciences or Legal (including Forensic Science) fields and ISO15189 and the NPAAC Requirements for the *Facilities and Operation of Mortuaries* for the Forensic Medicine branch.
Greater Murray Water Testing Laboratory, located within our Wagga Wagga Hospital Laboratory, is NATA-accredited in the field of Life Sciences to ISO/IEC 17025:2017.

Internal Audits

NSWHP has an Executive level internal audit unit and program, which includes examination of various aspects of laboratory operations.

The location and procedures for the NSWHP internal audit program are in the respective quality management systems.

The internal audit programs: -

a) Provide assurance that the QMS is operating as intended
b) Review elements essential for patient care and employee safety
c) Demonstrate ongoing compliance with requirements for accreditation and certification
d) Demonstrate ongoing compliance with NSWHP documented policies and test and operational procedures
e) Ensure NSWHP meets the needs and requirements of its users
f) Investigate the causes of problems and customer complaints and facilitate appropriate action
g) Identify risks opportunities for improvement in the QMS or how it is implemented
h) Provide a mechanism for the investigation of deficiencies reported during third party assessments and to facilitate appropriate action.

Audits are conducted according to a regular pre-determined schedule and procedure, addressing managerial and technical or process elements critical to the operation of and to patient care. The local quality manager or delegate creates an audit plan to schedule audits in consultation with laboratory management and the plan is available for viewing in the audit calendar of the QMS.

Elements and aspects pertaining to the QMS (management and technical) are audited on a regular basis and the frequency of audits is based on risks associated with the process / area being audited, taking into consideration the results of previous audits.

Unscheduled audits are conducted if there is a major breach in the QMS, a recurring problem is reported or if the nonconformity seriously affects examination results and if any of these conditions applies then testing is halted. Ad hoc audits may be scheduled in response to an external audit finding by an accreditation or certification body, e.g. NATA.

Trained and competent personnel perform audits as the lead auditor and may utilise specialised experts to assist with aspects of technical audits.

The results of the audits are recorded. A copy is given to the manager with responsibility for the area concerned as soon as practicable after the audit. The management personnel responsible for the laboratory/area/division take timely corrective action if deficiencies are found by the audit. Prompt corrective actions are implemented through the respective nonconformity systems and these corrective and preventive actions are reviewed. Senior management review internal audit findings and, where necessary, additional steps are taken to improve the quality performance of the organisation. The success of corrective and preventive actions is reviewed, and re-auditing is carried out.

Key Performance Indicators

NSWHP produces key performance indicators (KPIs) designed to measure internal and comparative clinical, financial and operational performance. Indicators evaluating patient care including turnaround times are measured and reported to management on a regular basis. KPIs are reported to LHD customers in accordance with the Customer Charter. High level performance indicators are reported to senior management and committees of NSWHP including the NSWHP Quality and Clinical Safety Board subcommittee.

Key Performance measurements vary according to identified risks and the needs of NSWHP and users. KPIs may, but are not restricted to, include: -

a) Turnaround times of routine and critical results
b) NATA audit performance
c) Laboratory supervision compliance
d) Pre- and Post-Analytical error rates
e) Complaint frequency
f) Incident notification rates and resolution times
g) Vertical audit completion

(See: ISO 15189:2022 Clause: 8.8; ISO/IEC 17025:2017 Clause: 8.8; ISO 9001:2015 Clause(s) 9.2

8.9 Management Review

Management review is conducted at least annually to evaluate the effectiveness and suitability of the NSWHP quality management system, testing, PoCT and other activities of laboratories and examine whether the laboratory has and can continue to provide for the needs of requestors, patients, health services, hospitals and other users of the laboratory. Improvement and change management plans are developed. Senior management and supervisors are involved with the management review and the minimum review is, at least, to meet the requirements of ISO15189:2022, ISO/IEC 17025:2017 and ISO 9001:2015.

Management review processes may be undertaken ad hoc addressing specific issues. Planning and scheduling is undertaken to demonstrate that a complete management review is completed at least annually.

During a review, laboratory management will utilise all available information including internal and external quality audit results, customer feedback, employee feedback, supplier feedback, quality objectives, non-conformance reports and corrective and preventive actions to improve the system.

Findings and actions from the review are recorded and laboratory employees are notified of the findings and decisions made. An action plan is prepared and items that are actionable are managed through the normal nonconformity processes using corrective and preventive actions and/or quality improvement methods and monitored in monthly management meetings. The timeframe for resolution of a finding is set appropriate to the risk identified.

(See: ISO 15189:2022 Clause: 8.9; ISO/IEC 17025:2017 Clause: 8.9; ISO 9001:2015 Clause(s) 9.3

9 Point of Care Testing

NSWHP manages the largest accredited Point of Care Testing (PoCT) service in the world, with more than 1080 devices in 190 health services across NSW.

PoCT uses mobile devices to analyse pathology samples, like blood and saliva, and provide on-the-spot results at a patient's hospital bedside or in the community.

Samples are processed instantly, rather than transported to a lab for testing, delivering accurate results in minutes to inform clinical decision-making and improve patient care and outcomes. PoCT enables greater access to quality, reliable pathology tests for patients without the need for travel.

It means health services without access to 24/7 laboratories can perform key, sometimes lifesaving, pathology tests at any time.

Patients requiring critical care can be identified earlier and transported to larger hospitals if needed. Paramedics can decide where to transport a patient, based on the diagnosis and treatment needed.

PoCT devices are used in emergency departments, cardiac theatres, intensive care units and specialty medical facilities. Our PoCT team continually trials new and emerging technology. The relevant discipline Clinical Stream reviews the outcome of these trials to determine which devices are considered suitable for use in the PoCT setting.

We are committed to supporting Local Health District clinical staff. We ensure they have the resources, training and support they need to correctly and confidently integrate PoCT into their daily work.

Any health service wishing to utilise PoCT testing makes a request through NSWHP's online application portal. The PoCT Team review requirements and propose a device, user training, quality assurance, and support combination. These arrangements are documented in a service level agreement between NSWHP and the health service.

The PoCT Team includes staff with the appropriate training and experience to oversee Quality Assurance and the training and competency assessment of users.

The very same standards for quality and clinical safety described in this document apply to the PoCT service as equally as they apply to the conventional testing laboratories.

(See: ISO 15189:2022 Annex A)

Reference

NPAAC Requirements for *Point of Care Testing*

10 Roles and Responsibilities

NSWHP Strategic Leadership Team is accountable for the quality assurance and accreditation of services provided by NSWHP with key responsibilities being to:

- Establish and endorse the NSWHP Quality Manual and to champion a culture that promotes continuous quality improvement.
- Ensure efficient allocation of resources to deliver services that meet the needs of patients and customers and exceed accreditation standards.
- Ensure robust and transparent auditing practices and reporting practices occur regularly and permeate all levels of the organisation.
- Create a culture that encourages, supports, and empowers staff to speak up and raise concerns related to quality and compliance.
- Delegate the implementation, review, and evaluation of operational quality to relevant leaders within the organisation.
- Ensure that staff are supported in their involvement in quality activities.
- Regularly report to the board on quality and accreditation risks and continuous quality improvements to progress towards excellence. Regularly evaluate the NSWHP Quality Manual to ensure ongoing relevance and contemporary best practice.

Laboratory Managers are accountable for the quality assurance and accreditation of services provided by their laboratories with key responsibilities being to:

- Ensure that there are appropriate numbers of staff with the required education, training, and competence to provide laboratory services that meet the needs and requirements of the users.
- Define, implement, and monitor standards of performance and quality improvement of the laboratory services.

Quality Managers are accountable for the quality assurance and accreditation of services provided by their facilities with key responsibilities being to:

- Ensure that the process needed for the quality management system are established, implemented, and maintained.
- Report to laboratory management on the performance of the quality management system and any need for improvement.
- Ensure the promotion of awareness of users' needs and requirements throughout the organisation.

11 Review

The NSWHP Quality Manual will be reviewed for ongoing fitness for purpose by the Quality and Patient Safety Team. Review shall occur at least annually and when required by changes to the design of the Quality Management System or the release of new or updated legislation, relevant standards, or accreditation requirements.

12 Risk

Risk Statement	The NSWHP Quality Manual addresses the following risks • Non-compliance with relevant NSW Health Policy and State and Commonwealth legislation • Failure to meet relevant Standards To maintain accreditation NSWHP Pathology implements an integrated quality management strategy and system, promotes a culture of continuous improvement and actively monitors compliance, performance reporting and accountability to deliver quality, safe and innovative outcomes.
Risk Category	Clinical Care and Patient Safety

13 Further Information

For further information, please contact:

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14 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	01/04/2020	Clinical Governance, Quality and Risk Committee	01/04/2020	Linda Sorum	High	New manual
1.1	24/07/2020	Executive Director Clinical Governance & Quality	30/07/2020	Collin Sheppard	High	3, 4.1.2, 4.1.5 4.3 4.5.1, 4.8 4.13.1, 7
2.0	01/12/2023	Director Clinical Governance (Patient Safety)	28/11/2023	Clinical Governance Team	High	Major reformat & revision in line with ISO 15189:2022