

Compliance Management Framework



Health
Pathology

Compliance Management Framework

NSWHP_CG_010

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1. Introduction

NSW Health Pathology recognises that an important part of achieving our strategic direction is to have an effective system of governance. This includes conducting our activities in accordance with applicable laws, regulations, professional codes, industry standards and NSW Health and NSW Health Pathology policy documents.

NSW Health Pathology commits to maintaining high standards of diligence in all areas of public accountability, including by implementing a compliance management system and promoting a culture of compliance.

2. Purpose

This Framework establishes the state-wide compliance management system that ensures NSW Health Pathology's operations are conducted in accordance with our Compliance Obligations.

The Framework stipulates the key principles that guide compliance management within NSW Health Pathology, consistent with our [values](#), [strategy](#) and [risk appetite](#).

The Framework assists NSW Health Pathology to:

- a) Demonstrate our commitment to the highest standards of ethics and compliance
- b) Embed a culture of compliance
- c) Integrate effective policy, systems, controls and delegations of authority necessary to ensure compliance
- d) Inform staff of mechanisms to facilitate compliance and
- e) Establish and maintain an assurance program to monitor and report on compliance activities.

3. Background

The Framework is aligned with:

- a) [International Standard AS ISO 19600 Compliance Management Systems – Guidelines](#)
- b) [International Standard AS ISO 15189 Medical laboratories – Requirements for quality and competence](#)
- c) [National Pathology Accreditation Advisory Council \(NPAAC\)](#)
- d) [National Safety and Quality Health Service Standards](#)
- e) [NSW Health Code of Conduct PD2015_049](#)
- f) [NSW Health Corporate Governance and Accountability Compendium](#)
- g) [NSW Health Legal Compendium](#)
- h) [NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026](#)
- i) [NSW Health Pathology Policy Framework NSWHP_CG_003](#)
- j) [NSW Health Services Act 1997](#)
- k) [NSW Health Significant Legal Matters and Management of Legal Services PD2017_003](#)
- l) [NSW Treasury Internal Audit and Risk Management Policy for the NSW Public Sector \(TPP 15-03\)](#).

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4. Definitions

Compliance Obligations means applicable laws, regulations, professional codes, industry standards and NSW Health and NSW Health Pathology policy documents.

Compliance Register means the register referred to in section 7.

Compliance Report means the [compliance report](#) described in section 9.4.

Controls means the policies, procedures, processes and other systems put in place to manage compliance with Compliance Obligations and associated risk of non-compliance.

Framework means this Compliance Management Framework.

Personnel means NSW Health Pathology staff, as well as students on clinical placement or work experience, visitors, volunteers, contractors and consultants performing work within or using NSW Health Pathology facilities.

Other terms used in the Framework are, where applicable, consistent with the definitions in the [International Standard AS ISO 19600 Compliance Management Systems – Guidelines](#).

5. Scope

The Framework is mandatory and applies to all Personnel, and encompasses all Compliance Obligations.

6. Key Components of Compliance Management System

The key components of NSW Health Pathology's compliance management system are:

- a) This Framework
- b) A Compliance Register – an accurate and complete record of key Compliance Obligations and associated Controls and risks of non-compliance
- c) Allocation of accountability for assessing, monitoring and ensuring compliance to members of the Strategic Leadership Team based on their respective functional areas
- d) A clear process for escalating identified instances of potential or actual non-compliance
- e) Annual attestation of compliance
- f) An embedded compliance culture led by the Strategic Leadership Team that is committed, proactive, visible and consistent
- g) Staff awareness and training on specific compliance responsibilities and
- h) Continual review of compliance risk.

7. Compliance Register

A Compliance Register will be maintained by NSW Health Pathology's Strategy and Reform Portfolio. The Compliance Register will record:

- a) Key Compliance Obligations that impact on the operations of NSW Health Pathology
- b) The nominated officer (generally a member of the Strategic Leadership Team) who will be responsible for maintaining compliance with each Compliance Obligation allocated to it, known as the Compliance Owner
- c) A summary of Controls for each Compliance Obligation, as well as any additional Controls required to improve compliance and
- d) A [risk assessment](#) for each Compliance Obligation, determined on the basis of the likelihood and the consequences of non-compliance. The risk rating will inform the priority of compliance activities. Identified risks must be managed and reported in accordance with the [NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026](#).

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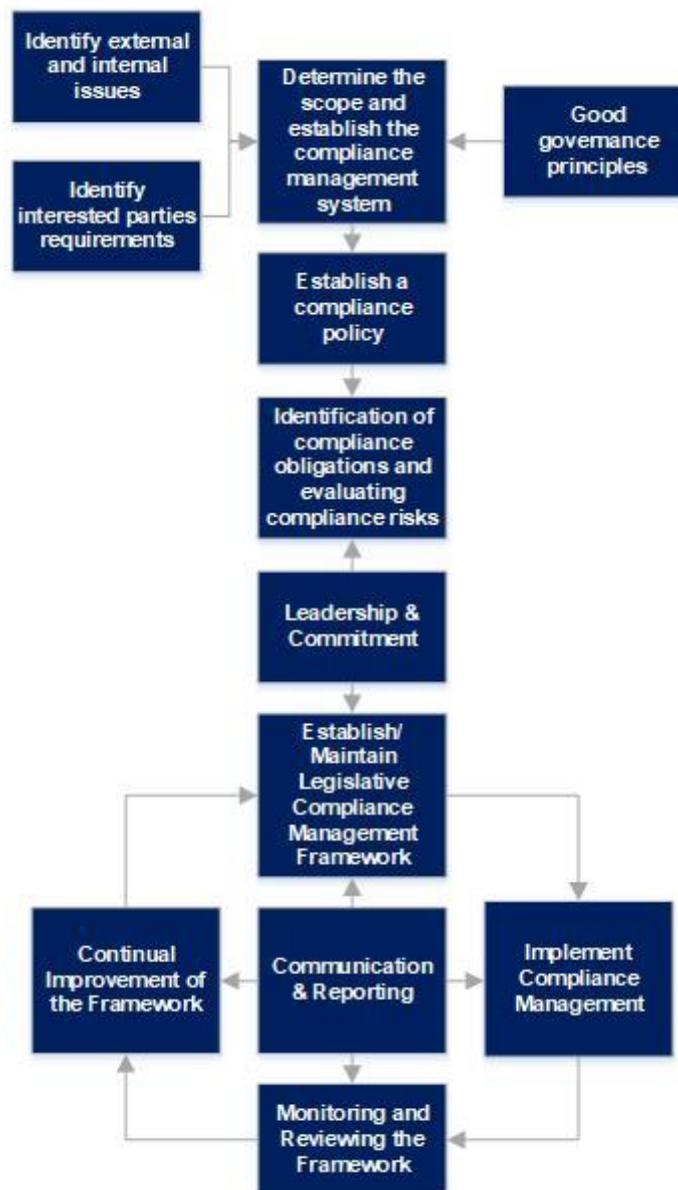
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It must be noted that all legislative and regulatory obligations are *mandatory* regardless of the risk rating.

The Compliance Coordinator will be responsible for updating the Compliance Register regularly to incorporate relevant changes to Compliance Obligations and Controls, and ensuring that it is made available to relevant Personnel.

Compliance Owners (with assistance from the Compliance Coordinator) will be responsible for ensuring that any changes to Compliance Obligations for which they are responsible are identified, communicated to affected areas and reported to the Compliance Coordinator so that they may be incorporated into the Register.

8. Flowchart: Compliance Management System



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9. Monitoring and Reporting

9.1 Monitoring

The Compliance Owner must be familiar with Compliance Obligations within their area of functional responsibility and must ensure that there are adequate Controls in place to continually monitor and review compliance with those obligations, and that any Control gaps or instances of actual or potential non-compliance are promptly identified and where possible resolved. This includes ensuring that:

- a) Risk ratings remain accurate and
- b) Controls remain appropriate and effective, notwithstanding any changes in the operational or regulatory environments.

9.2 Reporting Compliance Issues or Incidents

Actual or potential non-compliance may be a result of:

- a) Changes to Compliance Obligations which have not been pre-empted
- b) Missed regulatory deadlines
- c) Activities that are undertaken without the required accreditation, licence, permit or regulatory authorisation or which are otherwise prohibited by law
- d) Regulatory compliance audit findings (internal or regulatory audits)
- e) Notices, directives or fines issued by regulators and
- f) Pending prosecutions, regulatory investigations or other legal enforcement actions.

In accordance with the [NSW Health Code of Conduct PD2015_049](#), all Personnel must comply with all Compliance Obligations relevant to their role and responsibilities. Behaviour that compromises compliance will not be tolerated and, in addition to disciplinary action, a failure to comply with Compliance Obligations may also be punishable by law.

Personnel are required to proactively identify, and as soon as possible report to their line manager, any actual or potential non-compliance. The line manager must escalate the matter in a hierarchical fashion to the responsible Compliance Owner, who must report it to the Compliance Coordinator as soon as practical. The non-compliance must also be recorded in the NSW Health Pathology Risk Register and reported in accordance with the [NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026](#).

If Personnel are not comfortable reporting to their manager, they should report the matter to the relevant Compliance Owner or anonymously by contacting the Disclosures Coordinator (the Executive Director, Strategy and Reform) via the insurable risk [email account](#).

The Compliance Coordinator will report instances of non-compliance to the Chief Executive, the Strategic Leadership Team, the Audit and Risk Management Committee and other officers or committees, as appropriate, within timeframes determined according to the assessed risk rating of the applicable non-compliance.

In some instances, such as allegations of corruption, there is a mandatory requirement to report matters to external agencies. Such instances should be reported to the [Disclosures Coordinator](#) immediately, who will ensure that the matter is reported to the responsible agency.

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Instances of non-compliance that constitute a 'Significant Legal Matter' must also be notified to NSW Health in accordance with the [NSW Health Significant Legal Matters and Management of Legal Services Policy Directive PD2017_003](#).

Complaints alleging compliance breaches should be handled in accordance with the [NSW Health Complaint Management Policy PD2006_073](#) and [NSW Health Complaint Management Guidelines GL2006_023](#).

NSW Health Pathology is committed to protecting any person who raises concerns about a breach of a Compliance Obligation from retaliation or reprisals. Any attempt to take detrimental action against a person who raises a legitimate breach of a Compliance Obligation will be treated seriously and may result in disciplinary action.

9.3 Resolving Compliance Issues or Incidents

Once an instance of potential or actual non-compliance has been identified and reported, the relevant Compliance Owner will:

- a) Implement appropriate corrective action in consultation with the Compliance Coordinator and NSW Health Pathology Legal Counsel where appropriate
- b) Assess, document and monitor the timeframe and implementation of corrective actions and
- c) Continue to report on non-compliant matters until rectified.

Any residual risks remaining after corrective action has been taken will be assessed and managed in accordance with the [NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026](#).

9.4 Annual Attestation

The NSW Health Pathology Board and the Chief Executive are required to report to the Ministry in the annual [Corporate Governance Attestation Statement \(the Statement\)](#) that NSW Health Pathology has complied with the relevant legislation and regulations in the preceding 12 months. To facilitate this, and verify compliance more generally, Compliance Owners will be required to complete a [Compliance Report](#) and provide it to the Compliance Coordinator by 31 July each year.

The [Compliance Report](#) is designed to provide reasonable assurance to the Board and the Chief Executive that NSW Health Pathology has appropriate mechanisms in place to ensure that all facilities and units comply with all relevant Compliance Obligations.

10. Continual Improvement

NSW Health Pathology will continually assess and seek to improve the suitability, adequacy and effectiveness of the Framework by:

- a) Keeping abreast of compliance best practice
- b) Reviewing the Framework at least every two years to ensure currency, including by identifying opportunities for improvement
- c) Encouraging staff to provide feedback on the Framework to the Compliance Coordinator.

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11. Training and Awareness

The Compliance Owner is responsible for promoting understanding and awareness and ongoing reinforcement of Compliance Obligations within their area of functional responsibility, as follows:

- a) Referencing obligations in relevant policy documents and position descriptions
- b) Incorporating compliance as a component of the on-boarding process
- c) Incorporating compliance training in appropriate staff developmental activities
- d) Facilitating targeted compliance training to staff with specific responsibilities affected by legislative changes
- e) Conducting annual audits of professional registrations where relevant and
- f) Ensuring NSW Health Pathology's commitment to compliance is visible and ongoing.

The Compliance Coordinator will arrange training sessions on legislative compliance management on an as needs basis.

12. Performance Measures

NSW Health Pathology's overall compliance performance will be assessed annually by measuring:

- a) % of compliance requirements that are being met
- b) % of policy documents that are reviewed within the specified timeframes
- c) % of reported breaches investigated and resolved within 45 days in accordance with the [NSW Health Incident Management Policy PD2007_061](#)
- d) Annual review of the obligations including a risk assessment
- e) Staff awareness and training on specific compliance responsibilities.

13. Roles and Responsibilities

To ensure that we achieve our intended compliance outcomes, the Framework establishes key responsibilities for Personnel as follows:

13.1 Board

It is the responsibility of the Board to:

- a) Oversee the development, implementation and monitoring of the Framework
- b) Promote a positive compliance culture and
- c) Review and monitor compliance.

13.2 Chief Executive

It is the responsibility of the Chief Executive to:

- a) Oversee the effective management of the Framework
- b) Provide leadership for, and actively support, compliance
- c) Promote, monitor and uphold a positive compliance culture
- d) Embed compliance into the operational processes of NSW Health Pathology by ensuring that Personnel are aware of their responsibilities pursuant to the Framework
- e) Ensure NSW Health Pathology complies with all Compliance Obligations

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- f) Approve correspondence with regulators in relation to the resolution of non-compliance as required and
- g) Attest annually to the Ministry that the legal and policy obligations of NSW Health Pathology are identified and understood and the responsibilities for compliance are allocated in accordance with the [Corporate Governance and Accountability Compendium for NSW Health](#).

13.3 Audit and Risk Management Committee

It is the responsibility of the Audit and Risk Management Committee to:

- a) Ensure that the Framework contributes to enterprise-wide risk management processes
- b) Determine whether management has appropriately considered legal and compliance risks as part of NSW Health Pathology's risk assessment and management arrangements and
- c) Review the effectiveness of the Framework in ensuring NSW Health Pathology's compliance with Compliance Obligations.

13.4 Compliance Owners (Strategic Leadership Team)

It is the responsibility of the Compliance Owners (Strategic Leadership Team members) to:

- a) Adopt the Framework and promote, monitor and uphold a positive compliance culture
- b) Maintain an awareness of Compliance Obligations (including changes to existing Compliance Obligations) relevant to their area of operational responsibility and notify the Compliance Coordinator and affected Personnel of any new Compliance Obligations or changes to existing Compliance Obligations
- c) Identify and assess compliance risks to manage compliance risk in their area of operational responsibility
- d) Ensure that Personnel within their area of operational responsibility are aware of their responsibilities in relation to compliance
- e) Effectively manage and monitor compliance with all Compliance Obligations within their area of operational responsibility
- f) Attest annually that the Compliance Obligations within their area of operational responsibility have been identified and are understood and (except as otherwise indicated) complied with, and that appropriate Controls are in place
- g) Review the Compliance Obligations allocated to it in the Compliance Register at least annually, including by reviewing the Controls and risk rating and prioritising any strategies to minimise the risk of non-compliance
- h) Allocate appropriate resources for compliance management within their area of operational responsibility
- i) Encourage Personnel to raise compliance concerns and actively participate in managing and resolving compliance issues or incidents and
- j) Report, manage and where possible resolve (including by seeking legal advice where appropriate) actual or potential non-compliance in accordance with this Framework.

13.5 Compliance Coordinator

The Compliance Coordinator is located in Strategy and Reform in the NSW Health Pathology Corporate Office. It is the responsibility of the Compliance Coordinator to:

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- a) Ensure a coordinated and consistent approach across NSW Health Pathology to meeting its Compliance Obligations
- b) Develop, implement, communicate and review the Framework
- c) Maintain the Compliance Register
- d) Report to the Strategic Leadership Team and the Audit and Risk Management Committee on compliance matters and the effectiveness of the compliance management system, including reporting on compliance trends or issues as required
- e) Prepare a consolidated compliance statement each year for the Chief Executive and Audit and Risk Management Committee incorporating individual compliance reports from Compliance Owners
- f) Establish and maintain appropriate systems or processes for recording instances of reportable non-compliance and
- g) Identify systemic issues arising from instances of reportable non-compliance and reporting them to the Strategic Leadership Team, Chief Executive and Audit and Risk Management Committee as appropriate.

13.6 All Personnel

It is the responsibility of all Personnel to:

- a) Comply with all relevant Compliance Obligations within the scope of their roles and
- b) Identify and report any concerns in relation to non-compliance to their line manager (or otherwise in accordance with this Framework).

14. References and Links

14.1 Legislation

[Federal Register of Legislation](#)

[NSW Legislation](#)

[NSW State Records Act 1998](#)

14.2 Standards

[International Standard AS ISO 19600 Compliance Management Systems – Guidelines](#)

[International Standard AS ISO 9001 Quality Management Systems](#)

[International Standard ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories](#)

[International Standard AS ISO 15189 Medical laboratories – Requirements for quality and competence](#)

[National Pathology Accreditation Advisory Council \(NPAAC\)](#)

[National Safety and Quality Health Service Standards](#)

[SAI Global](#) (NSW Health Pathology access to International and Australian Standards)

14.3 Policies

[NSW Health Code of Conduct PD2015_049](#)

[NSW Health Corporate Governance and Accountability Compendium](#)

[NSW Health Complaint Management Guidelines GL2006_023](#)

[NSW Health Complaint Management Policy PD2006_073](#)

[NSW Health Pathology Delegations Manual CG_001](#)

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[NSW Health Patient and Clinical Quality Program PD2005_608](#)

[NSW Health Incident Information Management System](#)

[NSW Health Incident Management Policy PD2007_061](#)

[NSW Health Legal Compendium](#)

[NSW Health Pathology Clinical Governance Framework](#)

[NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026](#)

[NSW Health Pathology Policy Framework CG_003](#)

[NSW Health Risk Management – Enterprise-Wide Risk Management Policy and Framework PD2015_043](#)

[NSW Health Significant Legal Matters and Management of Legal Services Policy Directive PD2017_003](#)

[NSW Treasury Internal Audit and Risk Management Policy for the NSW Public Sector \(TPP 15-03\)](#)

14.4 Regulatory

[National Association of Testing Authorities, Australia](#)

[Royal College of Pathologists of Australasia Quality Assurance Programs](#)

[Therapeutic Goods Administration](#)

15.Review

The framework will be reviewed by 31/12/2020.

16.Risk

| | |
|-----------------------|---|
| Risk Statement | Compliance with relevant legislative and regulatory obligations will mitigate the risk of: <ul style="list-style-type: none">- Loss of funding given the legislative compliance conditions in the <i>Health Services Act 1997</i>- Complaints, penalties, fines, litigation, investigations, inquiries, loss of services and management time, injuries and adverse outcomes- Reputational damage. |
| Risk Category | Leadership and Management |

17.Further Information

For further information, please contact:

| | |
|-------------------------------|--|
| Policy Contact Officer | Position: Compliance Coordinator |
| | Name: Samantha Brookes |
| | Telephone: 4920 4082 |
| | Email: NSWPATH-LegislativeCompliance@health.nsw.gov.au |

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18. Version History

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

| Version No | Effective Date | Approved By | Approval Date | Policy Author | Risk Rating | Sections Modified |
|------------|----------------|-------------------------------------|---------------|--|-------------|-------------------|
| V1.0 | 24/10/18 | Transformation Governance Committee | 10/10/2018 | Samantha Brookes Senior Policy Officer and Compliance Coordinator | High | New framework. |

19. Supporting Documents

[Compliance Report](#)