

Guideline

Policy Framework

NSWHP_CG_003

1. Purpose

The clinical and corporate governance of NSW Health Pathology is based on legislation, standards and NSW government policies (including NSW Health policies).

The NSW Health Pathology Policy Framework supports business performance through the efficient and effective management of policy.

2. Background

The NSW Health Pathology Policy Framework establishes a defined and enforceable system for the development, approval, implementation and review of NSW Health Pathology Policy Documents.

To achieve this, NSW Health Pathology Policy Documents shall:

- Be consistent with all relevant Commonwealth and NSW legislation and standards
- Be consistent with the NSW Health Pathology vision, strategic objectives, purpose and values
- Be consistent with, and not duplicate, amend, or rebadge NSW Health Policy Directives
- Assign responsibility and accountability to ensure due diligence in the operations of NSW Health Pathology
- Be transparent and developed in consultation with stakeholders
- Be binding and apply to NSW Health Pathology staff, volunteers, visitors, contractors and students where applicable and
- Comply with the requirements of this framework.

3. Scope

The Policy Hierarchy is an overview of the policy documents that define and govern NSW Health Pathology's operations. The Policy Hierarchy is illustrated below and each level is described in order of precedence.



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Documents lower in the hierarchy must relate to, and be consistent with, a document higher in the hierarchy. If there is an inconsistency between levels of the Policy Hierarchy, the higher level provision prevails.

4. Definitions

References in this Framework to ‘**Policy Documents**’ should be read as references to all NSW Health Pathology Policies, Procedures, Guidelines and Supporting Documents.

- **Commonwealth and NSW Legislation**
NSW Health Pathology is governed by Commonwealth and NSW legislation (Acts, Regulations and other legislative instruments), administrative decisions and the common (i.e. court-made) law.
- **Ministry of Health Policy Directives**
The Ministry of Health sets Policy Directives for all NSW Health Organisations. NSW Health Pathology is required to comply with and implement all relevant [Ministry of Health Policy Directives](#).
- **Ministry of Health Guidelines**
[Ministry of Health Guidelines](#) establish best practice in relation to clinical and non-clinical activities and functions. Although compliance with Ministry of Health Guidelines is not mandatory, the intention is that Guidelines are to be adopted. NSW Health Pathology must ensure that sound reasons exist and are documented for departing from recommended standards or practices within a Guideline.
- **Ministry of Health Information Bulletins**
[Ministry of Health Information Bulletins](#) contain information on new or amended requirements imposed by external sources of authority. These include changes to statutory, award or other legal provisions, or contain broader Government policy requirements, such as Premier’s Memoranda, Treasurer’s Directions or Federal Government initiatives.
- **Ministry of Health Policy and Procedure Manuals**
[Ministry of Health Policy and Procedure Manuals](#) are a compilation of resources and advice on a specific subject, and may include related Policy Directives, Guidelines and other information. A Manual is used where there is a significant body of information on a critical and complex function or set of functions brought together to provide practical support for NSW Health Organisations in exercising their functions.
- **NSW Health Pathology Policy**
NSW Health Pathology may develop and implement policies in the absence of a Ministry of Health policy, or where a remedy to a statewide risk, or operational situation, is required. Policies are an official position statement of NSW Health Pathology and establish the key

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principles and provisions that govern decision-making processes. Compliance with Policies is mandatory.

Local Health District or hospital policy documents may apply where no Ministry or NSW Health Pathology Policy document exists (for example, site-specific policy documents relating to emergency procedures).

- **NSW Health Pathology Procedures**
[NSW Health Pathology Procedures](#) detail the operational steps that should be taken when implementing a Ministry or NSW Health Pathology Policy. Procedures should be linked to the Policy, explain how to implement the particular Policy and include roles and responsibilities. Compliance with Procedures is mandatory. Procedures may be applicable statewide, or limited to a particular business unit, service or program.
- **NSW Health Pathology Guidelines**
[NSW Health Pathology Guidelines](#) provide advice on best practice and context related to legislation, standards and policy. Although compliance with Guidelines is not mandatory, it is strongly encouraged. NSW Health Pathology must ensure that sound reasons exist, and are documented, for departing from recommended standards or practices within a Guideline.
- **NSW Health Pathology Supporting Documents**
Supporting Documents may be developed to assist the implementation of and facilitate compliance with legislation, standards and policy documents. Supporting Documents may include forms, checklists, instructions, templates, flowcharts, test methods and frameworks which require similar levels of document control and standardisation throughout NSW Health Pathology. When preparing Supporting Documents, Policy Authors should follow the general principles outlined in this framework and follow the [NSW Health Pathology Templates and Style Guide](#).

When clinical forms intended for statewide use are being developed, Policy Authors and Policy Sponsors must consider whether there is a need to have the form approved by the [NSW Health State Health Forms Committee](#). (The SLT currently act as the Health Records Forms Committee for NSWHP).

5. Roles and Responsibilities

To facilitate appropriate governance of Policy Documents, this framework establishes several key roles as follows:

5.1. Policy Sponsor

NSW Health Pathology Policy Documents must be sponsored by a member of the NSW Health Pathology Strategic Leadership Team.

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It is the responsibility of the Policy Sponsor to:

- Endorse the creation of a new Policy Document prior to its development
- Provide advice to the Policy Author in relation to the development and implementation of Policy Documents in accordance with this Framework
- Consult, or ensure that the Policy Author consults, with all relevant stakeholders
- Obtain endorsement from the Strategic Leadership Team (SLT) for new NSW Health Pathology Policies (and any NSW Health Pathology Procedures, Guidelines or Supporting Documents the Policy Sponsor considers should be escalated).
- In consultation with the Author, ensure that Policy Documents do not contravene any relevant legislative requirements or compliance obligations
- Conduct a final review of proposed new Policy Documents and, if approved, sign the [Policy Document Approval Checklist - NSWHP_F_001](#), for submission to NSWPATH-Policy@health.nsw.gov.au
- Ensure that staff who are required to comply with Policy Documents are notified of any new or amended requirements
- Review, or delegate the review of, Policy Documents assigned to the Sponsor before the review expiration date, and submit any changes to NSWPATH-Policy@health.nsw.gov.au with the completed [Policy Document Review Form - NSWHP_F_002](#).

5.2. Policy Author

It is the responsibility of the Policy Author to:

- Seek approval from the Policy Sponsor before developing a new Policy Document
- Develop and review Policy Documents in accordance with this framework
- Conduct relevant background research into best practice and ensure compliance with any relevant legislative requirements or compliance obligations
- Consult with stakeholders to identify implications and ensure expert input
- Conduct a detailed review to ensure accuracy of content, spelling and grammar, as well as formatting, before submitting to the Corporate Governance unit
- Complete the [Policy Document Approval Checklist - NSWHP_F_001](#) and obtain final check and approval/endorsement from the Policy Sponsor, before submission, with the final document, via email to NSWPATH-Policy@health.nsw.gov.au to request ID document number and publication.
- Assist the Policy Sponsor in ensuring staff comply with Policy Documents or any new or amended requirements.
- Assist the Policy Sponsor to co-ordinate review of Policy Documents assigned to the Sponsor before the review expiration date. Submit any changes, with [Policy Document Review Form - NSWHP_F_002](#) to NSWPATH-Policy@health.nsw.gov.au for re-publication of the document.

5.3. Policy Contact

It is the responsibility of the Policy Contact to:

- Act as the primary point of contact for the Policy, for advice on the policy and on implementing its provisions.

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- Undertake Policy Sponsor responsibilities as assigned to them by the Policy Sponsor. It should be noted that the Policy Sponsor remains accountable for ensuring compliance with the Policy Framework.

5.4. NSW Health Pathology Corporate Governance Unit

It is the responsibility of the NSW Health Pathology Corporate Governance Unit to:

- Provide statewide advice and support in relation to NSW Health Pathology Policy Documents
- Manage, oversee and continually improve the efficient and effective functioning of the NSW Health Pathology Policy Framework and the Policy Library
- Notify Policy Sponsors and Policy Authors when Policy Documents require review
- Ensure document control is in place for NSW Health Pathology Policy Documents
- Distribute new Ministry of Health policy documents, and notifications of obsolete policy documents, relevant to the operations of NSW Health Pathology, to all staff
- Monitor and report on policy implementation across NSW Health Pathology to the Strategic Leadership Team and the Board as required.

5.5. Managers

It is the responsibility of managers to:

- Distribute information to, and facilitate discussion with, their staff about relevant policy documents and maintain a record of such action, for example, minutes of staff meetings
- Ensure relevant Policy Documents are made available to staff who do not regularly access the NSW Health Pathology intranet, document management system, records management system and quality management system
- Assist with the implementation of relevant policy documents in their area and
- Monitor compliance and assess, manage and review non-compliance. If necessary, managers may escalate the matter through normal reporting structures to the relevant Policy Sponsor.

5.6. NSW Health Pathology Staff

It is the responsibility of all NSW Health Pathology staff to:

- Understand their responsibilities and comply with all Ministry of Health Policy Directives and NSW Health Pathology Policy Documents relevant to their area of responsibility and
- Report non-compliance to their manager.

5.7. Strategic Leadership Team

It is the responsibility of the Strategic Leadership Team to:

- Set expectations for policy requirements
- Oversee the implementation of the NSW Health Pathology Policy Framework
- Approve (or decline, with reasons) all new NSW Health Pathology Policies, and any NSW Health Pathology Procedures, Guidelines or Supporting Documents escalated to it by a Policy Sponsor for approval
- Act as the Health Records Forms Committee in accordance with the NSW Health State Health Forms Policy Directive PD2009_072 including reviewing and approving all clinical

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forms intended for statewide use and filing in the Health Care Record, and other forms as required.

6. Policy Development

The development and management of NSW Health Pathology Policy Documents follows a process as illustrated in the cycle below.

6.1. Initiate

Identify requirement for new Policy Document

The identification of the need for policy development may be for a range of reasons including to:

- Meet gaps in a Ministry of Health or NSW Health Pathology policy document, or where no policy document exists
- Implement a Ministry of Health policy document
- Address changes in the external environment such as legislative change or the internal environment such as a critical mass of issues
- Operationalise strategic directions
- Communicate expectations about how to deal with NSW Health Pathology matters
- Establish best practice and transparent, consistent and equitable standards and processes
- Support changes in clinical practice
- Manage or minimise risk and
- Provide rights and protections to individuals.

6.2 Research and Analysis

Before developing a new Policy Document, a critical assessment of the requirements of the document should be undertaken as follows:

- The type of Policy Document that is suitable to address the issue, for example, a Policy, Procedure, Guideline or Supporting Document
- The level of policy document that is appropriate, for example, a Ministry of Health or NSW Health Pathology Policy Document if a statewide approach is required
- The potential implications including legal, financial, industrial, workforce, training, on patients or consumers, and externally, for example, on other NSW Health Organisations such as Local Health Districts
- The interrelationship with other Policy Documents, for example, it may be more appropriate to update or extend existing Policy Documents rather than create a new Policy Document
- The impact of having too many policy documents for staff to operate within and
- Obtain advice from subject matter experts, undertake a literature review and explore theoretical scenarios. If a new Ministry of Health policy document is to be developed, the approvals required, and the issues for consideration, are outlined in clause 3 of the [NSW Health Policy Directives and Other Policy Documents PD2022_047](#).

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6.3 Draft and Consult

Draft

Once approval is received to develop a new Policy Document, the Policy Author must draft a new NSW Health Pathology Policy Document using the relevant [policy, procedure and guideline templates](#).

The policy templates:

- Ensure consistency across the NSW Health Pathology Policy Documents
- Assist Policy Authors to order their information and present it in a logical sequence and
- Benefit readers in being able to more readily find and understand policy information.

When developing the Policy Document, the Policy Author should:

- Use plain English, assume little prior knowledge and define any technical terms
- Give consideration to the target audience
- Ensure Policy Documents are as brief as possible while containing as much information as needed to outline the requirements
- Refer to relevant research including legislation, NSW Health Policy Directives, literature reviews and/or other authoritative sources
- Ensure Policy Documents are evidence-based and conform to best practice and relevant standards, for example, with [National Pathology Accreditation Advisory Council](#), [National Association of Testing Authorities Australia](#), [Standards Australia](#), [National Safety and Quality Health Service Standards](#) and [Australian and International Standards such as ISO Standards](#)
- Consider convening a working party with representatives appropriate to the purpose of the Policy Document
- Cover all facilities in order to reduce the need for local Policy Documents, where possible
- Include hyperlinks to other documents, where possible, to limit excessive content
- Determine the current risk rating of the policy in accordance with the [NSWHP Risk Management Procedure – NSWHP_PR_026](#). The final ranking of low, medium, high or extreme should be included in the Version History table on the Policy Document template. For further information, refer to the [NSWHP Enterprise Risk Management Policy - NSWHP_PD_034](#).
- Consider whether the Policy Document will have an impact on:
 - Aboriginal people – please consider [NSW Health Aboriginal Health Impact Statement PD2017_004](#) and if required, complete and submit to the Corporate Governance Unit (via email to NSWPATH-Policy@health.nsw.gov.au). Should you require advice on the impact, please contact NSW Health Pathology’s Aboriginal Workforce Unit at NSWPATH-Learning@health.nsw.gov.au
 - Priority and/or marginalised groups – use inclusive language to reflect the diversity of the people that we serve and work with.
 - Culturally diverse communities – please refer to the [NSW Health Plan for Healthy Culturally and Linguistically Diverse Communities 2019-2023 - PD2019_018](#) and
 - People with disabilities – please refer to the [NSW Health Disability Inclusion Action Plan](#)

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- Image Consent – Obtain permission for use of photographic images [NSW Health Pathology Media Consent Form](#)
- Copyright Permission – Ensure permission to use material has been obtained and attributed.

Consult

Consultation is an important part of ensuring a Policy Document meets the requirements of its audience. Some of the key considerations are:

- Consultation must take place as broadly as possible to ensure all stakeholders are considered. The areas that are likely to be affected, or areas for which policy may have implications, should be consulted, for example, clinical operations, clinical streams and portfolio areas
- NSW Health Pathology's Clinical Governance Unit must be consulted in relation to all clinical Policy Documents
- Mechanisms for consultation include placing draft Policy Documents on the agendas of relevant meetings and holding one-on-one meetings or workshops
- Acknowledge matters that are non-negotiable in the consultation process, that is, what stakeholders can and cannot influence

6.4 Approve

All NSW Health Pathology Policy Documents must be approved by the relevant delegate prior to publication as follows:

- **NSW Health Pathology Policies** must be approved by the Strategic Leadership Team.
- **NSW Health Pathology Procedures, Guidelines and Supporting Documents** must be approved by the Policy Sponsor. Policy Sponsors should consider escalating a Procedure, Guideline or Supporting Document to the Strategic Leadership Team for approval where it relates to a controversial matter or there is a need to demonstrate broad executive endorsement.
- The Chief Executive may also approve NSW Health Pathology Policies, Procedures, Guidelines or Supporting Documents.
- The Audit and Risk Committee (ARMC) and SLT will be notified of all new Policies and Procedures, via a Policy Information Brief, annually, or as requested.

6.5 Publish, Communicate and Implement

Publish

NSW Health Pathology publishes Policy Documents through the [Policy Library](#) on the NSW Health Pathology intranet.

The [Policy Library](#) is the sole authoritative source for all NSW Health Pathology Policy Documents.

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In order to publish an approved Policy Document, the following documentation must be submitted to the Corporate Governance Unit by email at NSWPATH-Policy@health.nsw.gov.au:

- [Policy Document Approval Checklist – NSWHP_F_001](#)
- Approved Policy Document

When published, the Policy Document will be assigned a unique identification number which will remain for the life of the document.

As a general rule, hard copy manuals or policy documents stored on shared computer drives are not valid and cannot be used to guide practice. Where staff do not have access to online platforms, managers are responsible for ensuring relevant copies are made available to staff. The process for managing hard copy policy documents must be in strict accordance with the relevant procedures for controlling hard copy records.

Communicate and Implement

Communication and implementation are key elements of the policy development process.

- **Communication:** The messaging that will be required to all impacted staff. Tactics for consideration include staff forums, team meetings, group emails, newsletters and the intranet
- **Training:** Identify strategies to ensure all relevant staff are capable of implementing the new requirements. A minor policy document change may not require any training, whereas a substantial new operational procedure may require a comprehensive training program.

6.6 Review, Evaluate and Attest

Review

All NSW Health Pathology's Policy Documents are subject to a cycle of review.

The Policy Sponsor will determine the review date. Depending on the nature of the Policy Document, review dates are set between one and five years (typically set at 3 years), taking into consideration accreditation, legislative and corporate duty of care requirements.

A thorough review must be completed by the assigned review date. NSW Health Pathology's Corporate Governance Unit will be responsible for notifying Policy Sponsors and Policy Authors of Policy Documents that require review.

All reviewed documents must be approved by the Sponsor, whether the document requires material change, or an extended review date without material change.

The following documentation should be submitted to the Corporate Governance Unit by email at NSWPATH-Policy@health.nsw.gov.au:

- [Policy Document Review Form - NSWHP_F_002](#)
- Reviewed and amended Policy Document
- Copy of document including tracked changes

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A Policy Document may be rescinded by completing the appropriate sections of the [Policy Document Review Form - NSWHP_F_002](#) and submitting by email to NSWPATH-Policy@health.nsw.gov.au

In addition to reviewing Policy Documents by the assigned review date, Policy Sponsors should ensure reviews are undertaken in the following circumstances:

- A deficiency or error is identified in a Policy Document
- Changes in the external environment such as a legislative change, changes in clinical best practice or the internal environment such as an accumulation of a critical mass of issues, or
- Any other circumstance that the Policy Sponsor determines warrants a review of the Policy Document.

Evaluate

At the time of review, evaluation should determine whether the Policy Document is meeting the need for which it was developed – and assess any issues or gaps. For Policy Documents with a high-risk rating, evaluation should be undertaken regularly, for example, annually.

Attest

Policy Sponsors will be required on an annual basis to attest to NSW Health Pathology's compliance with the requirements in the Ministry of Health Policy Directives and NSW Health Pathology Policy Documents.

7. Distribution of Ministry of Health Policy Documents

When publishing a new Ministry of Health Policy Directive, Guideline or Information Bulletin, the Ministry of Health will notify NSW Health Pathology.

The NSW Health Pathology Corporate Governance Unit will:

- Distribute new Ministry of Health policy documents and notifications of obsolete policy documents to all staff, by publishing links on the intranet - [New and revised policy documents](#)
- Circulate via the monthly Latest Policy Updates communication.

8. Access, Control and Record Keeping

8.1. Access

Ministry of Health Policy Directives are accessible through the [Ministry of Health Policy Distribution System \(PDS\)](#)

Ministry of Health Policy and Procedure Manuals are accessible through the website at <https://www.health.nsw.gov.au/policies/manuals/Pages/default.aspx>

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NSW Health Pathology policy documents are accessible from the Policy Library on the NSW Health Pathology Intranet <http://intranet.pathology.health.nsw.gov.au/tools---resources-/policies-and-procedures>

Any NSW Health Pathology Policy Documents that affect, or could affect our customers, business partners and members of the public are published on the NSW Health Pathology Website <http://www.pathology.health.nsw.gov.au/about-us/our-policies>. This also meets our obligations under the [Government Information \(Public Access\) Act 2009 \(GIPA Act\)](#).

8.2. Document Control

Policy Document version control and revision notifications are managed and stored centrally in the approved records management systems.

It is the responsibility of the author to ensure all records relevant to the development, update or revision of the Policy Document are retained and stored on the organisation's approved record management system. This must include the final Word version of the policy documents, approvals, other stakeholder feedback and endorsements, and any other relevant documentation.

To ensure that the most up-to-date policy information is being used at all times, Policy Documents must not be saved on local drives or stored in hard copy. The only exception to this rule is where it is not operationally feasible to access Policy Documents electronically.

8.3. Record Keeping

All Policy Documents maintained by NSW Health Pathology are considered to be state records and subject to the [State Records Act 1998](#). NSW Health Pathology must ensure that all Policy Documents and versions are maintained and archived as per the requirements specified in the [Records Management Policy - NSWHP_PD_028](#)

9. Legal and Procedure Framework

This section describes the legal and policy context within which the policy operates and with which the policy must conform.

Related Policy Document Suite

Supporting documents are provided to assist the implementation of the Policy Framework:

- [Policy Document Approval Checklist - NSWHP_F_001](#)
- [Policy Document Review Form - NSWHP_F_002](#)
- [Policy Template - NSWHP_SD_033](#)
- [Procedure Template - NSWHP_SD_034](#)
- [Guideline Template - NSWHP_SD_035](#)
- [NSWHP Risk Management Procedure - NSWHP_PR_026](#)

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Related Legislation and Supporting Documents

- [National Association of Testing Authorities](#)
- [National Health and Medical Research Council, Guide to the development, evaluation and implementation of clinical practice guidelines 2009](#)
- [National Pathology Accreditation Advisory Council \(NPAAC\)](#)
- [National Safety and Quality Health Service \(NSQHS\) Standards 2021](#)
- [NSW Health Aboriginal Health Impact Statement Policy Directive PD2017_034](#)
- [NSW Health Code of Conduct Policy Directive PD2015_049](#)
- [NSW Health Disability Inclusion Action Plan 2016_2019](#)
- [NSW Health Pathology Media Consent Form](#)
- [NSW Health Pathology Templates and Style Guide](#)
- [NSW Health Plan for Healthy Culturally and Linguistically Diverse Communities 2019-2023 PD2019_018](#)
- [NSW Health Policy and Procedure Manuals](#)
- [NSW Health Policy Distribution System \(PDS\)](#)
- [NSW Health Policy Directives and Other Policy Documents Policy Directive PD2022_047](#)
- [NSW Health Risk Management – Enterprise-Wide Risk Management Policy Directive PD2022_023](#)
- [NSW Health State Health Forms Policy Directive PD2009_072](#)
- [NSW Government Information \(Public Access\) Act 2009 \(GIPA\)](#)
- [NSW State Records Act 1998](#)
- [Record Keeping in the Public Sector - NSW Government State Records](#)
- [Standards Australia](#)
- [Therapeutic Goods Administration](#)

10. Review

This framework will be reviewed by 30/06/2026

11. Risk

Risk Statement	This framework sets out the governance, development and management of policy to ensure high quality and current policy documents that are supported by evidence, best practice, aligned to legislative requirements and implemented to improve and promote high quality pathology and forensic services.
Risk Category	Legal & Compliance

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12. Further Information

For further information, please contact:

Policy Contact Officer	Position: Policy Officer
	Name: Ruth Jacklin
	Telephone: 02 4920 4070
	Email: NSWPATH-Policy@health.nsw.gov.au

13. 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	Risk Rating	Policy Author	Sections Modified
1.0	03/04/16	ELT	03/04/16	High	Samantha Brookes, Senior Policy Officer	New Framework.
2.0	10/04/17	SLT	10/04/16	Medium	Samantha Brookes, Senior Policy Officer	New approval process, new policy sponsors, removal of network documentation from the policy hierarchy, notation in relation to the transition of network policy and other minor updates.
3.0	25/07/18	Chair, TGC	25/07/18	Medium	Samantha Brookes, Senior Policy Officer	Minor updates such as revised template, position titles, update Aboriginal Health Impact Statement process.
4.0	07/05/19	Chair, TGC	07/05/19	Medium	Samantha Brookes, Senior Policy Officer	Minor updates to include revised organisation structure and revised policy templates.
5.0	03/03/20	SLT	03/03/20	Medium	Tammy Boone, Director Corporate Governance	New approval process and delegations, other minor changes.

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6.0	02/04/24	Tammy Boone, Director Legal & Corporate Governance	26/03/24	Medium	Ruth Jacklin, Policy Officer	Document updated to align with streamlined approval/review process and forms
7.0	21/05/24	Tammy Boone, Director Legal & Corporate Governance	20/05/24	Medium	Ruth Jacklin, Policy Officer	Document re-templated to align with new NSWHP Comms templates