

Document Hierarchy for NPAAC Standards (August 2021)

<p>Tier 1 The Principles</p>	<p>Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017</p>
<p>Tier 2 Overarching standards for all Pathology Services</p>	<p>Requirements for Medical Pathology Services (Third Edition 2018)</p>
<p>Tier 3A Supervisory Requirements for pathology laboratories</p>	<p>Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* Requirements for the Communication of High Risk Pathology Results (First Edition 2020)</p>
<p>Tier 3B Technical and specific detailed Requirements for good medical practice in all pathology services</p>	<p>Requirements for the Estimation of Measurement Uncertainty (2007 Edition) Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)* Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018) Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021) Requirements for Information Communication (Fourth Edition 2021) Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs) (Fourth Edition 2018) Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection) (Third Edition 2013)</p>
<p>Tier 4 Technical publications for specific areas of pathology</p>	<p>Anatomical Pathology Requirements for the Performance of Anatomical Pathology Cut-up (Fourth Edition 2013) Requirements for the Facilities and Operations of Mortuaries (Third Edition 2013) Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019) Requirements for Validation of Self-Collected Vaginal Swabs for Use in the National Cervical Screening Program (First Edition 2019) Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015)</p> <p>Genetic Pathology Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017) Requirements for Medical Testing of Human Nucleic Acids (Second Edition 2013) Requirements for Cytogenetic Testing (Third Edition 2013)</p> <p>Haematology Requirements for Transfusion Laboratory Practice (Fourth Edition 2019) Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fifth Edition 2015)</p> <p>Microbiology Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Third Edition 2013) Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013)</p> <p>Reproductive Technologies Requirements for Semen Analysis (First Edition 2017)</p>
<p>Tier 5 Endorsed third-party documents</p>	<p>AS ISO 15189 Medical Laboratories – Particular requirements for quality and competence ISO 14971 Medical Devices-Application of Risk Management to Medical Devices ISO 13485 Medical Devices Quality Management Systems – Requirements for Regulatory Purposes ANZSBT Guidelines for Pre-transfusion Laboratory Practice</p>
<p>Best Practice Pathology Guidelines</p>	<p>The Provision of Direct to Consumer Genetic Tests: Guiding Principles for Providers (Second Edition 2014)* Guidelines for Point of Care Testing (PoCT) (First Edition 2015)*</p>