

# Document Hierarchy for NPAAC Standards (Jan 2015)

<b>Tier 1</b> <b>The Principles</b>	Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002
<b>Tier 2</b> <b>Overarching standards for all Pathology Services</b>	Requirements for Medical Pathology Services (First Edition 2013)
<b>Tier 3A</b> <b>Supervisory Requirements for pathology laboratories</b>	Requirements for the Supervision of Pathology Laboratories (2007 Edition)*
<b>Tier 3B</b> <b>Technical and specific detailed Requirements for good medical practice in all pathology services</b>	Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection) (Third Edition 2013) Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013) Requirements for Information Communication (Third Edition 2013)* Requirements for the Estimation of Measurement Uncertainty (2007 Edition)* Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs) (Third Edition 2014) Requirements for Enrolment and Participation in External Quality Assessment (Fifth Edition 2013) Requirements for the Retention of Laboratory Records and Diagnostic Material (Sixth Edition 2013)
<b>Tier 4</b> <b>Technical publications for specific areas of pathology</b>	<b>Anatomical Pathology</b> <ul style="list-style-type: none"><li>○ Requirements for the Performance of Anatomical Pathology Cut-up (Fourth Edition 2013)</li><li>○ Requirements for the Facilities and Operation of Mortuaries (Third Edition 2013)</li><li>○ Performance Measures for Australian Laboratories Reporting Cervical Cytology (2006 Edition)*</li><li>○ Requirements for Gynaecological (Cervical) Cytology (Second Edition 2014)</li></ul> <b>Genetic Pathology</b> <ul style="list-style-type: none"><li>○ Requirements for Medical Testing of Human Nucleic Acids (Second Edition 2013)</li><li>○ Requirements for Cytogenetic Testing (Third Edition 2013)</li></ul> <b>Haematology</b> <ul style="list-style-type: none"><li>○ Requirements for Transfusion Laboratory Practice (Second Edition 2013)</li><li>○ Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fourth Edition 2013)*</li></ul> <b>Microbiology</b> <ul style="list-style-type: none"><li>○ Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Third Edition 2013)</li><li>○ Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013)</li></ul>
<b>Tier 5</b> <b>Endorsed third-party documents</b>	AS ISO 15189 Medical Laboratories – Particular requirements for quality and competence NATA (Field Application Document) Medical Testing - Requirements for Accreditation* NATA (Field Application Document) Amendments Sheet* 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

\* Documents under review