

## International Accreditation New Zealand

### Medical Testing Guidelines and Standards

Two of the fundamental purposes of laboratory accreditation are to foster continuous improvement and to promote best practice. Thus, standards, guidelines and expectations will constantly change, perhaps every time someone publishes a paper in one of the many relevant professional journals.

It will never be possible, therefore, to issue a definitive list of guidelines and criteria, and the onus is on laboratory staff to keep up with quality and technical advances in their field. An added value from the IANZ assessment process is that it provides an environment for the dissemination of quality initiatives and technical improvements from a huge range of sources, including the assessors themselves.

Having said that, one of the commonest questions we receive is “What guidelines and standards do you use?” The following lists some of the standards and guidelines we commonly refer to. The list can be expected to grow and we will attempt to update it regularly.

1. ANZSBT Guidelines for Blood Grouping and Antibody Screening in the Antenatal and Perinatal Setting, 3<sup>rd</sup> Edition 2007
2. ANZSBT Guidelines for Pretransfusion Laboratory Practice, 5<sup>th</sup> Edition 2007
3. ANZSBT Guidelines for Laboratory Assessment of Fetomaternal Haemorrhage 1<sup>st</sup> Edition 2002
4. Archives NZ: DA262 District Health Boards General Disposal Authority 2010
5. AS/NZS 2243 Safety in Laboratories
  - i. AS/NZS 2243.1:2005 Safety in laboratories - Planning and operational aspects
  - ii. AS/NZS 2243.2:2006 Safety in laboratories - Chemical aspects
  - iii. AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment
  - iv. AS/NZS 2243.5:2004 Safety in laboratories - Non-ionizing radiations - Electromagnetic, sound and ultrasound
  - v. AS/NZS 2243.6:2010 Safety in laboratories - Plant and equipment aspects
  - vi. AS/NZS 2243.8:2014 Safety in laboratories - Fume cupboards
  - vii. AS/NZS 2243.9:2009 Safety in laboratories - Recirculating fume cabinets
  - viii. AS/NZS 2243.10:2004 Safety in laboratories - Storage of chemicals
6. AS/NZS 2982:2010 Laboratory design and construction
7. AS 3864.2 2012 Medical refrigeration equipment - For the storage of blood and blood products. User-related requirements for care, maintenance, performance verification and calibration.
8. AS/NZS 4308:2008 Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine
9. ASCIA: Skin prick testing for the diagnosis of allergic disease. A manual for practitioners 2013
10. ASM: Guidelines for Assuring Quality of Medical Microbiological Culture Media, 2<sup>nd</sup> Edition 2012
11. Coroners Act 2006 revised 2013
12. CLSI: Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture; 6<sup>th</sup> Edition 2007
13. CLSI: Performance Standards for Antimicrobial Susceptibility Testing
14. EUCAST: Antimicrobial Susceptibility Testing
15. Health Practitioners Competence Assurance Act 2013
16. Health (Retention of Health Information) Regulations 1996; reprinted July 2013

17. IANZ Specific Criteria for Accreditation- Medical Testing, 2<sup>nd</sup> Edition 2014
18. IANZ Technical Guide: Laboratory Balances Calibration requirements 2002
19. IANZ Technical Guide: Uncertainty of Measurement Precision and Limits of Detection in Chemical and Microbiological Testing Laboratories 2004
20. IANZ Technical Guide: UV/Vis Spectrophotometer Calibration Procedures 2005
21. IANZ Technical Guide: Working Thermometers Calibration Procedures 2<sup>nd</sup> Edition 2008
22. ISO 8655-6: 2002, Piston-operated volumetric apparatus – Part 6: Gravimetric methods for the determination of measurement error
23. ISO 15190:2003 Medical Laboratories - Requirements for safety
24. ISO 22870:2006 Point-of-care testing (POCT) Requirements for quality and competence
25. ISO 15189:2012 Medical laboratories - Requirements for quality and competence
26. ISO TS 22367:2008 Risk management in the Medical Laboratory
27. MOH: Direct Laboratory Notification of Communicable Diseases: National Guidelines 2007: Update 2009
28. MOH: Human Tissue Act 2008
29. MOH: National Laboratory Guidelines for Pandemic Influenza: Collection and handling of human specimens for laboratory diagnosis of influenza with pandemic potential 2006
30. MSL Technical Guide 1: The Ice Point 2002
31. MSL Technical Guide 6: Magnetic Effects in Weighing 2004
32. MSL Technical Guide 7: Calibrating Standard Weights 2004
33. MSL Technical Guide 8: Calibration of Stop-watches 2004
34. MSL Technical Guide 12: Assuring the Quality of Weighing Results 2012
35. MSL Technical Guide 17: Measuring Volume by Weighing Water 2007
36. MSL Technical Guide 25: Calibrating Balances 2012
37. NCSP: Policies and Standards Section 5 Providing a Laboratory Service
38. NCSP: Guidelines for Cervical Screening in New Zealand 2008
39. NCSP: Guidance on HPV Testing Update 2010
40. New Zealand National Coronial Pathology Service: Code of Practice and Performance Standards for Forensic and Coronial Pathologists 2006
41. New Zealand Best Practice Guidelines for Point-of-care testing 2014. New Zealand Point-of-Care Testing Advisory Group
42. NPAAC: Classification of Human Genetic Testing: A Supplementary Guide to Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis 2007
43. NPAAC: Guidelines for the Performance of Anatomical Pathology Cut-Up 4<sup>th</sup> Edition 2013

44. NPAAC Requirements for Medical Testing of Microbial Nucleic Acids 2<sup>nd</sup> Edition 2013
45. NPAAC Requirements for Human Nucleic Acids 2<sup>nd</sup> Edition 2013
46. NPAAC: Requirements for Cytogenetic Testing 3<sup>rd</sup> Edition 2013
47. NPAAC: Requirements for the Facilities and Operations of Mortuaries, 3<sup>rd</sup> Edition 2013
48. NPAAC: Requirements for the Retention of Laboratory Records and Diagnostic Material; 6<sup>th</sup> Edition 2013
49. NZBS Refrigeration Guidelines, 4<sup>th</sup> Edition 2011
50. Occupational Safety and Health Information Series: Managing Health and Safety Risks in New Zealand Mortuaries, Guidelines to promote safe working conditions 2000
51. WHO: Ethical Practice in Laboratory Medicine and Forensic Pathology 2000