specific criteria for accreditation

Medical Testing

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1 Introduction

International Accreditation New Zealand (IANZ) Specific Criteria are an elaboration of the General Criteria for Accreditation for specific fields of test and calibration, test technologies, products or materials. They address items that are either essential or most important for the proper conduct of a test or calibration. Specific Criteria either provide detail or extra information to the generally stated requirements of the IANZ General Criteria for Accreditation, which remains the governing document. A list of all published Specific Criteria is available on www.ianz.govt.nz/publications or from IANZ on request.

This criteria document must be read in conjunction with the IANZ publication Procedures and Conditions of Accreditation, the latter document describing the organisation and operation of the IANZ Laboratory Accreditation Programme.

It must also be noted that NZS/ISO/IEC 17025 is listed as a normative reference to NZS/ISO 15189. Thus, compliance with the medical testing standard presupposes compliance with NZS/ISO/IEC 17025.

NZS/ISO 15189 is a general document designed to apply to all types of medical testing laboratories. This Specific Criteria provides information on the application of the International Standard to New Zealand medical testing laboratories being accredited against NZS/ISO 15189.

2 Scope

This document sets out the specific requirements a medical testing laboratory has to meet, in addition to the general requirements of NZS/ISO 15189, if it is to be accredited by IANZ. The principles embodied within these criteria should be applied equally, where relevant, to all types of medical testing laboratories.

In addition to this document, there are other criteria documents applicable to medical testing laboratories working in specialised areas of testing, which have their own set of unique criteria.

Point-of-care testing

The particular requirements pertaining to point-of-care testing are detailed in a complementary standard, ISO 22870. The general principle to be applied is that testing equipment operated remotely from the laboratory must be subject to the same maintenance, calibration and quality control criteria applied to equipment located within an accredited laboratory. Non-laboratory personnel operating the equipment must also be trained appropriately, with full records kept.

The accredited laboratory within an institution or laboratory service should be responsible for the management of point-of-care testing equipment associated with that institution or service. A laboratory may seek inclusion of point-of-care testing activities within its accredited scope, having demonstrated conformity with the governing standard, NZS/ISO 15189, and the additional requirements of ISO 22870.

Accreditation for point-of-care testing will be recorded in a laboratory’s scope listings against specific locations and the associated testing, rather than on an organisation-wide basis.

Workplace drug testing

The particular procedures for specimen collection and the detection and quantitation of drugs of abuse in urine are detailed in a separate standard, AS/NZS 4308.

A laboratory may seek inclusion of this type of testing within its accredited scope, having demonstrated conformity with the governing standard, NZS/ISO 15189 and the additional requirements of AS/NZS 4308.

Accreditation can be granted separately for laboratory screening and confirmation, and for on-site screening.

Other criteria

The National Cervical Screening Programme (NCSP) Operational Policy and Quality Standards (OPQS) specify criteria to be met by laboratories completing gynaecological cytology and histology examinations. Conformity with these criteria is required.
The Australian and New Zealand Society of Blood Transfusion have published guidelines for various aspects of testing related to Transfusion Medicine. These guidelines apply.

The National Pathology Accreditation Advisory Council (NPAAC) has published a series of documents giving requirements for various aspects of operation of medical testing laboratories. Some of these will be adopted as criteria and conformity will be expected unless they include requirements peculiar to Australia. Where alternative criteria are either included in or referenced by this Specific Criteria Schedule, these alternatives take precedence over adopted NPAAC requirements.

3 Classes of examination
IANZ accreditation does not constitute a blanket approval for all a laboratory's activities. Therefore, a means of identifying activities for which accreditation is granted, is necessary. The classes of examination given in Appendix 1 provide the framework within which the scope of accreditation is expressed for medical testing laboratories.

These classes are an arbitrary subdivision of the potential range of activities involved in medical testing laboratories on the basis of the types of samples being examined, the disciplines involved and the examination methods employed. These classes/subclasses do not however constitute any restriction on the work a laboratory can perform but provide a convenient means of expressing an accredited laboratory's capabilities.

Commentary
The following remarks are referenced to specific clauses of NZS/ISO 15189. Where it is considered that no explanatory commentary in relation to application of the clause is needed and/or there are no supplementary criteria this is noted.

4 Management requirements

4.1 Organisation and management

4.1.1 Where the laboratory is a contracted provider not part of the organisation served or a joint venture operation this must be specified.

4.1.2 The contribution of the laboratory service to patient care should remain paramount through all activities.

4.1.3 Where a laboratory operates as a single entity across multiple sites or as a group of laboratories under a common organisational structure this must be specified. The location of all collection centres must be given. Where point-of-care testing is an accredited activity of the laboratory details of the sites and the nature of testing provided must be specified. Mobile operations, whether independent or associated with a permanently-located laboratory, must be identified.

4.1.4 The summarised responsibilities of key personnel and organisation chart should enable identification of any areas of influence and conflict.

4.1.5 The success of the quality management system depends on the commitment of management and the active participation of each member of the laboratory staff. Laboratories should provide guidance to personnel on ethical issues additional to those of applicable professional bodies.
Responsibilities of key personnel should be summarized. An organisation chart should be used to show interrelationships of key personnel. The organisation chart should include or reference the names of key personnel.

The scope of responsibilities and authority of the quality manager must be clearly defined and documented and include the following:

(a) Maintenance of the quality manual and associated operations documentation.
(b) Monitoring of laboratory practices to verify continuing compliance with policies and procedures.
(c) Maintaining evaluation of instrument calibration and maintenance records.
(d) Ensuring the validation of new technical procedures.
(e) Administration of proficiency testing and evaluation of results.
(f) Selection, training and evaluation of internal auditors.
(g) Scheduling and coordination of quality system audits.
(h) Maintenance of training, competency and continuing development records for laboratory personnel.
(i) Review of feedback received from clients.
(j) Proposing corrections and improvements to the quality system.

The responsibilities of the quality manager are broad and it may be necessary to delegate some functions. However, it is the responsibility of the quality manager to ensure that these activities are undertaken in accordance with the procedures and within the timeframes specified by the quality system.

4.1.6
In addition to general communication on the effectiveness of the quality management, dissemination of the outcome of management review in this regard to all staff members is expected (see 4.15).

4.2  Quality management system

4.2.1
A quality management system should provide laboratory management with continuing confidence that results and conclusions are valid and reliable. To ensure that everyone fully understands what the expectations are, all elements of the quality management system must be clearly explained in the quality manual and related documentation. Where information is in electronic format only, reasonable access by all staff members must be assured.

4.2.2
No explanatory commentary.

4.2.3
Overarching policies should be quantifiable, wherever possible.

4.2.4
The quality manual should detail or refer to the other documentation that describes how the laboratory addresses all elements of the standard. It may contain all relevant information in the case of a small laboratory with limited scope or be supervisory in nature for a larger organisation. Where the laboratory operates across several sites or comprises a group under a common structure, it may elect to define
universal aspects in the quality manual with site-specific detail included in a separate section or separate documentation.

4.3 Document control

4.3.1
Out-takes from quality management system documentation must be under the document control system and should be referred to within the procedural documentation from which they arise unless an alternative record is maintained.

4.3.2
The expected frequency for review of documentation to ensure that it is adequate for continuing use is annual unless otherwise approved by IANZ.

4.3.3
Worksheets that contain instructional material and/or calculations need to be controlled in a manner similar to procedural documentation. Worksheets used to record results do not need to include all document control information expected for instructional material but must contain sufficient information to preclude inadvertent use of superseded versions.

4.4 Review of contracts

A contract in its simplest sense may involve a single test request form presented to the laboratory by a patient or clinician. However, this sub-clause is primarily intended to address those situations where the laboratory enters into contractual arrangements with clients, such as the National Screening Unit, a District Health Board, Medical Clinic, General Practitioner and/or Medical Specialist, prior to accepting work.

Contracts with service providers and referral laboratories, consultants and advisors should also be in place but addressed under applicable elements (see 4.5 and 4.6).

4.4.1
No explanatory commentary.

4.4.2
No explanatory commentary.

4.4.3
No explanatory commentary.

4.4.4
No explanatory commentary.

4.4.5
No explanatory commentary.

4.5 Examination by referral laboratories

4.5.1
The laboratory must monitor the quality and performance, including turnaround times, of referral laboratories, even in those circumstances where the laboratory does not have complete freedom of choice in their selection. The laboratory must also document the basis for their selection and use of particular consultants providing second opinions in relevant disciplines. Ideally a referral laboratory should be accredited either by IANZ or an IANZ mutual recognition partner for the testing offered. Similarly, referral consultants should ideally work in accredited laboratories.
4.5.2
A copy of the current Schedule to Certificate of Accreditation for accredited referral laboratories should be obtained as part of the monitoring process.

4.5.3
Where results provided by a referral laboratory are included into a report issued by the referring laboratory, either by transcription or electronically, the name of the referral laboratory must be incorporated into the report. Where work is done in a non-accredited laboratory any report of the results must state same.

4.5.4
The application of this sub-clause requires the laboratory to determine whether it is acting as a referring laboratory or as a sample collection agency on behalf of another laboratory. Note: A medical laboratory is differentiated from a collection centre in “Terms and definitions”, Sub-clause 3.9 of NZS/ISO 15189:2007.

The responsibility lies with the referring laboratory for ensuring that referral laboratory examination results are reported to the person making the request, and that these results are correctly interpreted. However, in some circumstances it will be appropriate clinically for the referral laboratory to contact requesting clinicians directly, to discuss results or to request additional clinical information. With this in mind, the referring laboratory must ensure that request forms sent to referral laboratories comply with Clause 5.4.1, which details the information to be provided.

If the results of referred work are not reported through the referring laboratory information system, the referring laboratory may discharge the responsibility for reporting as follows:

(a) By forwarding the report from the referral laboratory, in its entirety, to the requester for inclusion in the patient record and retaining a copy within the permanent file of the laboratory.

(b) By instructing the referral laboratory to send the original report (paper or electronic version) directly to the requester for inclusion in the patient record. The referral laboratory should also send a copy of the report to the referring laboratory, but in any case must ensure that the referring laboratory is made aware that reports have been issued. In the latter case the referring laboratory will be responsible for retention of reports in the permanent system of the laboratory.

Where the referring laboratory has already performed related tests, any additional tests performed by another laboratory may be reported as part of a composite report issued by the referring laboratory. In this case the laboratory/pathologist responsible for completing each test in the composite report must be clearly identified, as noted above. Similarly, if explanatory comments are added by a referring laboratory pathologist to the results obtained from the referral laboratory, responsibility for the added comments must be identified.

If results from the referral laboratory add to results of work that have already been completed and reported by the referring laboratory, either reference to the earlier results or incorporation of them into any subsequent report must occur.

Transcription checking procedures must be followed when results from referral laboratories are incorporated into a referring laboratory report (see 5.8.3 and 5.8.12).

Laboratories must adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, accuracy of transcription processes, and interpretative skill requirements, in the best interests of patient care. In many cases the correct interpretation and application of test results will require collaboration between pathologists and specialists from both referring and referral laboratories.

4.6 External services and supplies

4.6.1
Where possible and relevant, the laboratory must purchase external services, equipment and consumables from suppliers able to demonstrate compliance with relevant standards. Wherever possible, laboratories
should use accredited suppliers. For example, microbiological media manufacturers holding accreditation for quality control testing of media they produce, or service agents accredited for the inspection and testing of biohazard cabinets, and for calibration of blood-product storage equipment.

Consumables must be stored in accordance with the manufacturer’s instructions. These instructions need to be documented and included in inventory control.

4.6.2 Procedures and facilities should be established for quarantining of supplies until subjected to acceptance testing and approved for use.

4.6.3 Expiry dates for relevant reagents, control materials, calibrators and kits must also be included as part of the inventory control records.

4.6.4 When an accredited supplier is used, laboratories should assure themselves that such accreditation is held by obtaining the current terms of the supplier’s accreditation with IANZ.

4.7 Advisory services

Pathologist(s) and/or appropriate specialists must be available to provide clinical advice prior to test ordering and to advise on the interpretation of all test results. Where specialist pathologists are not available on site, arrangements for outside input must be made. At times this may entail referring the clinician to an appropriate specialist in another laboratory or institution. A laboratory handbook or electronic equivalent, developed in conjunction with appropriate pathologists or specialists, may be seen as a convenient adjunct for providing guidance to clinicians on the choice and interpretation of tests. The handbook will need to be reviewed and updated in a timely manner, ideally with full review at least annually. This does not negate the need to provide direct access for clinicians to specialist advice, as needed.

Scientific/technical staff members must make their qualifications and experience clear to clinicians when making comment in relation to interpreting results. Clinical interpretation provided for laboratory test results remains the responsibility of the supervising pathologist(s) unless defined and delegated by their written authority.

4.8 Resolution of complaints

Users of laboratory services must have ready access to the means of providing feedback to the laboratory. For example, forms developed to allow comment from patients attending the laboratory should be displayed prominently, in relevant areas.

4.9 Identification and control of non-conformities

4.9.1 The possible impact of outlier quality control values of patient results must be recognised and considered when such events occur.

4.9.2 No explanatory commentary.

4.9.3 Persons competent to over-rule the normal criteria for release of results must be clearly defined and documented along with the procedures to be followed in such situations. Particular circumstances in each case need to be recorded.
4.10 Corrective action

4.10.1 Activities such as internal audits, accreditation assessments, customer feedback, quality control data, proficiency testing may identify issues in need of corrective action, which must be evaluated, prioritised, implemented and evaluated for effectiveness. Consequently, the system for monitoring progress must be comprehensive and adequately cross-referenced. The quality manager should coordinate this system.

4.10.2 No explanatory commentary.

4.10.3 No explanatory commentary.

4.11 Preventive action

4.11.1 Following an incident resulting in non-conforming work, the laboratory must give attention to future prevention of similar incidents, as well as corrective action. However, preventive action should be primarily a pro-active process to identify improvement opportunities, rather than solely a reaction to the identification of problems or complaints. This approach is particularly relevant for health and safety issues. Consideration should also be given to providing staff with a formal mechanism for contributing suggestions for improvement.

4.11.2 No explanatory commentary.

4.12 Continual improvement

4.12.1 No explanatory commentary.

4.12.2 No explanatory commentary.

4.12.3 No explanatory commentary.

4.12.4 The continual improvement process is closely allied to, and will form an integral part of, management review. The laboratory needs to review periodically its contribution to patient care, having considered at least the following:

(a) Test repertoire, including standard testing profiles, reflex testing, and procedures for follow-up and confirmatory testing.

(b) Methodology and instrumentation considerations, including specificity, sensitivity and uncertainty of results, in relation to clinical decision making.

(c) Appropriateness and timeliness of interpretations provided, including automatic-comment generation, if relevant.

(d) Follow-up of significantly abnormal test results.
(e) Follow-up of adverse incidents resulting in incorrect information being made available for clinical use.

(f) Quality of pre-examination services such as number of re-bleeds, incorrect samples, poor-quality samples, mislabelled samples.

(g) Clinically relevant turnaround times; from time of sampling to result send-out.

(h) Systematic collection and evaluation of clinically relevant feedback.

Compliance with this clause imposes on the laboratory a need to develop close links with clinical users of its services, to include full and active participation in clinical audit processes that connect the technical output of the laboratory with patient outcomes.

Quality indicators could be a combination of common laboratory-wide key performance indicators or discipline/area-specific measures.

4.12.5
No explanatory commentary.

4.13 Quality and technical records

4.13.1
The laboratory must retain records of original observations, derived data and sufficient information to establish an audit trail for all test results reported. All records must include the identity of the person making each entry. It is recognised that a number of staff members may be involved in test processes or other laboratory procedures. It is the laboratory’s responsibility to identify the critical steps in the procedure and to ensure that the identities of the staff members concerned are recorded.

When mistakes occur on paper records, they must not be erased, made illegible or deleted but crossed out and the correct value entered alongside. All such alterations to records must be signed or initialed by the person making the correction. In the case of electronic records, equivalent measures must be taken to avoid loss or change of original data (see also Sub-clause 5.8.16). Spreadsheets may require annotation of the record to effect this expectation.

4.13.2
Organisations must ensure that records stored electronically can be retrieved throughout the stated retention period despite changes in technology that may occur.

4.13.3
In defining the minimum retention periods for records the laboratory is expected to meet the requirements of the relevant General Disposal Authority as minimum. When hard copy records are scanned and stored electronically the retention periods apply to the electronic versions. The hard copy should be retained for a reasonable period, 1-3 months is suggested, to allow for clarification of any anomalies in the electronic record. Time-frames for immediate on-line access to results will also need to be established.

The records system must include a copy of each report issued or must allow for one to be reproduced in full.

4.14 Internal audits

4.14.1
The internal audit programme does not necessarily mean that the entire laboratory must be covered in a single audit, but the laboratory needs to devise a schedule to ensure all elements of its quality management system and technical operations are audited at an appropriate frequency.

4.14.2
Auditors should use a combination of auditing techniques to verify the effectiveness of systems in place, to include vertical, horizontal and witness audits as relevant. Auditors need to be knowledgeable of auditing principles and techniques and deemed competent to complete audits. Provision of formal training for auditors should be considered.

Audits must be scheduled and planned well in advance. Use of a checklist is advised to ensure complete coverage of the important aspects of an audit. It also enhances objectivity of findings and the credibility of the audit team. The laboratory must determine which elements of its operations are critically important to patient care, and focus in particular on these areas. However, the audit must provide a full review of all elements of the quality management system.

After the audit is completed, the team should brief relevant key personnel regarding the results. This discussion should include commendable findings as well as shortcomings. A written report should be prepared as soon as possible after the completion of the audit and should identify problem areas and the remedial action required. The degree of concern pertaining to any shortcoming must be indicated with major items being highlighted. Time frames for completion of any corrective action required and responsibility for addressing issues should also be detailed. The report should also contain suggestions that the auditors may have, to improve the quality management system. The report and responsive comments from appropriate key personnel should be submitted to the quality manager to ensure that corrective actions are taken in a timely manner.

Comprehensive internal audits must be completed at least annually, ideally six-month out-of-phase with the external accreditation assessment.

Registration accuracy audits and data integrity audits should constitute components of pre-examination procedures and post-examination procedures respectively.

4.14.3
The outcome of internal audits must be reviewed by management either separately or as part of management review.

4.15 Management review

4.15.1
The overall purpose of management review is to evaluate past and present performance, in order to develop strategies that will optimise the laboratory’s continuing contribution to patient care. A management review must occur at least once each year. Some laboratories may find it convenient to review aspects of performance at different times during the year or to review each discipline/area of operation separately, but it is important that the laboratory director is able to collate all relevant information to form a coherent, documented overview.

4.15.2
Use of a standard pro-forma agenda will facilitate the management review process.

4.15.3
Key performance indicators for the laboratory’s contribution to patient care must be reviewed and revised regularly.

4.15.4
Goals, objectives and action plans arising from management review must be followed up with defined time frames.
5 Technical requirements

5.1 Personnel

The laboratory must be operated and managed by suitably qualified and competent personnel. Designated personnel with primary responsibility for management, quality, clinical and technical activities of the laboratory will be termed key personnel for the purposes of accreditation and details of their roles will be retained by IANZ along with other records pertinent to the accreditation of the laboratory.

Expectations with regard to the roles and responsibilities of these key personnel will be detailed under 5.1.4 for the laboratory director and under 5.1.5 for clinical and scientific/technical persons.

5.1.1 Appointment, induction, training and continuing competency evaluations must be according to a documented organisational plan.

5.1.2 Evidence confirming receipt of the applicable Annual Practicing Certificate for each staff member must be held on file. Retaining a copy is suggested as an effective and simple means.

In larger organisations where copies of job descriptions and other related records may be held centrally, copies must be readily available for review during assessments of the laboratory.

5.1.3 No explanatory commentary.

5.1.4 The standard prescribes a number of responsibilities that need to be accepted by the laboratory director (person or persons), and there is an expectation that each of the designated roles will be formally assigned to, and accepted by, an appropriate person or persons. Thus, the role may be thought of in terms of a directorship. Under normal circumstances at least one pathologist (see Key Personnel: Clinical) must be formally included within the directorship. Where the pathologist component of the directorship is provided by an organisation external to the laboratory, the roles and responsibilities of all parties must be formally agreed and documented, in a manner acceptable to IANZ.

Some of the duties listed, and other sub-clauses of the standard, such as 4.7, impose the need for a significant amount of clinical input to the laboratory’s activities. The laboratory must have access to personnel who are able to provide this clinical input, at a level appropriate to the scope of testing provided. While some clinical input may be derived from the laboratory directorship directly, each discipline of the laboratory must have access to appropriate specialist guidance. It is important to differentiate between the laboratory directorship role and that of other key clinical personnel whose role may be to provide clinical input to specific disciplines under the direction and control of the laboratory directorship. However, pathologist and specialist input from organisations external to the laboratory must be in accordance with a formally ratified contractual agreement acceptable to IANZ (see Key Personnel: Clinical).

5.1.5 The number of staff members, and the skill mix required, will vary between laboratories. The adequacy of the staffing complement and the appropriateness of the skill mix in any laboratory will be carefully scrutinised at assessment. Indicators of adequate staffing include annual leave accrual, the need for extended hours of work, on-call roster duties, time allocated/available for quality management issues and the availability of back-up support for key staff members. The skill mix will be examined in relation to the scope of testing provided by the laboratory.
Key personnel: General

During all working hours, an accredited laboratory must also have at least one staff member who is competent for the testing work being done. Each accredited laboratory must therefore designate key scientific/technical and key clinical personnel, who will be formally responsible for supervision of its accredited testing repertoire. In larger laboratories responsibilities may be delegated to other supervisory staff on a day-to-day basis, provided the delegations and the basis for them are clearly documented. Such delegation of authority does not absolve the listed key person from taking full responsibility for the validity of the work.

The requirements of the New Zealand Medical Laboratory Science Board with regard to supervision and direction of technicians and unqualified staff members must be met. The provisions of the NCSP OPQS apply for cytoscientists and cytotechnicians involved in gynaecological cytology screening.

Appointment of key personnel will ultimately be the responsibility of the laboratory director. The laboratory directorship may choose to appoint an individual as a consultant or locum, with key clinical/scientific/technical personnel responsibilities relating to work done within the scope of accreditation. In such circumstances, there must be a written agreement between the parties setting out the extent of the authority and responsibility of the consultant in relation to the services provided. The consultant’s position in the laboratory organisation must be such that they can complete their role as a decision maker as effectively as if they were an employee.

Laboratories are required to formally identify clinical and scientific/technical key personnel within quality management system documentation and to ensure that these individuals are aware of their responsibilities regarding accreditation. The list of key personnel and their individual scope of responsibility must be notified to IANZ, which will maintain this listing for each accreditation. The list will also be reviewed with laboratories during their annual assessments. Changes to key personnel listings, including individuals who have left the laboratory, new key personnel appointments, or changes in the scope of responsibility, made between annual on-site assessments must also be notified to IANZ. When new key persons are appointed, the laboratory may be required to provide IANZ with a brief CV-type summary of qualifications and experience.

There is an expectation that key personnel or their formal deputies will be available on-site or be otherwise contactable during assessments, regardless of whether they are employees or contracted advisors.

Where a laboratory loses the listed clinical or scientific/technical key personnel for all or part of their scope of accreditation, and no new appointment is made by the laboratory director, the laboratory’s accreditation, or part thereof, may be suspended until such time as a new appointment is recognised by IANZ. Arrangements for ongoing provision of service must be provided to IANZ until a reappointment is made. Where new key personnel appointments are made outside of routine reassessments, and particularly when a new appointment is the sole key person for all or part of the accreditation, IANZ reserves the right to conduct an on-site assessment of the laboratory to be assured the laboratory’s systems, and the integrity of the laboratory’s test results, will continue to be maintained.

Key Personnel: Clinical

Each discipline must receive professional direction and control, under the auspices of the laboratory directorship, by an appropriately trained pathologist who is competent to interpret all of the tests that are completed by the discipline, and is also competent to complete specialised procedures where relevant. Competence must be demonstrated by evidence of training and experience in a pathology specialty. This would normally require membership of the Royal College of Pathologists of Australasia (RCPA), or an equivalent body. Pathologists are also expected to satisfy the requirements of the Medical Council of New Zealand in order to practise as such.

In some circumstances it may be appropriate for the professional direction to be provided by either a consultant from a specialty other than pathology or a specialist clinical scientist of equivalent status. In such circumstances there must be evidence that the laboratory is providing a limited range of specialised tests directed by an appropriately trained consultant, demonstrating special qualifications or skills in the area of these tests.
The appropriate level of pathologist or equivalent input to laboratories must be interpreted using the following guidelines:

(a) Major hospital and community laboratories within each region must ideally employ single discipline pathologist(s), with training and experience relevant to each pathology discipline included within that laboratory and to the range and complexity of the tests provided by each discipline. Pathologists with academic appointments will be considered on the basis of their contribution to the laboratory service.

(b) Laboratories with a resident pathologist(s), who is unable to cover all disciplines, must invite appropriately qualified and experienced pathologist(s) to visit and provide direction and control for those disciplines not adequately covered. Laboratories with no resident pathologist must be visited by either appropriately trained or experienced general pathologist(s), or relevant single discipline pathologists. The directorship of those laboratories without appropriate cover for any particular discipline must, in consultation with appropriately qualified pathologists, evaluate the level of input required to meet the needs of the service.

(c) District Health Board laboratories operating transfusion medicine services that include the issue of blood must be subject to clinical oversight from the New Zealand Blood Service (NZBS), through participation in the NZBS District Health Board Clinical Oversight Programme.

(d) The laboratory directorship must be responsible for ensuring that guidance and advice of visiting clinical and non-clinical specialists is implemented. These visits must occur with a frequency and duration consistent with the needs of the service. The adequacy of such involvement will be judged following a peer-review assessment.

The appropriate level of pathologist input to any laboratory will be determined by its scope of testing and the expertise of the on-site scientific/technical staff. Thus, peer assessment teams will be requested to assist in determining the appropriate amount of pathologist input for particular laboratories as part of initial assessment and routine reassessment.

Laboratories without on-site pathologists able to provide cover for each discipline will need to present formal plans to IANZ to satisfy the requirements outlined above. Input provided by pathologists from organisations external to the laboratory must be formally agreed by all parties. The duties and responsibilities of all parties need to be explicit. Clinical responsibility for the output of the laboratory must also be formally agreed between visiting pathologists and the laboratory directorship.

In the absence of an alternative formally agreed arrangement with IANZ, and for the purposes of assessment, the acceptability of arrangements for on-site clinical input for medical testing laboratories must be based on a minimum of quarterly visits to each discipline. These visits must be of not less than four hours in duration, and must be undertaken by pathologists qualified in each medical testing discipline for which the laboratory holds accreditation. Arrangements made by laboratories which do not meet this minimum requirement, will be subject to review by the MTPAC. Where assessment teams specify greater levels of input, such as from regional centres, the MTPAC may be asked to review assessment reports, proposals and responses to ensure that the laboratory’s arrangements are consistent with IANZ expectations and requirements nationwide.

The responsibilities of a visiting pathologist are similar to those of a resident pathologist and must include but not be limited to the following:

(a) Review and sign-off of the results of the laboratory’s participation in inter-laboratory comparison programmes and of the action taken by the laboratory to address performance problems.

(b) Review of internal quality control programmes and related issues.

(c) Review and revision of the testing methods of the laboratory including the biological reference intervals applied to results reported.
(d) Provision of advice to referring clinicians on the choice of tests, availability of new tests, the best utilisation of the laboratory service and the interpretation of test results.

(e) Review and sign-off of complaints and other quality incidents and of the action taken by the laboratory to address each issue.

(f) Presentation of educational sessions on relevant topical issues to laboratory staff members and referring clinicians.

(g) Provision of advice on management issues including laboratory staffing, equipment acquisition, laboratory accommodation and the selection of reference laboratories.

A laboratory may substitute a maximum of two of the scheduled visits by a pathologist in each discipline, with either of the following in relation to each visit:

(a) A visit of not less than four hours in duration, by a senior member of the scientific/technical staff from a larger regional laboratory offering services in the testing discipline for which the laboratory holds accreditation. These non-clinical specialists must report directly to pathologists with the training and experience to provide clinical guidance, as necessary.

(b) A visit of not less than eight hours duration by a senior member of the laboratory’s own scientific/technical staff to a larger regional laboratory offering services in the same testing discipline.

Any other proposals to substitute pathologist visits with alternatives involving scientific/technical personnel will be submitted to MTPAC for review.

In order to satisfy IANZ of the adequacy of the level of external input, the following criteria must also be met:

(a) Records of days spent on-site by visiting pathologists and senior scientific/technical staff members must be kept, to include the duration of the visit, topics and issues discussed and interactions with on-site clinical and scientific staff members. The number of days deemed to be appropriate will depend on the scope and extent of the laboratory’s operations. The level of daily/weekly communication by the laboratory with visiting specialists will be taken into account as will the availability of electronic links which enable remote supervision of laboratory output.

(b) Records must be kept detailing the interaction between on-site personnel and any supervising laboratory to show that there is an effective means of regular, real-time communication between laboratory staff members and pathologists and senior scientific/technical staff members of the relevant testing discipline at a larger regional laboratory. Mechanisms for this communication may include telephone discussions, tele-conferencing, exchange of images and other data via digital data links, circulation of memos and information bulletins for example. Attendance at the supervising laboratory site for meetings to review service issues and to set quality objectives, training sessions and CPD activities are all relevant.

(c) Interpretative clinical advice must be readily available within a timescale appropriate to the urgency of the clinical situation. Users must be made aware of the availability of clinical advice and have ready access to it at all times.

Key Personnel: Scientific/Technical

Supervisory scientific/technical staff members in accredited laboratories must be competent and experienced in the scientific/technical areas covered by the laboratory’s accreditation. They must be able to oversee the scientific/technical operations and cope with any problems that might arise in their work or that of their colleagues or subordinates.

Key scientific/technical persons are expected to have registration with the MLSB as a Medical Laboratory Scientist, Medical Laboratory Technician or Qualified Phlebotomy Technician with appropriate expertise and experience in the disciplines/areas for which they are responsible. They must have a position in the staff structure which provides for the authority to implement necessary changes in the laboratory operation to
ensure the integrity of test results is maintained. The position in the staff structure should ensure the individual can maintain a working knowledge of the quality assurance and technical systems in operation in the laboratory on a day to day basis.

These key personnel are required to have the necessary scientific expertise and experience to:

(a) Develop and implement new procedures.

(b) Be aware of, and understand any, limitations of the test procedures, and to understand fully the scientific basis of the procedures.

(c) Design quality control programmes, set action criteria and take corrective action when these criteria are exceeded.

(d) Identify and resolve problems.

(e) Take responsibility for the validity of the outputs.

5.1.6
No explanatory commentary.

5.1.7
No explanatory commentary.

5.1.8
No explanatory commentary.

5.1.9
Any continuing education and development programme should include in-house and external components and there must be access to appropriate reference texts and journals. Components of an appropriate continuing education programme may include external activities such as conferences, visits to other laboratories, training courses, regional quality control/assurance meetings, user-group meetings, seminars, lectures and assessments/audits. Internal activities may include regular educational presentations, journal article reviews, case presentations, review of quality assurance programme educational material, reviews of interesting/abnormal blood films and cultures, and internal audits.

All scientists and technicians must fulfil the requirements of a continuing development programme recognised by the MLSB. Cytoscientists and cytotechnicians performing gynaecological cytology screening must also meet the continuing development requirements described in the NCSP OPQS.

Detailed records of participation in continuing education and development must be kept, additional to records of competency to perform assigned tasks.

5.1.10
All staff members must be made aware of applicable health and safety aspects of the laboratory operation. An induction process must be completed for all staff members. Ideally this should be followed at regular intervals by refresher training. Records must be kept of training in health and safety. An appropriate and applicable number of staff members should be trained in CPR, especially when the laboratory is outside a hospital environment.

5.1.11
The competency of all staff members to perform assigned tasks must be re-assessed/re-affirmed following initial training, at least annually. Staff members who undertake scientific/technical duties intermittently are expected to undergo retraining and reassessment as necessary. Records of training and competency attainments must be endorsed by both trainer and trainee. Competency declarations must be traceable to
the laboratory directorship. Where the staff member is the senior person in the discipline/section, records should be endorsed by either an appropriately qualified colleague or supervising pathologist.

Where staff members are expected to work in areas other than those in which they would normally work, such as when working on-call or at weekends, a programme of regular refresher training must be established and records retained.

Staff members working only “out-of-hours” must have regular contact with routine and in particular supervisory personnel. As a guide, one day per month spent in the laboratory during normal working hours would be appropriate, with two full days per annum considered a minimum to ensure most relevant activities are covered. The amount of refresher training will need to be commensurate with the extent and nature of work completed outside normal working hours.

5.1.12
Pathologists and other specialist consultants must participate in the RCPA CME programme or equivalent as determined by assessment. Other evidence of CME will be assessed, such as active participation in training courses, workshops, conferences, clinical meetings, journal clubs and quality assurance programmes.

5.1.13
No explanatory commentary.

5.2 Accommodation and environmental conditions

5.2.1
For any new laboratory or modification to an existing laboratory, including collection sites, the provisions of AS/NZS 2982:2010 must be taken into account.

5.2.2
The Health and Safety in Employment Act and the Hazardous Substances and New Organisms Act place specific legal obligations on all employers, including laboratories. Safety auditing is a specialist activity and the responsibility for ensuring compliance with each above Act rests entirely with laboratory management. As such health and safety will not be audited formally during an accreditation assessment.

However, it is an expectation of the NZS/ISO 15189 that all applicable health and safety standards and guidelines relating to medical laboratories in New Zealand will be implemented. Attention will be drawn to any unsafe practices that are encountered. Where instructions and advice related to safety are written into test methods covered by accreditation, these must also be observed.

A Safety Manual detailing the laboratory’s policies and procedures in relation to health and safety must be readily available to staff. International and New Zealand standards and guidelines such as ISO 15190 and AS/NZS 2243 must be consulted when laboratory safety procedures are being prepared and implemented, as conformity with the requirements of these standards is expected. Generic organisational health and safety information may not always encompass specific aspects relevant to laboratory operations.

Declaring understanding of health and safety information contained in the manual should occur.

5.2.3
No explanatory commentary.

5.2.4
No explanatory commentary.

5.2.5
No explanatory commentary.
5.2.6
Wherever possible, there should be clear demarcation between “clean” areas, such as areas used for clerical aspects of laboratory work and “dirty areas”, such as areas used for testing procedures.

Clinical laboratories in general must meet Physical Containment (PC) level 2 requirements as described in AS/NZS 2243. Where the laboratory regularly handles pathogens in risk group 3, or where there is a significant risk of encountering such pathogens, PC3 levels of containment must be maintained.

5.2.7
No explanatory commentary.

5.2.8
No explanatory commentary.

5.2.9
No explanatory commentary.

5.2.10
No explanatory commentary.

5.3 Laboratory equipment

5.3.1
The laboratory is reminded that the term “equipment” includes reagents, media and consumables whether obtained from commercial sources or prepared in-house. Quality control, traceability and record keeping associated with materials prepared in-house is expected to be equivalent to that applied to materials purchased from reputable external suppliers. This entails proper labelling of in-house reagents to include details such as date of preparation, expiry dates, health and safety notices, and accurate traceable records being maintained of preparation, quality control and usage, where relevant.

5.3.2
Guidelines relating to equipment calibration are detailed in Appendix 2. It should be noted that calibration requirements will vary depending on method specifications. For equipment not listed, reference must be made to manufacturer’s specifications. The guidelines set out maximum periods of use before equipment must be re-calibrated or checked. Where a test method or environment requires more frequent calibration, this consideration will over-ride these guidelines.

IANZ may accept reduced calibration intervals based on such factors as history of stability and accuracy/precision requirements. It is the responsibility of the laboratory to provide clear evidence that its calibration and maintenance systems are appropriate and effective.

Laboratories performing their own calibrations must apply a procedure to estimate the uncertainty of measurement in these calibrations. The full rigour of this requirement will be expected to be applied where the equipment item being calibrated has performance (accuracy and precision) requirements that are critical to the accuracy and/or proper performance of a test, particularly when approaching the performance specification of the item of equipment. Examples include the calibration of analytical balances or thermometers requiring a high level of relative accuracy. Laboratories are recommended to have such items calibrated by an accredited external agency. If the laboratory elects to perform these calibrations, a full measurement uncertainty budget/analysis must normally be completed in accordance with the relevant published texts.

Precision balances that are being used to their full readability will also require full re-calibration by an appropriate external calibration agency if they are moved to a different location. Balances being used for less than this accuracy limit may be re-validated using appropriate quality control methods such as single point and repeatability checks with standard check masses.
Records of calibrations and validations carried out in-house must confirm traceability of measurement (see 5.6.2). This is normally achieved by the record specifically identifying the reference item used, the date, and the identity of the person performing the work, using the documented procedure. Calibration of an instrument as a whole, rather than its individual components, is sometimes appropriate.

Laboratories providing transfusion medicine services must comply with guidelines issued by the New Zealand Blood Service (NZBS) with regard to the calibration and monitoring of blood-product storage refrigerators and deep-freezers. Where such equipment is out of the direct control of the laboratory but within the organisational sphere of influence of the laboratory, all efforts must be made to ensure that these guidelines are followed. Caution should be exercised in returning blood product from remote storage units to stock when there is any concern that requirements have not been met.

Preventive maintenance programmes must be established for all major and ancillary items of equipment. Major analytical instrumentation should be under preventive maintenance contracts with the suppliers or their agents. Other key items of equipment such as microscopes should also be subjected to an organised servicing preventive maintenance programme by the suppliers or their agents, or completed by competent laboratory staff members according to the manufacturer’s instructions.

IANZ reserves the right to assess all relevant aspects of the equipment’s use, including accommodation and environment, maintenance and calibration records and the training and competency attainments of all personnel who may operate the equipment, whether employees of the laboratory or otherwise.

5.3.3
No explanatory commentary.

5.3.4
No explanatory commentary.

5.3.5
No explanatory commentary.

5.3.6
No explanatory commentary.

5.3.7
No explanatory commentary.

5.3.8
No explanatory commentary.

5.3.9
No explanatory commentary.

5.3.10
In those cases where the laboratory needs to use equipment outside of its permanent control, such as when sharing specialised equipment with university or research establishments, laboratory management must ensure that the requirements of the standard are met. This could be achieved by any or a combination of the following:
(a) Ensuring that the organisation controlling the equipment is accredited accordingly.
(b) Carrying out audits of the controlling organisation to verify conformity with relevant aspects of the standard.
(c) Maintaining independent records of equipment calibration and maintenance.
(d) Implementing a quality control regimen that will verify equipment performance at each time of use.
5.3.11 Compliance with Informative Annex B of NZS/ISO 15189:2007, Recommendations for Protection of Laboratory Information Systems (LIS) is effectively mandatory and each sub-clause of the Annex should be considered accordingly. Internal audits therefore should include a review of LIS policies and procedures against Annex B.

5.3.12 No explanatory commentary.

5.3.13 No explanatory commentary.

5.3.14 No explanatory commentary.

5.4 Pre-examination procedures

5.4.1 It is the responsibility of the laboratory to ensure or endeavour to ensure that primary samples are collected optimally. Where the laboratory undertakes collection of samples by its own employees, this aspect will be formally assessed and included in the laboratory’s accredited scope. In cases where laboratory personnel are not directly involved in sample collection, the laboratory maintains responsibility for providing guidance to extra-laboratory collectors aimed at ensuring that collections are carried out correctly (see 5.4.3), and that samples are transported to the laboratory with regard to Clause 5.4.6.

IANZ reserves the right to review and assess all relevant aspects of sample collection, whether under the direct control of the laboratory or not, to verify compliance with NZS/ISO 15189.

5.4.2 The laboratory must make all reasonable attempts to ensure that pertinent clinical data is provided on requests forms. Caution should be exercised when issuing reports where a lack of relevant clinical details on the request form could result in misleading information being provided to requesting clinicians. All efforts should be made to obtain the information needed for correct interpretation of results, before reports are released.

5.4.3 The primary collection manual must include all procedural aspects related to the management of patients and the collection of specimens. In addition the manual must provide guidance on hand washing procedures, recording of actual or potential adverse events, needle-stick injuries, restraint and domiciliary visits, where relevant.

On presentation for specimen collection, patients must be positively identified by the collector, using open instead of leading questions wherever possible. In situations where there is doubt about the identity of the patient, such as an unconscious or not able to communicate person, alternative mechanisms must be used and the means of identification recorded. This may involve having an appropriate care-giver provide confirmation of identity. In the case of specimens collected for transfusion medicine purposes, the person responsible for identifying the patient and collecting the specimen must sign a specifically-worded declaration accordingly. Use of the NZBS request form and worksheet designed for the purpose is advocated. For self-collected specimens the instructions provided should be in a language understood by the patient or care-giver.
All patient specimens accepted by the laboratory for testing must be labelled appropriately in accordance with defined procedures. Although special exemptions may apply, for example HIV examinations, guidelines for specimen labelling are as follows:

(a) Family name and given name(s).
(b) Date of birth and/or NHI number.
(c) Date of sampling.
(d) Time of sampling if relevant to patient care.
(e) Collection site if relevant.

The minimum requirements for labelling specimens are two identifiers attributable to the patient. Generally, these will be the patient's full name and date of birth or NHI medical record number. In the case of specimens collected for cross-match purposes samples must be labelled by hand and include the signature or initials of the collector. Where samples are collected for POCT, one patient at a time and the specimen is retained by the collector through all stages, labelling requirements may be relaxed. Otherwise, the labelling requirements above must be met. In special circumstances where the identity of the patient is not to be revealed, HIV examinations for example, a coding system must be agreed between requesting clinicians and the laboratory.

In general, specimen collection containers must not be pre-labelled. An exception may be when a sample container is provided directly to a patient.

Consumables in the collection area, in particular tubes containing additives, must be monitored for expiry dates.

Where specimen collection is outside the direct control of the laboratory, the collectors must be informed of the laboratory's collection requirements.

5.4.4
No explanatory commentary.

5.4.5
If, having given full consideration to the standard requirements, specimens which do not meet minimum acceptability criteria are accepted and tested, a record must be kept of the circumstances and any subsequent action taken. Where possible, the requester or person responsible for the sample collection must be contacted and must formally accept responsibility for verifying the identity of the sample. Where this is not possible the laboratory director, or delegate, must authorise the continuation of processing and testing. These circumstances must be formally recorded. A comment on the nature of the problem (5.4.8), and of any subsequent actions must be included on test reports.

There may be special circumstances where the identity of the patient will not be revealed to the laboratory, for example HIV examinations. In such cases, adequate precautions must be taken to uniquely identify specimens at all stages.

Specimens and associated records (worksheets, slides etc.) must be uniquely identified at all stages of testing. This may be achieved by the use of a unique laboratory label. This is usually the most practical option especially where large numbers of specimens are processed. In general, all specimens including histology blocks, slides, sub-samples and associated records must be uniquely identified by the use of at least two identifiers, ideally with one being the patient's family name or abbreviation thereof.

The uniqueness of a numbering system should take into consideration the specimen storage time and the possibility of two specimens with the same number being in the laboratory at the same time.
5.4.6
No explanatory commentary.

5.4.7
The identity of the person applying laboratory numbers to specimen(s) and request forms after checking that labelling of the specimen(s) and details on the request form meet requirements must be recorded. This applies whether completed within the laboratory or at extra-laboratory sites.

5.4.8
No explanatory commentary.

5.4.9
No explanatory commentary.

5.4.10
No explanatory commentary.

5.4.11
No explanatory commentary.

5.4.12
No explanatory commentary.

5.4.13
No explanatory commentary.

5.4.14
No explanatory commentary.

5.5 Examination procedures

5.5.1
Accreditation is normally granted only for internationally or nationally accepted standard test procedures or non-standard procedures, in-house methods that have been appropriately validated, and which are performed regularly.

Where standard methods are prescribed or followed, the laboratory is required to maintain current versions of the said methods and update laboratory procedures in accordance with these. Although full validation is not required, a laboratory must verify that the performance is suitable for purpose with respect to biological reference intervals, specified limits of detection, specificity, sensitivity, repeatability and reproducibility.

Commercial test kits will require further validation if the laboratory is unable to source the validation data from manufacturers with a recognised quality assurance system or reputable validation based on collaborative testing.

In-house methods could include but not be restricted to methods developed in the laboratory or by an industry group or modified standard test methods.

Validation and verifications must be completed according to internationally recognised guidelines, relevant to the particular discipline. The means of validation must be fully documented and referenced, and be made available for review by IANZ, on request.
Any deviations from documented procedures must be authorised by the laboratory director or a delegate with authority traceable to the laboratory director. Such incidents must be fully recorded and reviewed and any significant implications to test results conveyed to clinicians.

5.5.2

Each procedure or set of procedures must be dated and authorised by an appropriate staff member, who will usually be a listed key person.

Method documentation must be reviewed at least annually and completion of the method review must be recorded. Where there are no changes, a date and signature will be sufficient. Under circumstances of a demonstrably effective system the need for annual review may be relaxed. Some manufacturers provide method documentation in the form of kit inserts with their product and these may be included in method manuals. Where this information is not sufficiently detailed to cover all required elements it must be supplemented by the laboratory. Inserts for new batches received must be checked for changes in procedure and a copy of the new insert either placed in or appended to the manual. Document control expectations must be met.

Where a test may be completed by more than one method, there must be documented criteria for method selection. Where relevant, the degree of correlation between the methods must be established and documented.

5.5.3

Where procedures are not immediately to hand at the workstation they must be readily accessible.

5.5.4

No explanatory commentary.

5.5.5

In reviewing biological reference intervals, the laboratory must take into account the intervals developed and implemented by other laboratories within its geographic and ethnic catchment. Laboratories must make all attempts to minimise potential confusion amongst clinical requesters, particularly where patients are commonly tested at more than one institution within a region. This will entail a collaborative/cooperative approach in the best interests of patient care being adopted.

5.5.6

Estimates for uncertainty of measurement, where relevant and possible, must be made available to users of laboratory services, upon request.

5.5.7

No explanatory commentary.

5.6 Assuring quality of examination procedures

5.6.1

For internal quality control the laboratory must be guided by established best-practice within each discipline, national and internationally published guidelines and any supplementary criteria published by IANZ. The following general principles must apply where relevant:

(a) The quality control material used must cover the analytical concentrations encountered.

(b) Combinations of low-abnormal, normal, high-abnormal, negative and positive controls must be used, as appropriate for the test.

(c) The use of controls independent of those produced by the manufacturer of the test or analyser should be considered.
(d) Control material should be matrix matched, wherever possible.

(e) All internal quality control results must be recorded.

(f) A protocol for action to be taken where quality control results fall outside acceptable ranges must be documented.

(g) Details of action taken on outlier results must be recorded.

(h) The laboratory must have a system of longer-term monitoring of internal quality control results to assess method performance.

(i) The outcome of the longer-term monitoring and of any actions arising must be recorded.

For quantitative internal quality control the following additional principles apply:

(a) Acceptable ranges must be defined for internal quality control material. These ranges must be statistically valid and clinically relevant.

(b) Means and standard deviations supplied by manufacturers of quality control material must be validated to ensure that adequate control of assays is achieved. In general, laboratories are expected to determine means and standard deviations using their own data.

(c) Graphical presentation of numerical quality control results must be considered, to assist the early detection of trends.

Each new lot of kits, cartridges, reagents and materials, including those prepared in-house, must be subjected to quality control checking wherever possible. The checks may be completed on acceptance or before being introduced for use or in use, with preference for the first two options.

Laboratories or, where appropriate, departments within laboratories, should nominate a person responsible for quality control activities. This must be a primary responsibility and the appointee must be provided with resources and authority sufficient to carry out this role effectively. Primary responsibility implies that the task must have a priority and must not be compromised by other responsibilities. The time commitment will depend on the size and scope of the laboratory operation. A deputy must be nominated for the person having quality control responsibility.

5.6.2

The extent to which the estimation of uncertainty of measurement will be applicable in medical laboratories will vary between tests and between disciplines. In medical testing, uncertainty of measurement arises not only from analytical error, but also from test-method interferences, the inherent limitations of methodology used and extra-laboratory contributions. Where methods operate with a systematic bias which has not been corrected, this may need to be taken into account in uncertainty estimates, unless biological reference intervals quoted are specific for the particular method.

Laboratories must attempt to estimate the uncertainty of measurement for all examinations in their scope of accreditation that provide numerical results. Examinations that are reported as qualitative results based on numerical information should also be subjected to uncertainty of measurement estimation, particularly at the decision values. Where results of examinations are either not numerical or not based on numerical data such as detected/not detected, pass/fail, positive/negative, or based on visual or other qualitative examinations, estimates of uncertainty are not required.

Where an estimate of measurement uncertainty is made, laboratories need to document the procedures used with reference to published procedures. Whether the estimate is based on quality control data or replicate patient sample information must be stated.
Medical testing laboratories are not currently required to report their estimated measurement uncertainty on test reports as a matter of routine. However, Clause 5.8.3(k) of the standard suggests reporting the estimate of measurement uncertainty may be appropriate when it is required for the correct application or interpretation of a test result.

5.6.3
The fundamental motivation for establishing and demonstrating traceability in medical testing measurements is to enable comparability of results from different laboratories across both space and time. Critical to this, and the first step in establishing traceability, is for the measurand to be clearly and unambiguously defined to ensure the results compared are of the same biological entity. Often in medical testing, the measurand is defined by the methods of measurement used.

Where these parameters are defined physical measurements such as time, temperature and mass, the traceability chains are well established. Often however, the parameter is a visual or instrument response that often is or can be compared with a known response of the pure biological entity, usually a reference standard or organism. The mechanisms to ensure traceability of such reference material are not necessarily well developed. It is also recognised that availability of reference material complying with the generally accepted mechanisms to ensure traceability is limited.

The International Committee for Weights and Measures (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) have agreed to cooperate to establish a Joint Committee for Traceability in Laboratory Medicine (JCTLM). The goal of the JCTLM is to provide a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards. The JCTLM database lists endorsed reference measurement procedures, reference materials and reference laboratories and should be consulted during introduction and use of methods.

Where manufacturer-supplied biochemical and/or chemical procedures are used the onus is on the manufacturer to demonstrate traceability. In other situations, medical testing laboratories are expected to source their certified reference materials from national measurement institutes and reputable certified reference and reference materials producers, preferably accredited to ISO 17034, wherever possible. In-house produced reference standards/organisms may be used but caution in interpretation of results must be exercised. Without formal evidence of traceability it remains the laboratory’s responsibility to demonstrate that the materials are fit for their intended purpose.

For empirical methods, traceability relies on the laboratory complying in full with the method as published, as this defines the measurand. Any variations to the method must be validated or ‘calibrated’ against the primary reference method defining the measurand.

To ensure traceability for biological organism examinations laboratories must hold and maintain a collection of cultures of organisms required to complete verification checks on methods and for quality control purposes. Cultures specified in referenced methods must be traceable to a recognised culture collection. Additional wild strains, such as isolates from samples, can be used to supplement reference strains.

Medical testing laboratories are expected to source their organisms from national or international type culture collections, where availability permits. Without formal evidence of traceability it remains the laboratories’ responsibility to demonstrate the organisms are fit for their intended purpose.

All cultures held by a laboratory must be uniquely identified. The system of identification must maintain traceability to the recognised culture collection or sample from which the cultures were sourced. Documented procedures must be in place, covering the acquisition, preservation, maintenance and confirmation-testing of cultures in the collection.

Traceability of physical measurements must be established for test or calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement, including, where relevant instruments used for monitoring environmental conditions, directly to a national standards laboratory.
acceptable to the Measurement Standards Laboratory or from a third party accredited calibration laboratory that is accredited by IANZ or an organisation with which IANZ has a mutual recognition arrangement.

5.6.4
The primary purpose of external quality assessment programmes is to provide information on aspects of uncertainty associated with patient samples, including the competency of staff carrying out testing work. Thus, external quality assurance samples should be treated as patient samples, wherever possible. All staff who are directly involved in testing patient samples must participate fully in the testing of external quality assurance samples. Records of their participation must be maintained, particularly for cases of individual opinion, to enable an evaluation of performance as an adjunct to continuing quality improvement. A secondary purpose of external quality assurance testing is to provide a challenge to staff for purposes of continuing professional development. Consequently, slides and samples may be examined, tested and discussed for educational purposes.

For peripatetic specialists, participation in an appropriate proficiency programme at one or other of the laboratories involved may be acceptable. However, each laboratory must maintain documentary evidence of the participation and performance of such individuals.

5.6.5
No explanatory commentary.

5.6.6
Where the laboratory uses different instruments and/or methods for the same test, it must ensure that uncertainty estimates are documented for each instrument/method combination. Significant differences in measurement uncertainty will need to be taken into account when interpreting and reporting test results.

5.6.7
No explanatory commentary.

5.7 Post-examination procedures

5.7.1
Personnel authorised to release results must be defined by the laboratory director or person with authority traceable to the laboratory director. Persons providing clinical and/or scientific/technical evaluation of results must be documented, and must be of an appropriate level of competence. Such key persons should be available during assessments wherever possible, and may be required to demonstrate the appropriate level of competence to the assessment team.

5.7.2
Storage of primary specimens and sub-samples must be defined in documentation. In defining the minimum retention periods for specimens and sub-samples, the laboratory must conform to the NPAAC requirements for the retention of laboratory records and diagnostic material. Any deviations from the defined criteria must be approved by an appropriate pathologist on behalf of the laboratory director. Any deviation and authority for same must be detailed. Specimens and sub-samples include items such as microscope slides and tissue blocks.

5.7.3
All laboratories handling tissue and cellular material must have formally documented policies and procedures for the return of tissue and cellular material to patients if requested. All aspects must be in accordance with the Human Tissues Act.

Appropriate consideration must be given to the various cultural contexts experienced in New Zealand. Particular attention must be shown to the cultural needs of Maori. Policies and procedures regarding culturally appropriate methods of retention, handling and disposal of human tissue must be in accordance with local protocols.
5.8 Reporting of results

5.8.1 No explanatory commentary.

5.8.2 No explanatory commentary.

5.8.3 (k) Comments relating to the quality or adequacy of the primary sample, such as ‘haemolysed’, should make clear which tests may have been affected, and the nature of the likely effects, such as positive or negative interference, if known.

Results of examinations that are not covered by the scope of accreditation must be clearly identified as such.

(l) Any report containing a result based on opinion or with an attached comment having an impact on patient care must carry the identity of the most senior key clinical, scientific or technical person responsible for the opinion or comment and this identification must appear on all report formats and carry through into any Patient Information System and/or Clinical Data Repository. This includes pre-formatted, coded comments when selected by authorised personnel, but excludes observations of non-interpretive value. For key clinical personnel the identification comprises name and function/designation, such as pathologist, haematologist, or medical microbiologist as appropriate. For key scientific/technical personnel the identification comprises name or initials and function/designation, such as scientist or technician as appropriate. Apart from the situations above, reports will not be required to include the identity of the person authorising the release of the report or any generic statement regarding authorisation or auto-validation but these may be included if preferred and agreed to by the laboratory and requesters. Where results are released automatically via electronic validation systems associated with automated analysers the person(s) approving use of the particular algorithm for automatic release must be defined in supporting laboratory documentation.

5.8.4 No explanatory commentary.

5.8.5 No explanatory commentary.

5.8.6 No explanatory commentary.

5.8.7 No explanatory commentary.

5.8.8 It may be appropriate to have separate alert/critical intervals for hospital and community patients.

The status of any interim report, whether in hard copy or electronic format, must be clearly indicated to the requester.

5.8.9 No explanatory commentary.

5.8.10 No explanatory commentary.
5.8.11
When data are transcribed manually, or entered manually into an electronic database or laboratory information system, there must be a means of checking the accuracy of transcriptions and entries. Wherever possible, checking should be performed by an independent operator.

5.8.12
Details of who may release results must be detailed either in procedural documentation or in competency records.

5.8.13
It is essential that the integrity of data and confidentiality requirements are met during the transfer of results by any electronic system.

Where the clinician requests the electronic transmission of results from the laboratory to a remote location, the responsibility for ensuring the integrity of data transfer to the referring clinician and other designated addressees, such as a clinical enquiry system or regional clinical data repository rests with the laboratory. At appropriate intervals the laboratory must provide a means of confirming the integrity of the electronic transfer process, especially after any change to the laboratory information system. This interval may vary according to the frequency and mode of transmission and the complexity of test data. Records of transfer integrity checks must be kept.

5.8.14
No explanatory commentary.

5.8.15
Where the revised results may alter patient management the laboratory must ensure that persons with the authority to take action are informed.
Bibliography

Primary Criteria
AS 1, August 2007 Procedures and Conditions of Accreditation
AS/NZS 4308:2008 Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine
ISO 22870:2006 Point-of-care testing – Requirements for quality and competence
NZS/ISO 15189:2007 Medical Laboratories – Particular requirements for quality and competence
NZS/ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

Specific Criteria
ANZSBT Guidelines for Blood Grouping & Antibody Screening in the Antenatal and Perinatal Setting 3rd Ed 2007
ANZSBT Guidelines for Laboratory Assessment of Fetomaternal Haemorrhage 1st Edition 2002
ANZSBT Guidelines for Pretransfusion Laboratory Practice 5th Ed 2007
National Cervical Screening Programme Operational Policy and Quality Standards (Interim) 2009
NPAAC Requirements for Retention of Laboratory Records and Diagnostic Material
NPAAC Requirements for the Facilities and Operation of Mortuaries

Supplementary Criteria
AS 2243 Parts 1 to 10 Safety in laboratories
ISO 15190:2003 Medical Laboratories – Requirements for safety
AS/NZS 2982:2010 Laboratory design and construction
Appendix 1
Classes of Test

NZS/ISO 15189
Biochemistry
Cytology
Fertility Studies
Forensic Pathology/Mortuary
Genetics
Haematology
Histocompatibility/Immunogenetics
Histology
Immunology
Serology
Microbiology
Molecular Pathology
Newborn Screening
Patient Services
Specimen Services
Transfusion Medicine
Virology

ISO 22870
Point-of-care Testing

AS/NZS 4308
Workplace Drug Testing
Appendix 2

Equipment Calibration Intervals

The following table sets out the normal periods between successive calibrations following initial calibration for a number of reference standards and measuring instruments. It must be stressed that each period is generally considered to be the maximum appropriate in each case providing the other criteria as specified below are met:
(a) The equipment is of good quality and of proven adequate stability, and
(b) The laboratory has both the equipment capability and staff expertise to perform adequate internal checks, and
(c) If any suspicion or indication of overloading or mishandling arises, the equipment is checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.
(d) Where the above criteria cannot be met, appropriately shorter intervals may be necessary.

IANZ is, however, prepared to consider submissions for extension of calibration intervals.

Items marked (*) in the table are those which may be calibrated by staff of a laboratory if it is suitably equipped and the staff are competent to perform such recalibrations. Where staff members of a laboratory have performed calibrations, adequate records of these measurements must be maintained.

IANZ and the Measurement Standards Laboratory have produced a number of Technical Guides with further information on some calibration procedures (see Bibliography).

<table>
<thead>
<tr>
<th>Type of equipment</th>
<th>Calibration interval (years or as stated)</th>
<th>Checking interval (months or as stated)</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoclaves/Sterilisers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autoclaves</td>
<td>Following repair or maintenance*</td>
<td></td>
<td>Check heating profiles of typical loads with respect to chamber temperatures to determine lag times, by an accredited calibration laboratory, or *Using appropriately calibrated equipment following a fully documented procedure.</td>
</tr>
<tr>
<td></td>
<td>Each use*</td>
<td></td>
<td>Check the time and temperature of the cycle. Discard loads should be autoclaved for at least 30 minutes at 121°C.</td>
</tr>
<tr>
<td>Hot Air Sterilising Ovens</td>
<td>Each use*</td>
<td></td>
<td>Check of time and temperature. At least 160°C for 2 hours.</td>
</tr>
<tr>
<td>Automatic burettes and dispensers</td>
<td>6*</td>
<td></td>
<td>Inaccuracy and repeatability at the volumes of use by an accredited calibration laboratory, or *Using appropriately calibrated equipment following a fully documented procedure.</td>
</tr>
<tr>
<td>Type of equipment</td>
<td>Calibration interval (years or as stated)</td>
<td>Checking interval (months or as stated)</td>
<td>Procedures</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------------------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Balances</td>
<td>3</td>
<td></td>
<td>Complete calibration by an accredited calibration laboratory, or *Calibration using traceable certified masses (see MSL Technical Guide 25 – Calibrating Balances). Staff members completing calibrations need to be formally trained.</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td></td>
<td>Servicing. Where it can be demonstrated that the balance is used in a suitable environment and has a stable history of performance this period may be extended.</td>
</tr>
<tr>
<td></td>
<td>6*</td>
<td></td>
<td>Accuracy checks when balance is used to its best accuracy (see MSL Technical Guide 12 – Assuring the quality of weighing results and MSL Technical Guide 6 – Magnetic Effects in Weighing).</td>
</tr>
<tr>
<td></td>
<td>1*</td>
<td></td>
<td>One point check, using a known mass close to balance capacity.</td>
</tr>
<tr>
<td></td>
<td>Each use*</td>
<td></td>
<td>Zero point check.</td>
</tr>
<tr>
<td>Biological safety cabinets</td>
<td>1</td>
<td></td>
<td>Complete calibration by an accredited calibration laboratory. Documented procedures need to be in place for ongoing monitoring.</td>
</tr>
<tr>
<td>Centrifuges</td>
<td>1*</td>
<td></td>
<td>Calibrated tachometer (mechanical stroboscope or light cell type) where the operating speed/force is specified. Check the calibration of the timing device and temperature measurement device, where appropriate, when the time and temperature of centrifugation are specified.</td>
</tr>
<tr>
<td>Conductivity meters on water boards</td>
<td>12*</td>
<td></td>
<td>Check water quality using an independently calibrated meter.</td>
</tr>
<tr>
<td>Controlled environment incubators and containers</td>
<td>Daily or each use*</td>
<td></td>
<td>Check condition by appropriate means such as a chemical indicator, vacuum gauge, continuous CO₂ monitor, growth/no growth of appropriate organisms.</td>
</tr>
<tr>
<td></td>
<td>6*</td>
<td></td>
<td>Calibration of continuous CO₂ monitor.</td>
</tr>
<tr>
<td>Fume cupboards</td>
<td>1</td>
<td></td>
<td>By an accredited calibration laboratory.</td>
</tr>
<tr>
<td>Type of equipment</td>
<td>Calibration interval (years or as stated)</td>
<td>Checking interval (months or as stated)</td>
<td>Procedures</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------------</td>
<td>----------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Masses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference masses of integral construction stainless steel or nickel-chromium alloy</td>
<td>1 then 5</td>
<td></td>
<td>By an accredited calibration laboratory.</td>
</tr>
<tr>
<td>Working masses made of stainless steel or nickel-chromium alloy</td>
<td>1 then 3</td>
<td></td>
<td>By an accredited calibration laboratory.</td>
</tr>
<tr>
<td>Working masses made of other materials</td>
<td>1*</td>
<td></td>
<td>By an accredited calibration laboratory, or  *Using appropriately calibrated equipment following a fully documented procedure (see MSL Technical Guide 7 – Calibrating Standard Weights).</td>
</tr>
<tr>
<td><strong>pH meters</strong></td>
<td>Daily or each use*</td>
<td></td>
<td>Calibrate using at least two appropriate standard buffers. Buffers need to be stored in appropriate containers and marked with an expiry date. If a temperature compensation probe is used, it must be calibrated (see Thermometers).</td>
</tr>
<tr>
<td><strong>Pipettors – piston operated</strong></td>
<td>6*</td>
<td></td>
<td>Inaccuracy and repeatability at the volumes of use by an accredited calibration laboratory, or  *Using appropriately calibrated equipment following a fully documented procedure. Pipettors used in circumstances that could add significantly to the uncertainty of test results should be calibrated more frequently.</td>
</tr>
<tr>
<td><strong>Plate readers</strong></td>
<td>12*</td>
<td></td>
<td>Using a standard absorbance plate or appropriate calibration kit.</td>
</tr>
<tr>
<td><strong>Spectrophotometers</strong></td>
<td>6*</td>
<td></td>
<td>By an accredited calibration agency, or  *In accordance with IANZ Technical Guide AS TG 4 UV/Vis Spectrophotometer Calibration Procedures.</td>
</tr>
<tr>
<td><strong>Spectrophotometer filters</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wavelength</td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory</td>
</tr>
<tr>
<td>Transmittance/Absorbance</td>
<td>1 then 2</td>
<td></td>
<td>By an accredited calibration laboratory.</td>
</tr>
<tr>
<td><strong>Tachometers</strong></td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory.</td>
</tr>
<tr>
<td><strong>Thermo-cyclers</strong></td>
<td>12*</td>
<td></td>
<td>Temperature of each well or according to a manufacturer-advised plan.</td>
</tr>
<tr>
<td><strong>Thermometers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of equipment</td>
<td>Calibration interval (years or as stated)</td>
<td>Checking interval (months or as stated)</td>
<td>Procedures</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------------------------------------------</td>
<td>----------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Liquid in glass – reference</td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory, followed by an ice point check on receipt (see MSL Technical Guide TG1: The Ice Point).</td>
</tr>
<tr>
<td>Liquid in glass – working</td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory, followed by an ice point check on receipt (see MSL Technical Guide TG1: The Ice Point).</td>
</tr>
<tr>
<td>Liquid in glass – working, alternative procedure</td>
<td>6*</td>
<td></td>
<td>Check against reference thermometer across working range or at points of use (see IANZ Technical Guide 3 AS TG3: Working Thermometers Calibration Procedures).</td>
</tr>
<tr>
<td>Resistance – reference</td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory, followed by an ice point check on receipt (see MSL Technical Guide TG1: The Ice Point).</td>
</tr>
<tr>
<td>Resistance – working</td>
<td>5</td>
<td></td>
<td>By an accredited calibration laboratory, followed by an ice point check on receipt (see MSL Technical Guide TG1: The Ice Point).</td>
</tr>
<tr>
<td>Resistance – working, alternative procedure</td>
<td>6*</td>
<td></td>
<td>Check against reference thermometer across working range or at points of use (see IANZ Technical Guide 3 AS TG3: Working Thermometers Calibration Procedures).</td>
</tr>
<tr>
<td>Direct reading digital indicating systems – working</td>
<td>1*</td>
<td></td>
<td>By an accredited calibration laboratory, or Check against reference thermometer across working range or at points of use (see IANZ Technical Guide 3 AS TG3: Working Thermometers Calibration Procedures).</td>
</tr>
</tbody>
</table>

**Thermo-regulated equipment**

<p>| Refrigerators, cool rooms, incubators, freezers, water baths. | Daily or each use* | Monitor the temperature and record. Continual recording is preferred. The use of maximum/minimum type thermometers/devices may be advantageous for monitoring of critical conditions. |</p>
<table>
<thead>
<tr>
<th>Type of equipment</th>
<th>Calibration interval (years or as stated)</th>
<th>Checking interval (months or as stated)</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerators and cool rooms for storing pathological samples and critical reagents, incubators, water baths</td>
<td>3*</td>
<td></td>
<td>Spatial temperature variation within the working space by an accredited calibration laboratory, or *Using a working thermometer(s) following a fully documented procedure.</td>
</tr>
<tr>
<td>Refrigerators and cool rooms for storing reagents and materials with less critical requirements, freezers</td>
<td>5*</td>
<td></td>
<td>Spatial temperature variation within the working space by an accredited calibration laboratory, or *Using a working thermometer(s) following a fully documented procedure.</td>
</tr>
<tr>
<td>Refrigerators, cool rooms, freezers and platelet incubators used for storing blood products for transfusion (see NZBS Refrigeration Guidelines for full details of requirements).</td>
<td>Continuous*</td>
<td></td>
<td>Continuous temperature monitoring by chart recorder or electronic monitoring system.</td>
</tr>
<tr>
<td></td>
<td>1*</td>
<td></td>
<td>Spatial temperature variation within the working space by an accredited calibration laboratory, or *Using a working thermometer(s) following a fully documented procedure.</td>
</tr>
<tr>
<td></td>
<td>1*</td>
<td></td>
<td>Two point calibration of temperature monitoring and alarm probes by an accredited calibration laboratory, or *Using a reference thermometer following a fully documented procedure.</td>
</tr>
<tr>
<td></td>
<td>1*</td>
<td></td>
<td>Check digital and chart temperature displays using a working thermometer.</td>
</tr>
<tr>
<td></td>
<td>1*</td>
<td></td>
<td>Check alarm activation temperature(s) using a working thermometer.</td>
</tr>
<tr>
<td>Fresh frozen plasma thawing unit</td>
<td>1*</td>
<td></td>
<td>Check alarm activation temperature using a working thermometer.</td>
</tr>
<tr>
<td>Timers and stopwatches</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical</td>
<td>3*</td>
<td></td>
<td>Comparison against a recognised source such as the IRL Talking Clock or similar (see MSL Technical Guide 8 – Calibration of Stopwatches).</td>
</tr>
<tr>
<td>Electronic</td>
<td>12*</td>
<td></td>
<td>Comparison against a recognised source such as the IRL Talking Clock or similar (see MSL Technical Guide 8 – Calibration of Stopwatches).</td>
</tr>
</tbody>
</table>
### Volumetric Glassware

<table>
<thead>
<tr>
<th>Type of equipment</th>
<th>Calibration interval (years or as stated)</th>
<th>Checking interval (months or as stated)</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flasks, pipette, burettes and measuring cylinders used for reference purposes</td>
<td>5*</td>
<td></td>
<td>Inaccuracy at volumes of use by an accredited calibration laboratory, or *Using appropriately calibrated equipment following a fully documented procedure (see MSL Technical Guide TG17: Measuring Volume by Weighing Water).</td>
</tr>
</tbody>
</table>

### Bibliography

IANZ Technical Guide AS TG 4: UV/Vis Spectrophotometer Calibration Procedures


MSL Technical Guide 1: The Ice Point

MSL Technical Guide 6: Magnetic Effects in Weighing

MSL Technical Guide 7: Calibrating Standard Weights

MSL Technical Guide 8: Calibration of Stopwatches

MSL Technical Guide 12: Assuring the quality of weighing results

MSL Technical Guide 17: Measuring Volume by Weighing Water

MSL Technical Guide 25: Calibrating Balances

New Zealand Blood Service Refrigeration Guidelines 2011

IANZ guides can be found at [http://www.ianz.govt.nz/publications2/technical_guides.htm](http://www.ianz.govt.nz/publications2/technical_guides.htm).