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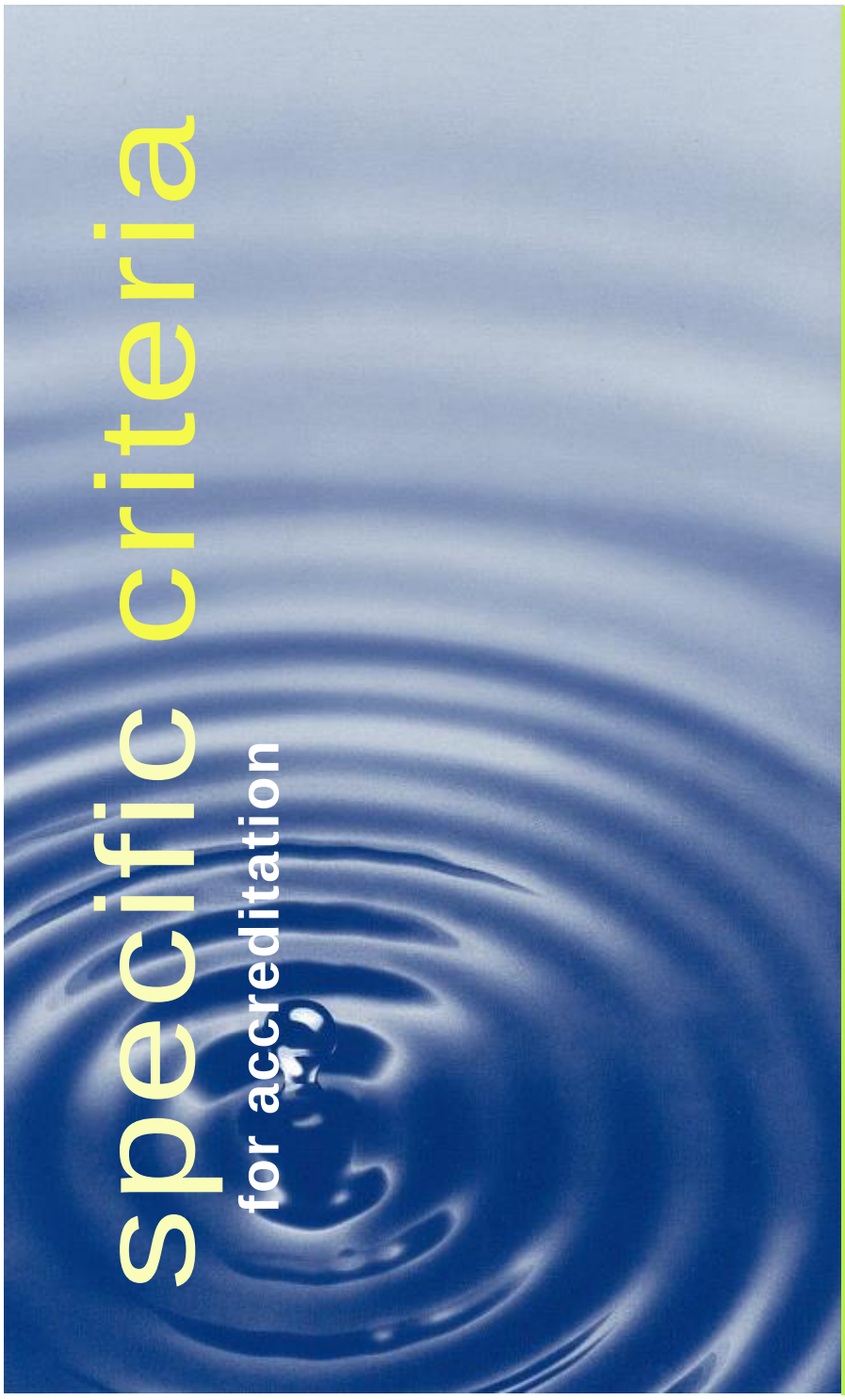

Medical Testing

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specific criteria for accreditation

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Contents

1 Introduction

IANZ Specific Criteria are an elaboration of the General Criteria for Accreditation for specific fields of test, 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.

ISO 15189:2012 *Medical laboratories — Requirements for quality and competence* (herein after referred to as ISO 15189) is an International Standard 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 ISO 15189.

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

2 Scope

2.1 General

This document sets out the specific requirements a medical testing laboratory must meet to be compliant with the requirements of ISO 15189 and any other applicable technical, regulatory or other supplementary criteria, if it is to be accredited by IANZ.

There are other criteria documents applicable to medical testing laboratories working in specialised areas of testing, which have their own set of unique criteria. A list of published documents that IANZ has adopted, on the basis of accepted industry practice, are listed in the Bibliography section of this document. Other requirements may be reviewed and adopted with any relevant laboratories informed accordingly.

Other useful standards and guides are listed on http://www.ianz.govt.nz/resources/documents-2/general/ - Medical Testing Guidelines and Standards – IG4.

2.2 Point-of-care testing

The particular requirements pertaining to point-of-care testing (POCT) are detailed in a complementary standard, ISO 22870 *Point-of-care testing – Requirements for quality and competence*. 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 be trained appropriately, with full records retained.

The accredited laboratory within an institution or laboratory service shall be responsible for the management of POCT equipment associated with that institution or service. A laboratory may seek inclusion of POCT activities within its accredited scope, having demonstrated conformity with the governing standard, ISO 15189, and the additional requirements of ISO 22870. In addition, The NZ POCT Advisory Group Guidelines must to be adhered to.

Accreditation for POCT will be recorded in the laboratory's Schedule to the Scope of Accreditation to provide detail of specific locations and the associated testing, rather than on an organisation-wide basis.

For remote POCT sites, IANZ will, at least, conduct an initial onsite visit, and thereafter scheduled site visits will occur at least once during the 4-year accreditation cycle. Consideration will be given to desktop/remote review for interim assessments provided:

- The service conducts and retains record of onsite visits completed at least once a year.
- The service ensures technical oversight of each POCT site, commensurate with the scope of testing provided.

- There are no significant discrepancies in either External Quality Assurance (EQA) or internal quality control (QC).
- All documentation pertaining to the POCT sites is available for review during the annual assessment process of the parent laboratory.

Any changes to service provision will be reviewed by IANZ and may involve a repeat onsite visit subject to the extent of change.

3 Classes of Examination

IANZ accreditation does not constitute a blanket approval of all a laboratory's activities. Therefore, a means of identifying activities for which accreditation is granted is necessary. The classes of examination (Class of Tests) provide the framework within which the scope of accreditation is expressed for medical testing laboratories.

The master Class of Tests will be available from IANZ.

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 constitute any restriction on the work a laboratory can perform but provide a convenient means of expressing an accredited laboratory's capabilities.

Scopes of Accreditation, as available on the website, are always the most current version and do not include an expiry date. Dates will only change with updates to the scope of testing.

4 Management Requirements

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

4.1 Organisation and management responsibility

4.1.1 Organisation

No explanatory commentary.

4.1.1.1 General

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

4.1.1.2 Legal entity

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

4.1.1.3 Ethical conduct

Laboratories are expected to provide guidance to personnel on ethical issues additional to those of applicable professional bodies. The contribution of the laboratory's service to patient care must remain paramount through all activities.

4.1.1.4 Laboratory director

The expectation is that laboratories must maintain clinical oversight and leadership for all laboratory activities relevant to clinical care.

4.1.2 Management responsibility

No explanatory commentary.

4.1.2.1 Management commitment

No explanatory commentary.

4.1.2.2 Needs of users

No explanatory commentary.

4.1.2.3 Quality policy

No explanatory commentary.

4.1.2.4 Quality objectives and planning

The defined objectives must be routinely monitored and reviewed.

4.1.2.5 Responsibility, authority and interrelationships

No explanatory commentary.

4.1.2.6 Communication

No explanatory commentary.

4.1.2.7 Quality manager

No explanatory commentary.

4.2 Quality management system

4.2.1 General requirements

No explanatory commentary.

4.2.2 Documentation requirements

4.2.2.1 General

No explanatory commentary.

4.2.2.2 Quality manual

The quality manual must detail or refer to any other documentation that describes how the laboratory addresses all elements of the ISO 15189 standard and related accreditation criteria. 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 provided separately.

There must be recorded evidence of familiarisation of all staff with documented procedures, quality systems and specific manuals.

4.3 Document control

Page numbers may not be fully applicable on some electronic systems. Mechanisms must be in place to ensure only complete and full versions are available for use.

It is understood that review of some documentation to ensure content is current and adequate for continued use is ongoing. In order to assure alignment with any industry, technological and/or management changes, there shall be a system of annual review. This frequency may be extended to biennial with the approval of IANZ, based on historical performance.

Completion of the review must be recorded. Where there are no significant changes, a date and signature/initials to acknowledge review will be sufficient.

All staff members are expected to be aware of any significant changes to relevant documentation.

Templates of worksheets and/or calculations or forms used to record results and other relevant information are expected to contain sufficient document control information to preclude inadvertent use of superseded versions.

4.4 Service agreements

4.4.1 Establishment of service agreements

A contract in its simplest sense involves 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 formal contractual arrangements with clients, such as the NSU, a DHB, Medical Clinic, and Healthcare providers, prior to accepting work.

Contracts/agreements must also be in place with service providers and referral laboratories, consultants and advisors, where applicable.

Policies for patient requested examinations and reporting of those examinations must be defined and understood by all relevant staff members (see 5.9.1).

4.4.2 Review of service agreements

No explanatory commentary.

4.5 Examination by referral laboratories

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. A medical laboratory is differentiated from a collection centre in ‘Terms and definitions’, Sub-clause 3.11 of ISO 15189, and a referral laboratory is defined in ‘Terms and definitions’, Sub-clause 3.23 of ISO 15189.

4.5.1 Selecting and evaluating referral laboratories and consultants

The laboratory must monitor the quality and performance of referral laboratories, including in those circumstances where the laboratory does not have complete freedom of choice in their selection. A referral laboratory should be accredited either by IANZ or an IANZ mutual recognition partner for the testing offered. Similarly, referral consultants should work in accredited laboratories, to ensure the requirements of ISO 15189 are readily met.

4.5.2 Provision of examination results

In the case of a referral laboratory which has the same QMS and organisational structure as the referring laboratory, or is under contractual obligation, the requirements of this clause may be reviewed accordingly.

Laboratories contractually required to enter into a joint laboratory service arrangement may claim exception from direct compliance with Clause 4.5.2 on the grounds that they do not meet the definition of the referring/referral laboratory construct defined in Clause 3.23. In such circumstances the ‘referring’ party must be proactive in making information on their relationship with the ‘referral’ party freely available to service users or potential service users. Joint and separate responsibilities for reporting results, clinical interpretations and advice must also be published openly and transparently in any relevant medium (electronic, handbooks etc.).

The referring laboratory must ensure that request forms sent to referral laboratories comply with Clause 5.4.3, which details the information to be provided.

4.6 External services and supplies

Preference for accredited suppliers is strongly encouraged.

4.7 Advisory services

A laboratory handbook or electronic equivalent, developed in conjunction with appropriate pathologists or appropriate specialists, may be seen as a convenient adjunct for providing guidance to clinicians on the choice

and interpretation of tests. This does not negate the need to provide direct access for clinicians to specialist advice, as needed.

Pathologist involvement in Multidisciplinary Meetings (MDMs) constitutes advisory service.

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

No explanatory commentary.

4.9 Identification and control of nonconformities

For Histology laboratories, compliance with the Histology Incidents - Identification, Management, Reporting and Monitoring as detailed in the Supplementary Criteria for Accreditation is expected.

4.10 Corrective action

No explanatory commentary.

4.11 Preventive action

No explanatory commentary.

4.12 Continual improvement

No explanatory commentary.

4.13 Control of records

The laboratory must retain records of original observations, derived data and sufficient information to establish an audit trail for all examination results reported.

When mistakes occur on records, they must not be erased or made illegible by such means as correction fluid, but crossed out and the correct value/data or information entered alongside. In the case of electronic records, equivalent measures must be taken to avoid loss or change of original data and achieve annotation of the record to meet this expectation.

Patient details on worksheets and associated records must be uniquely identifiable at all stages of testing by the use of at least two identifiers. Labelling must be such that it is traceable to the original laboratory episode number.

In defining the minimum retention periods for records the laboratory is expected to meet the requirements of the relevant District Health Board (DHB) General Disposal Authority (GDA) documents, National Pathology Accreditation Advisory Council (NPAAC) Requirements for Retention of Laboratory Records and Diagnostic Material and any National Screening Unit (NSU) contractual arrangement as a minimum. When hard copy records are scanned and stored electronically the retention periods apply to the electronic versions.

4.14 Evaluation and audits

4.14.1 General

Registration accuracy/data entry audits must be conducted as per a defined schedule and take into account different shifts and a range of staff.

IANZ will consider a reasonable, practical and evidence-based approach to the mechanisms utilised to monitor data provided within electronic referrals. For all manual entries for disciplines that are not subject to repeat review during the course of testing, IANZ will continue to expect a minimum 10% audit, with the expectation that this percentage increases with identified errors, new staff members or very low volumes. IANZ will review

data registration audit completion relative to quality management system (QMS) established discipline-specific procedures and key indicators.

The audit process is generally active and is linked with quality activities targeted with areas of risk.

To ensure the effectiveness of the QMS is maintained after a significant change in the Laboratory Information System (LIS), work practices, or personnel, targeted audits must be completed as soon as is practical.

Vertical and/or horizontal audits to cover the range of examinations and technologies are also expected to be included as part of a regular audit programme.

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

No explanatory commentary.

4.14.3 Assessment of user feedback

Obtaining feedback from patients and clinicians/referrers must utilise an appropriate mechanism commensurate with the services provided.

Users of laboratory services must have ready access to a means of providing feedback to the laboratory.

4.14.4 Staff suggestions

No explanatory commentary.

4.14.5 Internal audit

Internal audits covering relevant management and technical standards for each laboratory discipline, and including specific audits for each collection site, POCT locality or premises, where relevant, should be conducted at least annually. Determination of the frequency and focus of the internal audit cycle should take into account risk assessment of specific areas of laboratory function and historical performance.

Use of discipline-specific checklists or similar is expected to ensure complete coverage of the important aspects of an audit

4.14.6 Risk management

No explanatory commentary.

4.14.7 Quality indicators

No explanatory commentary.

4.14.8 Reviews by external organizations

No explanatory commentary.

4.15 Management review

4.15.1 General

All aspects of management review input are expected to be reviewed within a one year period in order to assure continuing suitability, adequacy, effectiveness and support of patient care.

It is important that management can demonstrate collation of all relevant information to support strategic review of the entire laboratory.

4.15.2 Review input

No explanatory commentary.

4.15.3 Review activities

No explanatory commentary.

4.15.4 Review output

No explanatory commentary.

5 Technical Requirements

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

5.1 Personnel

5.1.1 General

Key personnel: General

The following principles apply:

- During all working hours an accredited laboratory must have at least one staff member who is competent to perform the testing work being done.
- Each accredited laboratory must designate key scientific/technical and key clinical personnel, with appropriate qualifications and supervisory experience, who will be formally responsible for supervision of its accredited testing repertoire. In larger laboratories responsibilities may be delegated to other supervisory staff members 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.
- After hours supervision may be provided by remote consultation.
- Trainees will require direct supervision at all times as per the Medical Sciences Council of New Zealand (MSCNZ) policy.

Key Personnel: Clinical

Each testing discipline must receive professional direction and control, under the auspices of the laboratory directorship, by an appropriately trained pathologist or clinical scientist who is competent to interpret all of the tests that are completed by the discipline. The following principles apply:

- Competence must be demonstrated by evidence of training and experience in a pathology specialty. This requires membership of the Royal Collage of Pathologists of Australasia (RCPA) or an equivalent body and
- Evidence must be provided that pathologists satisfy the registration requirements of the MSCNZ in order to practice as such.
- Where a laboratory is providing a limited range of specialised tests it may be appropriate for the professional direction to be provided by either an appropriately trained, qualified and experienced consultant from a specialty other than pathology or a specialist clinical scientist of equivalent status. This must be clearly documented and have clinical approval.

The appropriate level of clinical input to any laboratory will be determined by its scope of testing and the expertise of the on-site scientific/technical staff members. Peer review teams may be requested to assist in determining the appropriate amount of pathologist input for a particular laboratory.

Pathologist/Clinical Scientist Input/Oversight

The requirement for Pathologist (or equivalent) oversight of laboratories must be interpreted using the following guidelines:

a) Major hospital and community laboratories within each region must ideally employ single discipline pathologist(s) or equivalent, 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.

b) Laboratories with a resident pathologist(s), who is unable to cover all disciplines, must invite appropriately qualified and experienced pathologist(s)/equivalent to oversee and provide direction and control for those disciplines not adequately covered.

c) Laboratories with no resident pathologist must be overseen by either appropriately trained or experienced general pathologist(s), or relevant single discipline pathologists or equivalent, which includes mandatory onsite visits with records retained accordingly

d) Transfusion Medicine laboratories are all subject to the national clinical oversight programme provided by New Zealand Blood Service (NZBS). Services do not need to incorporate additional onsite clinical visits pertaining to Transfusion Medicine.

e) For some laboratories that are accredited in disciplines with limited or restricted scope of testing overseen by a parent laboratory, frequency of formal clinical visits may be reviewed in consultation with IANZ assessment teams to determine relevance.

f) The directorship of those laboratories without appropriate onsite 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 and document contractual arrangements accordingly. The laboratory directorship must be responsible for ensuring that guidance and advice provision by visiting clinical and non-clinical specialists is implemented.

g) General Pathologist oversight for such as regional laboratories must take account of recency and scope of practice.

h) Any deviation from stated requirements will be subject to review by the IANZ Medical Testing Professional Advisory Committee (MTPAC).

Clinical Oversight Visits

The number of days deemed to be appropriate will depend on the scope and extent of the laboratory's operations.

For regional laboratories, where a common LIS and QMS are in use, it is understood that a proportion of clinical oversight can be provided remotely. Clinical visits still need to cover changes within the laboratory, provision of education and liaison/interaction with staff and clinicians.

Notwithstanding the above, the acceptability of arrangements for on-site clinical input for medical testing laboratories has been determined by MTPAC as a minimum of quarterly visits to each relevant discipline. Evidence must be provided that all elements of service provision per discipline have been covered within an appropriate timeframe. Visits must be undertaken by pathologists or equivalent in each medical testing discipline for which the laboratory holds accreditation.

A laboratory may substitute a maximum of two of the scheduled onsite visits by a pathologist or equivalent in each relevant discipline, with either:

(a) A visit by a senior scientific/technical staff member from a larger regional/parent laboratory. These non-clinical specialists must report directly to pathologists with the training and experience to provide clinical guidance, as necessary.

(b) A visit by a senior member of the laboratory's own scientific/technical staff member to a larger regional/parent laboratory.

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 all quality assurance (QA) programmes and related issues, with evidence of communication to staff of any actions or issues arising.

(b) Review and revision of the testing methods of the laboratory including the biological reference intervals applied to results reported.

(c) Ensuring appropriate consultation with referring clinicians.

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

(e) Input on management issues, where appropriate, including laboratory staffing, equipment acquisition, laboratory accommodation and the selection of reference laboratories.

Key Personnel: Scientific/Technical

Supervisory scientific/technical staff in accredited laboratories must be competent and have the necessary scientific/technical expertise and experience and must be able to oversee the scientific/technical operations. The following principles apply:

- Key scientific/technical persons are expected, where possible, to have registration with the MSCNZ as a Medical Laboratory Scientist (MLS), Medical Laboratory Technician (MLT), or Medical Laboratory Pre-analytical Technician (MLPAT).
- All key staff must have a working knowledge of the quality assurance and technical systems in operation in the laboratory on a day to day basis.
- Visits by senior phlebotomy and POCT personnel to outlying specimen collection centres and POCT sites must occur to ensure effectiveness of work practices and techniques and compliance with procedures.

5.1.2 Personnel qualifications

No explanatory commentary.

5.1.3 Job descriptions

No explanatory commentary.

5.1.4 Personnel introduction to the organisational environment

No explanatory commentary.

5.1.5 Training

Staff member's predominantly working out-of-hours must have regular contact with routine hours and supervisory personnel. As a pragmatic guide, the equivalent of two full days per annum is considered a minimum for time spent working with routine hours and supervisory staff to ensure review and refresher activities are covered.

Where out of hour's staff members are expected to work in areas/disciplines other than those in which they are primarily trained, a programme of regular refresher training for key aspects of testing must be established and records retained.

Staff members who undertake scientific/technical duties intermittently or on a casual basis are expected to undergo retraining and reassessment sufficient to ensure demonstration of competency.

The requirement of MSCNZ with regards to supervision and direction of technicians and unqualified staff members must be met.

Compliance with all regulatory or national standards is required.

There must be an established training programme for registrars or clinical personnel with the appropriate qualifying body such as RCPA or equivalent.

Under the Health and Safety at Work Regulations 2016, an appropriate number of staff must be trained in first aid, especially when the laboratory is outside a medical/hospital environment.

5.1.6 Competence assessment

The expectation is that competency reassessment of all technical/scientific staff, including those working in multiple disciplines, will be completed at least annually by suitably qualified personnel.

Where the staff member is the senior person in the discipline/section, competency must be attested by an appropriately qualified colleague competent in the area of work and/or additionally endorsed by an appropriate supervising pathologist or manager.

Records of training and competency evaluations must be endorsed by both the evaluator and the evaluatee.

5.1.7 Reviews of staff performance

The frequency of staff performance reviews must be defined and documented.

5.1.8 Continuing education and professional development

All scientists and technicians must fulfil the requirements of a continuing professional development programme recognised by the MSCNZ.

Pathologists and other specialist consultants must participate in Continuing Medical Education (CME) programmes relevant to their scope of practice. Evidence of CME will be assessed, such as active participation in training courses, workshops, conferences, clinical meetings, journal clubs and quality assurance programmes.

5.1.9 Personnel records

No explanatory commentary.

5.2 Accommodation and environmental conditions

5.2.1 General

For any new laboratory or modification to an existing laboratory, including collection sites, the provisions of AS/NZS 2982 *Laboratory design and construction* must be taken into account.

It is noted that there is a legal requirement for workplaces to take all practicable steps to provide first aid facilities under the Health and Safety at Work Regulations 2016.This also applies to patient sample collection facilities.

5.2.2 Laboratory and office facilities

The Health and Safety at Work Regulations 2016 place specific legal obligations on all employers. Whilst IANZ assessments are not health and safety assessments, various aspects impacting ISO 15189 compliance will be reviewed and attention drawn to any unsafe practices identified.

Generic organisational health and safety information may not always encompass specific aspects relevant to laboratory operations. A safety manual or similar detailing the laboratory's policies and procedures in relation to health and safety must be readily available to staff members. National and international guidelines, such as ISO 15190 and AS/NZS 2243 *Safety in laboratories*, must be consulted when laboratory safety procedures are being prepared and implemented, as conformity with the requirements of these standards is expected.

5.2.3 Storage facilities

No explanatory commentary.

5.2.4 Staff facilities

No explanatory commentary.

5.2.5 Patient sample collection facilities

No explanatory commentary.

5.2.6 Facility maintenance and environmental conditions

Clinical laboratories in general must meet PC1 and 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.

Air quality checks, such as for formaldehyde and xylene levels, should be performed at regular intervals in affected work areas, such as Histology, Mortuary and other facilities, to meet compliance with Workplace Exposure Standards (WES) and other legislative requirements.

5.3 Laboratory equipment, reagents, and consumables

5.3.1 Equipment

No explanatory commentary.

5.3.1.1 General

Where a laboratory utilises any unit of equipment outside their accredited facility, it is the responsibility of the laboratory to ensure that all aspects of operation of the equipment meets accreditation requirements. Should this not be achieved, the non-accredited status of the testing must be indicated on reports.

5.3.1.2 Equipment acceptance testing

No explanatory commentary.

5.3.1.3 Equipment instructions for use

No explanatory commentary.

5.3.1.4 Equipment calibration and metrological traceability

The IANZ policy on measurement (metrological) traceability is set out in the IANZ Technical Policy No.1: *Traceability of Measurement*, and will be applied as appropriate to applicant and accredited medical testing laboratories.

Requirements relating to equipment calibration and checks are detailed in Appendix 2 and set out maximum periods of use before equipment must be re-calibrated or checked. For equipment not listed specifically, reference must be made to manufacturer's specifications. Conditions may arise whereby more frequent checks or calibrations are required due to specific conditions and this must override manufacturers' general recommendations.

If a unit of equipment provides critical results, measurement uncertainty must be performed in conjunction with calibrations. Laboratories are recommended to have such items calibrated by an accredited external agency in conformance with ISO 15195.

5.3.1.5 Equipment maintenance and repair

Any critical items of equipment necessary for testing must be under preventive maintenance contracts with the suppliers or their agents.

5.3.1.6 Equipment adverse incident reporting

No explanatory commentary.

5.3.1.7 Equipment records

No explanatory commentary.

5.3.2 Reagents and consumables

No explanatory commentary.

5.3.2.1 General

No explanatory commentary.

5.3.2.2 Reagents and consumables — Reception and storage

No explanatory commentary.

5.3.2.3 Reagents and consumables — Acceptance testing

All materials that can affect the quality of examinations shall be verified for performance before use.

Suppliers of reagents and / or consumables should provide evidence of:

- Appropriate industry recognised (e.g. CE, FDA etc.) accreditation.
- Verification for the reagent &/or consumable – if appropriate.
- Proven logistical supply chain.
- Proven history of good performance.

If the above are satisfied, then the following apply:

- If the material is not temperature sensitive and no changes are evident upon delivery, then the original verification is accepted.
- If the material is temperature sensitive, and there is evidence of monitored controlled temperature during transport, then the original verification is accepted.
- If the material is not compliant to the above statements, then the material must be quarantined until all appropriate pre-acceptance testing has been performed, with acceptable results.
- The material must be subject to usual internal quality assurance procedures.
- The expectation is that if material is retained for longer than 6 months then re-verification of the material occurs to ensure ongoing acceptable performance is verified with consideration given to manufacturers' recommendations.

For shipments between parent and satellite laboratories repetition of acceptance testing may not be necessary, however effective transport monitoring must be in place. This does not negate the expected local internal quality procedures, where applicable, to ensure performance.

Where in-house reagents or QC material are utilised, these must be sufficiently validated for use to maintain the quality and suitability for purpose, with documentation retained.

5.3.2.4 Reagents and consumables — Inventory management

A reagent/consumable expiry policy must be developed regarding use of reagent or consumables that have passed the manufacturer expiry date.

5.3.2.5 Reagents and consumables — Instructions for use

No explanatory commentary.

5.3.2.6 Reagents and consumables — Adverse incident reporting

No explanatory commentary.

5.3.2.7 Reagents and consumables — Records

No explanatory commentary.

5.4 Pre-examination processes

5.4.1 General

No explanatory commentary.

5.4.2 Information for patients and users

No explanatory commentary.

5.4.3 Request form information

It is expected that users are consulted prior to any significant changes to the format of request forms.

If electronic requesting is utilised, it is essential that an alternative system is readily available, in the event that the electronic systems are not operational.

The laboratory must ensure pertinent clinical data is provided on requests forms. All efforts shall be made to obtain the information needed for correct interpretation of results before reports are released.

There shall be a documented process for self-referrals including any ethical considerations for management of significant or abnormal results.

In addition there shall be a policy taking into account ethical considerations when receiving requests from alternative practitioners.

5.4.4 Primary sample collection and handling

No explanatory commentary.

5.4.4.1 General

No explanatory commentary.

5.4.4.2 Instructions for pre-collection activities

No explanatory commentary.

5.4.4.3 Instructions for collection activities

There must be a documented protocol indicating how the patient is to be identified at the point of collection, presenting with or without a request form.

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 National Health Institute (NHI) number or other unique identifier.

When specimens for POCT are collected one patient at a time and the specimen is retained by the collector throughout all stages, full labelling requirements may not apply.

In special circumstances where the identity of the patient is not to be revealed, such as HIV examinations, a coding system must be agreed between requesting clinicians and the laboratory, which may be only one identifier but must be uniquely traceable to the patient.

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

5.4.5 Sample transportation

To verify all transportation requirements, periodic temperature checks to at least cover seasonal variation are expected.

5.4.6 Sample reception

Where there are several different identifiers for the one patient (e.g. baby of . . . , unknown patients, change of maiden to married name, multiple medical record numbers), there must be a policy relating to the merging or linkage of the data.

Where samples are pre-registered prior to arriving at the laboratory, such as in collection sites, then the time of receipt at the laboratory needs to be recorded. If specimens arrive together with the request form and are registered within a short period of time, the time of registration may be used to represent the time of receipt. Where a number of specimens arrive together, such as in large laboratories, these may be receipted as a group. The turnaround time and integrity of specimens for testing must be taken into account.

There must be a process and relevant documentation to manage any work referred to a referral laboratory.

There must be a system to ensure specimens referred have been received by the referral laboratory, with some mechanism of notification by the referral laboratory.

The laboratory registration records must include:

(a) patient identifiers

(b) sex

(c) date and time of collection (where supplied)

(d) date and time of receipt in the laboratory

(e) type of specimen (e.g. urine, joint aspirate) and anatomical site of tissue specimens where relevant

(f) person collecting (where relevant)

(g) clinical status of patient (e.g. fasting), where required

(h) specimen characteristics which may provide information relevant to interpretation of results

(i) informed consent where required

(j) the name of the requester.

5.4.7 Pre-examination handling, preparation and storage

No explanatory commentary.

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

No explanatory commentary.

5.5.1.1 General

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.

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

Validation and verifications must be completed according to internationally recognised guidelines, relevant to the particular discipline. In particular the extent of validation/verification must be commensurate with the risks associated with the patient or to public health in general. (See Appendix 3)

All validation/verification reports must be formally approved and accepted by authorised personnel (technical and clinical) prior to use.

Validation of examinations may be acceptable for use within laboratory networks/groups. However, appropriate local verification must apply.

5.5.1.2 Verification of examination procedures

No explanatory commentary.

5.5.1.3 Validation of examination procedures

Validation is required if the laboratory is unable to source the validation data from manufacturers with a recognised quality assurance system or a reputable validation based on collaborative testing.

Once a laboratory is accredited for a specific test method, the detailed procedures of that method must be adhered to at all times. Occasionally it may be necessary to deviate from the documented test method. Any departures must be reported with the test results and may invalidate accreditation status of that particular test.

5.5.1.4 Measurement uncertainty of measured quantity values

Measurement uncertainty arises from analytical error, test method interferences, the inherent limitations of methodology used and extra-laboratory contributions. Sources that primarily contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample, and changes of operator.

The frequency with which measurement uncertainty is reviewed and updated shall be determined by changes such as staffing, equipment, reagents and methodology.

5.5.2 Biological reference intervals or clinical decision values

No explanatory commentary.

5.5.3 Documentation of examination procedures

No explanatory commentary.

5.6 Ensuring quality of examination results

5.6.1 General

No explanatory commentary.

5.6.2 Quality control

No explanatory commentary.

5.6.2.1 General

No explanatory commentary.

5.6.2.2 Quality control materials

The Ministry of Health (MOH) has interpreted the Human Tissues Act as allowing for the use of human tissue samples as QC material without patient consent.

Animal control tissue may be used for QC when the use of human tissue is not possible.

5.6.2.3 Quality control data

No explanatory commentary.

5.6.3 Interlaboratory comparisons

No explanatory commentary.

5.6.3.1 Participation

The IANZ policy on participation in proficiency testing (EQA) activities is set out in IANZ Technical Policy No.2: *Participation in Proficiency Testing Activities*, and will be applied as appropriate to applicant and accredited medical testing laboratories.

The primary purpose of EQA programmes is to provide information on aspects of uncertainty associated with patient samples, including the competency of staff members carrying out testing work. A secondary purpose of EQA testing is to provide a challenge to staff members for purposes of ongoing training. Consequently, slides and samples may be examined, tested and discussed for educational purposes.

The following principles apply:

- It is an IANZ expectation that all staff members who are directly involved in testing patient samples shall participate in the testing of EQA samples to assure competency.
- Records of individual participation must be maintained.

- Where there is the same POCT instrument in more than one site it is acceptable to have one reference instrument enrolled in an EQA or inter laboratory programme, with regular sample comparisons between the other instruments.
- It is an IANZ expectation that the frequency of individual participation is once a year at a minimum.
- Where there are relatively few participants and a large number of specific target analytes e.g. genetic testing, the laboratory should consider participation in an EQA programme for the underlying technique or method.
- Review of EQA records is expected to be conducted with scientists and relevant pathologists, where applicable.

5.6.3.2 Alternative approaches

No explanatory commentary

5.6.3.3 Analysis of interlaboratory comparison samples

No explanatory commentary

5.6.3.4 Evaluation of laboratory performance

No explanatory commentary

5.6.4 Comparability of examination results

The IANZ policy on measurement (metrological) traceability is set out in the IANZ Technical Policy No.1: *Traceability of Measurement*, and will be applied as appropriate to applicant and accredited medical testing laboratories.

5.7 Post-examination processes

5.7.1 Review of results

No explanatory commentary.

5.7.2 Storage, retention and disposal of clinical samples

In defining the minimum retention periods for specimens and sub-samples, the laboratory must conform to relevant standards including the NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material, Australia and New Zealand Society of Blood Transfusion (NZSBT) Pre-transfusion requirements and any NSU contractual requirements.

New Zealand legislation requires that retention of any post mortem sample larger than a “minute” sample (i.e. less than 1.75cm^3) must be recorded on the PPM form and must be declared to the duty Coroner.

Samples, without prior consent, or residual samples may be used for research studies or as QC or EQA material provided the patient’s details are rendered anonymous. It is understood that on occasions use of clinical details may be warranted to determine any discrepancies and care shall be taken to meet privacy requirements.

IANZ has been endorsed by the IANZ MTPAC, National Laboratory and Pathology Roundtable and the MOH as being a Recognized External Professional Quality Assurance programme for the purposes of the Human Tissue Act 2008, and that activities performed to fulfil and maintain IANZ accreditation using the ISO 15189 standard reasonably come within the intent of the Act and relevant legislation.

Use of Residual Samples:

- In-house validation/verification – as long as the samples are de-identified and for purposes of QA, this is acceptable with no consent required as IANZ is recognised as a professional QA programme.
- Bacterial cultures – de-identified residual cultures can be used with no consent, but no more can be grown from patient samples.

- Haematology cell markers – can be used with no consent if de-identified for QA purposes.
- Genetics – patient consent required for ALL purposes where DNA/patient identification is possible.

Appropriate consideration must be given to the various cultural contexts experienced in New Zealand. Policies and procedures regarding culturally appropriate methods of retention, handling and disposal of human tissue must be in accordance with local regulations and organisational waste management policy.

5.8 Reporting of results

5.8.1 General

Rules for the endorsement of reports are detailed in AS 1 *Procedures and Conditions for Accreditation*.

ISO 15189 covers medical diagnostic testing results only – NOT environmental sampling. Disclaimers (in some form) excluding sampling processes must be included within environmental testing reports. Additionally, there must be clarification that the report represents presence of substances only, and does not determine conformance with regulatory (or other) requirements, or associated risk level. Please refer to Appendix 4 for specific requirements to environmental testing/screening.

5.8.2 Report attributes

Caution shall 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.

5.8.3 Report content

If the report for any test includes an interpretive comment which has a diagnostic impact that can affect patient outcome/treatment then the expectation is that identification (function/designation) of the individual making the interpretive comment is included within the report.

Reports must follow the vocabulary, syntax, structure and nomenclature recommended by recognised bodies.

5.9 Release of results

5.9.1 General

It is an IANZ expectation that all manual transcription checks must be performed using a mechanism that ensures independent review.

When an interim report is released because a staff member is working alone, retrospective transcription checks must be performed as soon as possible.

The status of any interim report, whether in hard copy or electronic format, must be clearly indicated to the requester. Any interim reports awaiting referred work must clearly state the aspects of the examination that have been referred.

5.9.2 Automated selection and reporting of results

No explanatory commentary.

5.9.3 Revised reports

Where the revised results, such as those presented in amendments or addendums, may alter patient management, the laboratory must ensure and document that persons with the authority to take action are contacted and duly informed.

There must be clear differentiation within reports between amendments to incorrect detail and addition of supplementary information.

5.10 Laboratory information management

5.10.1 General

Where tele-pathology/digital pathology are utilised, adequate systems must be developed to support review of request forms and laboratory results and reporting. Systems must provide ready access and appropriate security protocols must be adopted.

5.10.2 Authorities and responsibilities

No explanatory commentary.

5.10.3 Information system management

Interfacing of key items of equipment should be considered where possible in order to provide continuous systems/data back-up, and ready access to data and to eliminate the necessity of manual transcriptions.

The Laboratory must have a business continuity plan which includes procedures for regular backup of electronic data, systems recovery, application recovery, and data recovery or restoration and procedures for assessing the extent of damage or data loss in the event of a disaster and include alternative procedures to enable continued operation, receipt of requests, and delivery of reports.

To ensure the secure and confidential transmission of electronic pathology reports, the laboratory must:

- Ensure the completeness, accuracy and integrity of electronic messages (i.e. certainty that the message has not been altered during transmission)
- Ensure the pathology laboratory message can be authenticated by the recipient.
- Ensure messages must be appropriately encrypted to protect the confidentiality of data and prevent unauthorised access during transmission
- Implement a system to deal with delayed/failed messages or reports.

Calculation worksheets and algorithms defined for auto-reporting and auto-commenting must be periodically reviewed to ensure they are still functional, and relevant, especially after any changes.

Appendix 1: Bibliography

These standards are requirements for accreditation and will be assessed during assessments. An updated list of reference documents are available on the IANZ website.

1 Primary Criteria

1. AS 1, *Procedures and Conditions for Accreditation*
2. AS TP 1, IANZ Technical Policy No.1: *Traceability of Measurement*
3. AS TP 2, IANZ Technical Policy No.2: *Participation in Proficiency Testing Activities*
4. ISO 15189:2012 *Medical laboratories – Requirements for quality and competence*

2 Specific Criteria

1. American Society for Histocompatibility and Immunogenetics Standards for Accredited Laboratories
2. ANZSBT *Guidelines for the Administration of Blood Products*
3. ANZSBT *Guidelines for Laboratory Assessment of Feto-maternal Haemorrhage*
4. ANZSBT *Guidelines for Transfusion and Immunohaematology Laboratory Practice*
5. ASCIA: *Skin prick testing for the diagnosis of allergic disease. A manual for practitioners.*
6. ASM: *Guidelines for Assuring Quality of Medical Microbiological Culture Media*
7. AS 3864.2 *Medical refrigeration equipment* - For the storage of blood and blood products. User-related requirements for care, maintenance, performance verification and calibration
8. AS/NZS 4308 *Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine*
9. AS/NZS 4760 *Procedure for specimen collection and the detection and quantification of drugs in oral fluid*
10. AS/NZS 2982 *Laboratory design and construction*
11. AS/NZS 2243 *Safety in Laboratories*
    - (i) AS/NZS 2243.1 *Safety in laboratories - Planning and operational aspects*
    - (ii) AS/NZS 2243.2 *Safety in laboratories - Chemical aspects*
    - (iii) AS/NZS 2243.3 *Safety in laboratories - Microbiological safety and containment*
    - *(iv)* AS/NZS 2243.5 *Safety in laboratories - Non-ionizing radiations - Electromagnetic, sound and ultrasound*
    - (v) AS/NZS 2243.6 *Safety in laboratories - Plant and equipment aspects*
    - (vi) AS/NZS 2243.8 *Safety in laboratories - Fume cupboards*
    - (vii) AS/NZS 2243.9 *Safety in laboratories - Recirculating fume cabinets*
    - (viii) AS/NZS 2243.10 *Safety in laboratories - Storage of chemicals*
12. CLSI: GP 41 *Collection of Diagnostic Venous Blood Specimens*
13. CLSI: M100 *Performance Standards for Antimicrobial Susceptibility Testing*
14. EUCAST: *Antimicrobial Susceptibility Testing*
15. IDSA/ASM: *A Guide to Utilisation of Microbiology Laboratory for Diagnosis of Infectious Diseases*
16. ISO 15190 *Medical Laboratories – Requirements for safety*
17. ISO 22870 *Point-of-care testing – Requirements for quality and competence*

18. ISO 15195 *Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures*
19. Occupational Safety and Health Information Series: *Managing Health and Safety Risks in New Zealand*
20. Mortuaries, Guidelines to promote safe working conditions
21. NCSP: Policies and Standards Section 5 *Providing a laboratory service*
22. NCSP: *Guidance on HPV Testing Update*
23. NZBS Refrigeration Guidelines: *Requirements for the storage of blood, blood products and tissue for DHB blood banks*
24. NPAAC *Guidelines for the Performance of Anatomical Pathology Cut-Up*
25. NPAAC *Requirements for Retention of Laboratory Records and Diagnostic Material*
26. NPAAC *Requirements for the Facilities and Operation of Mortuaries*
27. NPAAC *Requirements for Medical Testing of Microbial Nucleic Acids*
28. NPAAC *Requirements for Human Nucleic Acids*
29. NPAAC *Requirements for Human Genome Testing Utilising Massively Parallel Sequencing Technologies*
30. NPAAC *Requirements for Cytogenetic Testing*
31. NPAAC *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials*
32. NZ-NAC Minimum laboratory requirements for the detection of carbapenemase-producing Enterobacteriaceae from clinical samples and screening specimens
33. NZ Point-of-Care Testing Advisory Group: *New Zealand best practice guidelines for point-of-care testing*
34. NZS 8181 *Fertility Services*
35. WHO Ethical Practice in Laboratory Medicine and Forensic Pathology, Annex 5, *Code of Conduct for Forensic Mortuary Personnel*
36. WHO *Laboratory manual for the examination and processing of human semen*

3 Supplementary Criteria

1. AS LAB C7.1 Mortuary Specifications – Classifications for Mortuary Facilities
2. AS LAB C7.2 Histology - Minimising Errors

Appendix 2: Equipment Calibration Intervals

The following table sets out the intervals for checks and/or calibrations for a number of reference standards and measuring instruments. Each period is considered to be the maximum (established by accepted industry practice and international convention) appropriate in each case providing the criteria specified below are met:

(a) The equipment performance demonstrates stability, and is appropriately used and housed.

(b) The laboratory has both the equipment capability and staffing expertise to perform required internal checks.

(c) If any evidence of poor performance or relocation arises, the equipment is checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.

(*) in the table denote those items of equipment which may be calibrated/checked by laboratory staff members if the laboratory is suitably equipped and the staff members are competent to perform such recalibrations. Staff members must be formally trained when performing calibrations/checks which would normally be performed by an accredited calibration laboratory/facility using appropriately calibrated equipment following a fully documented procedure. Full records of measurements must be maintained. Critical and Non-critical equipment must be adequately labelled as such.

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

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Agitator / rotator (Critical; such as platelet agitator placed in a within room or platelet incubator)		Continuous* or each use* 3 yearly* 6*	Continuous temperature monitoring Rotation rate or agitation frequency Alarm Check (AS 3864)
Alarm		1*	Check power failure test and alarm activation for critical items of equipment, including any external monitoring system (accepted industry practice).
Autoclaves/Sterilisers			
Autoclaves	Following repair or maintenance*		Check heating profiles of typical loads with respect to chamber temperatures to determine lag times (AS/NZS 4187).
		Each use*	Check of time and temperature of the cycle. Check condition by appropriate means such as a chemical or biological indicator (AS/NZS 4187).
Hot Air Sterilising Ovens		Each use*	Check of time and temperature (AS/NZS 4187).
Air quality monitoring devices		12*	Accuracy checks (OSH Guidelines).

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Area monitors		12*	1 year calibration checks (IAEA/IRCP – Area Monitoring)
Automatic burettes and dispensers		12*	Accuracy and repeatability at the volumes of use (MSL Guide 17).
Balances and weighing devices such as scales used for weighing absolute quantities (critical);	1		By an accredited calibration laboratory using traceable certified masses (MSL Technical Guide 25).
Alternative	3		By an accredited calibration laboratory
		12	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. If reduced performance is observed then a full calibration will be expected at least annually (MSL Technical Guide 25)
		6*	Repeatability checks. (MSL Technical Guide 12 and IANZ Technical Guide AS TG2)
		1*	One point check, using a known calibrated mass close to balance capacity or working range of use. (MSL Technical Guide 12 and IANZ Technical Guide AS TG2)
Balances and weighing devices such as scales (non-critical) such as weighing bulk substances		12*	Repeatability checks. (MSL Technical Guide 12 and IANZ Technical Guide AS TG2)
		1*	One point check, using a known mass close to balance capacity or working range of use.
Biological safety cabinets		12	Conformance checks by accredited personnel. Documented procedures need to be in place for ongoing monitoring. (AS/NZS 2647/AS2252)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Centrifuges		12*	Check of the operating speed/force, where specified, by a calibrated tachometer (mechanical stroboscope or light cell type). When the time and temperature of centrifugation are specified, check of the calibration of the timing device and temperature measurement device (accepted industry practice).
Conductivity/Resistivity meters on water boards		12*	Check at least critical/working range of meter using an independently calibrated meter or similar process (accepted industry practice).
Controlled environment incubators (such CO_2 and anaerobic)		Daily or each use*	Check condition by appropriate means (accepted industry practice).
	6 monthly*		Check of continuous CO_2 monitor by a calibrated meter or similar process (accepted industry practice).
Electrical Safety Checks		5 yearly* 12*	Checks of items of equipment deemed less-critical to diagnostic laboratory testing. For items of equipment where checks are not required, these shall be adequately labelled. Checks of items of equipment deemed critical to diagnostic laboratory testing and for equipment located in high risk areas (AS/NZS 3760)
Fume cupboards		12	Conformance checks by accredited personnel. Documented procedures need to be in place for ongoing monitoring. (Depending on cabinet type either AS/NZS 2243.8 or AS/NZS 2243.9).
Gamma Counters		6*	Background reading, repeatability and accuracy using standard counts (IAEA-Gamma Counters)
Hot plates for use at specified temperatures		3 yearly*	Temperature variation across the plate using a calibrated thermometer (AS 2853)
Masses			
Reference masses of integral construction stainless steel or nickel-chromium alloy	Initially then 5		By an accredited calibration laboratory (MSL Technical Guide 7)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Working masses made of stainless steel or nickel-chromium alloy	Initially then 3		Initial calibration may be withheld if acceptable evidence of calibration from an accredited facility. Checks using reference masses or compared against a reference value during a balance calibration (MSL Technical Guide 7)
Working masses made of other materials		12*	Checks using reference masses or compared against a reference value during a balance calibration (MSL Technical Guide 7)
Microscopes used for diagnostic purposes		12*	Appropriate checks/servicing to maintain optical quality (accepted industry practice)
pH meters	Daily or each use*		Calibrate using at least two appropriate standard buffers (accepted industry practice)
Pipettes – piston operated (manual, automated or electronic) – non-critical	1*		Where it can be demonstrated that the unit is stored and operated in a suitable environment and has a stable history of performance. • Accuracy and repeatability at the volumes of use or at least the minimum and maximum displacements • For multichannel pipettes all channels must be checked individually. • Check to ensure correct function use such as tip holders examined for marks of distortion/leakage and piston action. • Must be labelled accordingly. If reduced performance then a calibration will be expected at least at least monthly. (MSL Technical Guide 30)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Pipettes – piston operated (manual, automated or electronic) Pipettes used in circumstances that could add significantly to the uncertainty of test results or for critical measurements.	6*		Where it can be demonstrated that the unit is stored and operated in a suitable environment and has a stable history of performance. If reduced performance then a check of calibration will be expected at least monthly. • Inaccuracy and repeatability at the volumes of use or at least the minimum, and maximum displacements • For multichannel pipettes all channels must be checked individually. • Check to ensure correct function use such as tip holders examined for marks of distortion/leakage and piston action. • Must be labelled accordingly. (MSL Technical Guide 30)
Plate readers		12*	Background reading, wavelength and/or absorbance accuracy (linearity and precision) using a standard absorbance plate or appropriate calibration kit (accepted industry practice)
Spectrophotometers		12*	Relevant checks such as wavelength and/or absorbance accuracy, stray light error, band-pass, linearity of response, repeatability and matching of cells. MSL Technical Guide 38
		Daily or each use*	A blank and at least 2 points on the calibration curve must be checked. MSL Technical Guide 38
Spectrophotometer filters			
Wavelength and Transmittance/Absorbance	Initial then 3 yearly		By an accredited calibration laboratory (accepted industry practice)
		12*	Checks for damage (accepted industry practice)
Tachometers	Initial then 5 yearly		By an accredited calibration laboratory (MSL recommendation)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Thawers (e.g. plasma thawers for blood transfusion)		Daily or each use*	Check of temperature (AS 3864)
Thermometers			
Liquid in glass – reference	5		By an accredited calibration laboratory followed by an ice point check on receipt. (See MSL Technical Guide TG1 / IANZ Technical Guide 3 AS TG3)
		6*	Where it can be demonstrated that the unit is used in a suitable environment and has a stable history of performance. If reduced performance then a check will be expected at least monthly. Checks at working temperatures. An ice-point is also preferred. (MSL Technical Guide TG1/ IANZ Technical Guide 3 AS TG3)
Liquid in glass – working		12*	Where it can be demonstrated that the unit is used in a suitable environment and has a stable history of performance. If reduced performance then a check will be expected at least monthly. Check against a reference thermometer across working range or at points of use and/or ice point. A minimum 2 point check is also preferred. (MSL Technical Guide TG1/ IANZ Technical Guide 3 AS TG3)
Resistance – reference (Platinum resistance or thermistors)	5		By an accredited calibration laboratory, followed by an ice point check on receipt. (MSL Technical Guide TG1/ IANZ Technical Guide 3 AS TG3)
		6*	Checks at stated intervals. A minimum 2 point check is also preferred. (MSL Technical Guide TG1 / IANZ Technical Guide 3 AS TG3)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Resistance – working		12*	Where it can be demonstrated that the unit is used in a suitable environment and has a stable history of performance. If reduced performance then a check will be expected at least monthly. Check against a reference thermometer across working range or at points of use and/or ice point. A minimum 2 point check is also preferred. (MSL Technical Guide TG1/ IANZ Technical Guide 3 AS TG3)
Direct reading/digital non-resistance working systems (sensors that are thermocouples, infrared, electronic probes, lower-grade thermistors, solid state sensors or other integrated devices,) and/or data loggers		12*	Where it can be demonstrated that the unit is used in a suitable environment and has a stable history of performance. If reduced performance then a check will be expected at least monthly. Check against a reference thermometer across working range or at points of use and/or ice point. A minimum 2 point check is also preferred. (MSL Technical Guide TG1/ IANZ Technical Guide 3 AS TG3)
Thermo-regulated equipment			
Refrigerators, cool rooms, incubators, freezers, heat blocks, water baths.		Daily or each use*	Monitor the temperature during a 24 hr period and record. Continual recording such as an electronic monitoring system is preferred. The use of maximum/minimum type thermometers/devices are advised for critical equipment, especially if they are not being readily monitored. (AS 2853).
Refrigerators and cool rooms, chillers for storing pathological samples and critical reagents, incubators, water baths		3 yearly*	Spatial temperature variation for a time period relevant to duration of use or a minimum 24hour period for continuously operational units, to monitor for all relevant variables within the working space using appropriately calibrated equipment such as working data logger(s)/thermometer(s) (AS 2853)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Refrigerators and cool rooms for storing reagents and materials with less critical requirements, heat blocks, freezers, waterbaths		5 early*	Spatial temperature variation for a time period relevant to duration of use or a minimum 24hour period for continuously operational units, to monitor for all relevant variables within the working space using appropriately calibrated equipment such as working data logger(s)/thermometer(s) (AS 2853)
Refrigerators, cool rooms, freezers and platelet incubators used for storing blood products for transfusion.		Continuous*	Continuous temperature monitoring by chart recorder or electronic monitoring system (NZBS Refrigeration Guidelines)
		12*	Spatial temperature variation for a time period relevant to duration of use or a minimum 24hour period for continuously operational units, to monitor for all relevant variables within the working space using appropriately calibrated equipment such as working data logger(s)/thermometer(s) (NZBS Refrigeration Guidelines).
		12*	Two point check of temperature monitoring and alarm probes using a reference thermometer (NZBS Refrigeration Guidelines)
		1*	Check digital and chart temperature displays (See NZBS Refrigeration Guidelines)
		1*	Check alarm activation and backup battery where relevant (NZBS Refrigeration Guidelines)
Thermo-cyclers		3 yearly*	Spatial temperature variation/uniformity for the maximum time interval required across the block or according to a manufacturer-advised plan to monitor for all relevant variables within the working space using appropriately calibrated equipment. . Perform verification of digital display accuracy as required (AS 2853)
Timers and stopwatches (where deemed critical) Mechanical		3*	Comparison against a recognised source such as the IRL Talking Clock or similar (MSL Technical Guide 8)

Type of equipment	Calibration interval (years or as stated)	Checking interval (months or as stated)	Procedures
Electronic		12*	Comparison against a recognised source such as the IRL Talking Clock or similar. (See MSL Technical Guide 8)
Volumetric glassware Flasks, pipette, burettes and measuring cylinders used for reference purposes		5 yearly*	Accuracy at volumes of use ((MSL Technical Guide TG17)

Equipment References

1. AS 2252 *Biological safety cabinets*
2. AS 2853 *Enclosures - Temperature-controlled - Performance testing and grading*
3. AS 3864 *Medical refrigeration equipment – for the storage of blood and blood products*.
4. AS/NZS 2647 *Biological safety cabinets - Installation and use*
5. AS/NZS 3760 *In-service safety inspection and testing of electrical equipment*.
6. AS/NZS 4187 *Reprocessing of reusable medical devices in health service organisations*.
7. IANZ Technical Guide AS TG2: *Laboratory Balance Calibration Requirements*
8. IANZ Technical Guide AS TG3: *Working Thermometers Calibration Procedures*
   IANZ guides can be found at http://www.ianz.govt.nz/publications2/technical_guides.htm
9. International Atomic Energy Agency (IAEA)/International Commission on Radiological Protection (ICRP) Area Monitoring.
10. International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA- Gamma Counters
11. MSL Technical Guide 1: *The Ice Point*
12. MSL Technical Guide 6: *Magnetic Effects in Weighing*
13. MSL Technical Guide 7: *Calibrating Standard Weights*
14. MSL Technical Guide 8: *Calibration of Stopwatches*
15. MSL Technical Guide 12: *Assuring the Quality of Weighing Results*
16. MSL Technical Guide 17: *Measuring Volume by Weighing Water*
17. MSL Technical Guide 25: *Calibrating Balances*
18. MSL Technical Guide 30: *Calibrating Piston Pipettes*
    MSL guides can be found at http://measurement.govt.nz/training-and-resources/technical-guides

19. NZBS Refrigeration Guidelines: *Requirements for Storage of Blood and Blood Products and Tissue for DHB Blood Banks,* 8th edition 2019

20. Occupational Safety and Health Information Series: *Managing Health and Safety Risks in New Zealand*

21. Mortuaries, Guidelines to promote safe working conditions

Appendix 3 (informative): Method Validation / Verification

Validation and verification must be completed according to internationally recognised guidelines such as Eurachem, relevant to the particular discipline.

Validation/verification of testing methods should only be carried out by laboratories with the appropriate knowledge, skills, experience and resources to do so in a competent and thorough manner.

The following diagram provides for a generalised approach to method validation/verification that IANZ adopts when assessing the in-house validation/verification of methods by individual laboratories. It is not intended to be a comprehensive reference to validation/verification requirements but rather a starting point to assist laboratories to ensure the key components are considered. In some instances, laboratories may need to do more to demonstrate full validation or conversely in other instances depending on the purpose to which the method is to be applied some of the elements may not need to be considered. In particular the extent of validation/verification must be commensurate with the risks associated with the patient or to public health in general.

Method Validation or Verification Reports

This provides some basic guidance for what should be included in a validation/verification report for a new method/procedure:

(a) Title such as study to determine method equivalence or validation of in-house method.

(b) Author

(c) Date of report

(d) Customer/legislative/regulatory/laboratory requirements

(e) Objectives (analyte, scope, matrices) and description of the analytical method

(f) Applicable reference methods

(g) Method Performance:

- i. Precision, repeatability, reproducibility – with differences between the batches listed
- ii. Recoveries from spiked and/or real samples – with a description of how this was carried out
- iii. Matrix effects included for all matrices in the intended scope
- iv. Trueness of results by comparison with alternative methods, proficiency samples, certified reference materials
- v. Effect of method variation (robustness/ruggedness – acceptance criteria established for conditions found to be critical)
- vi. Effect of analyte levels (for unusually high or low levels – acceptable ranges should be determined)
- vii. Measurement uncertainty, limits of detection (instrument or method), limits of quantitation (method or instrument), quantitation of reporting
- viii. Selectivity/Specificity (are there interferences from other analytes), cross reactivities, bias, reagent and/or matrix blanks, positivity/negativity studies
- ix. Sensitivity/Linearity (over the intended working range)
- x. Stability studies, transport studies
- xi. Sample processing and storage

(h) Discussion (statistical analysis of results i.e. Deming regression, Passing-Bablock, Bland-Altman)

(i) Conclusion (was the objective achieved, including the fitness for purpose include any limitations found to be necessary, correlation with clinical findings and discordances evaluated) with formal sign-off by relevant personnel

(j) References

(k) Appendices (raw data, methods, statistical analysis i.e. ANOVA, significance test, linear regression etc.).

Method verification, that is determining that the laboratory can successfully perform in its own situation an analytical method previously validated and published by a recognised authority, may not need to include all the above aspects if the laboratory is fully compliant with the reference method. To claim it follows a particular reference method does, however imply that it can match any method performance criteria given in the reference method and this needs to be demonstrated and included in the report.

If accreditation of a test method is required, the following information must be available:

(a) A copy of the fully documented test method.

(b) Details of the origin of the test method.

(c) Details of the reason for its development and application.

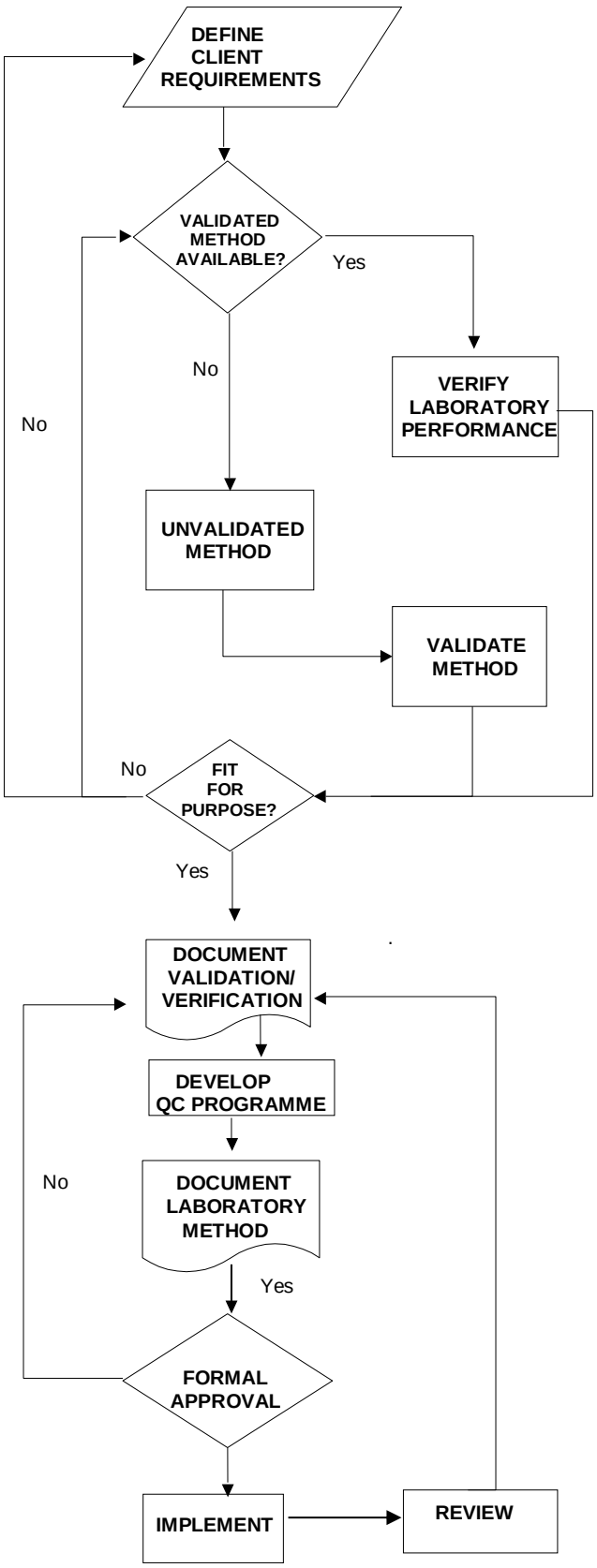
(d) The results of comparative tests with standard methods and/or other laboratories where possible using appropriate statistical tools.

(e) Full details of test method validation regarding performance characteristics that may include consideration of: measurement accuracy, measurement precision including measurement repeatability, measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity, sample/analyte stability, specimen type etc.

(f) Clinical evaluation (clinical performance and utility for specific population of patients) if required.

(g) Dated approval/signoff by appropriate authorised personnel and date of implementation.

Figure 1: Method validation/verification processes in Medical Testing



Client requirements should be defined and include:
- Reason for testing being done
- Specification limits
- Accuracy required
- Detection limit/precision required
- Turnaround time
- Cost

Source a validated method from:
- International standards
- National standards
- Other validated methods

Verify laboratory performance through:
- Proficiency testing
- Reference materials
- Detection limit determination
- Repeatability determination
- Reproducibility determination
- Consumables verified

Unvalidated methods may be available from:
- Journals
- Customers
- In house

All methods need validation for example by:
- Proficiency testing
- Reference materials
- Linearity confirmation
- Selectivity/Specificity confirmation
- Robustness assessment
- Matrix effects/spiking
- Detection limit determination
- Repeatability/reproducibility determination
- Consumables verified

If the method does not meet client requirements then alternative methods need to be sourced and verified/validated, and/or client requirements reviewed.

Develop and retain adequate documentation regarding validation/verification data /results.

Develop routine QC programmes which may include:
- Duplicates
- Spikes
- Reference materials
- Proficiency testing

Develop adequate documentation to ensure method instructions or procedures are readily followed.

Formal approval should be granted prior to implementation, including a final report.

Following implementation a review programme should be instigated after a period of time to ensure ongoing suitability.

Appendix 4: Environmental Testing

A number of samples currently received for testing by medical microbiology laboratories may be considered to be 'non-human' in nature as they are sourced from in-dwelling medical devices (catheter tips, tubing, endoscopes), and prostheses, as well as the environment in response to an infection control investigation or outbreak.

Testing on such samples is largely limited to the clinical setting so that Medical Microbiologists are able to provide appropriate interpretation of results within their field of expertise. For this reason, the testing is of clinical significance as it relates to patient management, rather than environmental surveillance. The following may be considered for accreditation of clinical non-human sample testing:

1. Any samples from tubing, implanted prostheses, etc. removed from a patient when only human pathogens are sought.
2. Environmental swabbing in line with an infection control investigation for a known pathogen (not routine) or response to an outbreak of a human pathogen known in advance (e.g. MRSA, VRE, Acinetobacter, other resistant organisms).
3. Endoscope testing.
4. Environmental air sampling in response to a clinical investigation or outbreak but not for routine surveillance.
5. Spore strips/capsules from routine autoclave internal quality control.
6. Dialysis waters – further details are provided below.
7. Used blood product bags when looking for evidence of microbial contamination as part of the investigation of a transfusion reaction.

Samples not intended to be included in this category are those that fall under a purely environmental screening category (i.e. for environmental organisms), testing for sterility purposes, or where special skills are required such as resuscitation of organisms or neutralisation of inhibitors. This would therefore exclude routine surveillance by environmental air sampling, settle plates and general swabbing.

15189 covers testing results only – NOT environmental sampling. Disclaimers (in some form) excluding sampling processes must be included within environmental testing reports. Additionally, clarification that the report represents presence of substances only, and does not determine conformance with regulatory (or other) requirements, or associated risk level.

Dialysis waters

Those laboratories associated with or providing a service to Dialysis Units may be asked to conduct testing on water and solutions derived from dialysis. Such bacteriological surveillance in dialysis centres is designed to monitor and detect bacterial contamination of dialysis fluids which can lead to pyrogenic reactions in patients. Special techniques, media and interpretation of results are involved in this testing which have been standardised into guidance documents produced by the Association for the Advancement of Medical Instrumentation (AAMI) from the USA.